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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

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

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

Attachment A:

Organophosphates included in the OP Cumulative Assessment

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

United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508C)

EPA 738-R-06-013
June 2006

62910

Interim Reregistration Eligibility Decision for Dichlorvos (DDVP)

Interim Reregistration Eligibility Decision (IRED) Document for Dichlorvos (DDVP)

List A

Case Number 0302

Approved by: _____ Date: _____

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

Table of Contents

DDVP Interim Reregistration Eligibility Decision Team

EPA Office of Pesticide Programs

Special Review and Reregistration Division
Dayton Eckerson
Eric Olson

Health Effects Division
William Dykstra
Susan Hummel
Ray Kent
David Jaquith
David Hrdy

Environmental Fate and Effects Division
Diana Eignor
Ibrahim Abdel-Saheb

Biological and Economic Analysis Division
Donald Atwood
TJ Wyatt
John Faulkner

Registration Division
George LaRocca

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a 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.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs

OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Abstract

This document presents EPA's interim reregistration and tolerance reassessment decisions for the pesticide dichlorvos (DDVP). Final risk management decisions for DDVP will be issued once the cumulative risks for all of the organophosphate pesticides have been addressed. EPA may need to pursue further risk management measures for DDVP once the cumulative risks are considered.

Pending completion of the organophosphate cumulative assessment, EPA has determined that DDVP will be eligible for reregistration and that tolerances will be reassessed once recent use deletions and label amendments requested by the registrant become effective. These use deletions and label amendments are summarized later in this document. EPA has assessed the human health and ecological risks associated with the remaining uses of DDVP and has determined that risks do not exceed levels of concern. Therefore, no additional risk mitigation measures are necessary at this time. Additional data are required to confirm these decisions.

EPA's screening-level ecological risk assessment indicated potential risks of concern resulting from DDVP use to control flying insects and granular bait uses. However, because the screening-level assessment methods included conservative assumptions, EPA believes that actual risks associated with these uses will not exceed levels of concern and no further mitigation is needed.

Based on EPA's screening-level assessment, potential risks to federally-listed threatened and endangered species ("listed species") cannot be precluded at this time. In the future EPA will conduct a species-specific risk analysis. A determination that there is a likelihood of effects to any listed species may result in further limitations on DDVP use, additional risk mitigation measures, and/or consultation with the Fish and Wildlife Service and/or the National Marine Fisheries Service as appropriate.

The Agency is issuing this Interim Reregistration Eligibility Decision (IRED) document for DDVP, as announced in a Notice of Availability published in the *Federal Register*. There will be a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to EPA. 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 a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not 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 amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food by August 3, 2006. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment would be accomplished through the reregistration process. Under FQPA, in reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that risks are not of concern and concludes that there is a reasonable certainty of no harm to any population subgroup, the tolerances are considered reassessed.

FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposure to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://epa.gov/pesticides/cumulative/.

DDVP is a member of the organophosphate class of pesticides. The Agency has classified the organophosphate pesticides and their common degradates as having a common mechanism of toxicity. The Agency is completing its cumulative risk assessment for this class, and the cumulative risks of these chemicals are being considered in the Agency’s final tolerance assessment decision for DDVP and the other organophosphates. The Agency may need to pursue further risk mitigation for DDVP to address any risks identified in the cumulative assessment for the organophosphate pesticides.

This document presents EPA's revised human health and ecological risk assessments (see Appendices J and K), its progress toward tolerance reassessment, and the interim reregistration eligibility decision for DDVP. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides the chemical identity and a profile of the use and usage of the chemical. Section III references the revised human health and ecological risk assessments attached as Appendices to this document. Section IV presents the Agency's risk management, reregistration eligibility, and tolerance reassessment decision. Section V summarizes any data requirements necessary to confirm the reregistration eligibility decision as well as label changes necessary to implement the risk mitigation measures outlined in the IRED. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents and present the human health and ecological risk assessments. The preliminary and revised risk assessments for

DDVP in their entirety are available in the Public Docket, under docket number OPP-2002-0302, and in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

Readers should be aware that the current human health risk assessment reflects recent changes in the DDVP registration voluntarily requested by the registrant. The changes requested in the registrant's terms and conditions letter, dated May 9, 2006, are summarized below. The Agency is in the process of approving the changes as requested in the letter. The full letter is available in the docket.

Voluntary Deletion of the Following:

Product Types
1. 100 gram (g) pest strip
2. 80 g pest strip (contingent on EPA granting the replacement registration for the 80g pest strip)
3. 65 g pest strip (contingent on EPA granting the replacement registration for the 65g pest strip)
4. 21 g pest strip (contingent on EPA granting the registration for 16 g pest strip)
5. Total release fogger

The registrant will split its end use registrations so that there will be one end use label for the large pest strips (65 g & 80 g) and another for the small pest strips (10.5 g, 5.25 g, and a new 16 g).

Use Patterns
6. Lawn, Turf, and Ornamentals
7. Crack and Crevice

Application Method
8. Mushroom house hand held fogger
9. Greenhouse hand held fogger
10. Warehouse hand held fogger

Label Amendments

Occupational Exposure -- Applicators
1. Mushroom house Hose End Sprayer -- add coveralls to personal protective equipment requirements.

Occupational -- Post Application
2. Mushroom houses – 18 hour re-entry interval (REI)
3. Greenhouse -- 12 hour REI

Pest Strips
65 and 80 g pest strips

Label language to read**:**

"For use in unoccupied areas; not for use in homes except garages, attics, crawl spaces, and sheds occupied for less than 4 hours per day.

Also for use in boathouses, museum collections, animal buildings, and milk rooms, or enclosed areas thereof, occupied for less than 4 hours per day.

For use in unoccupied areas such as trash dumpsters, catch basins, bulk raw grain bins, storage bins, insect traps, enclosed utility boxes, and storage units. Also for use in non-perishable packaged and bagged and bulk stored processed and raw agricultural commodities (including soybeans, corn, grains, cocoa beans and peanuts).

Also for use in the following unoccupied structures, provided they are unoccupied for more than 4 months immediately following placement of a pest strip: vacation homes, cabins, mobile homes, boats, farm houses, and ranch houses."

16 g (new), 10.5 g, 5.25 g pest strips

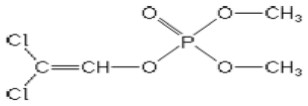
Label language to read:

"Within homes, use only in closets, wardrobes, and cupboards. Also for use in storage units, garages, attics, crawl spaces, boathouses, museum collections, garbage cans, trash dumpsters, animal buildings, milk rooms, catch basins, bulk raw grain, and storage bins."

II. Chemical Overview

A. Chemical Identity

Chemical Structure:



Empirical Formula:	$C_4 H_7 Cl_2 0_4 P$
Common Name:	Dichlorvos (DDVP)
CAS Name:	2,2-Dichlorovinyl dimethyl phosphate
CAS Registry Number:	62-73-7
OPP Chemical Code:	084001

Case Number:	0302
Technical or Manufacturing-Use Registrants:	AMVAC Chemical Corporation
Regulatory History	• First registered for use in 1948. • EPA initiated special review in 1988 (PD1) for carcinogenicity, liver effects, and cholinesterase inhibition. • Preliminary determinations (PD2/3) issued in 1995, proposing cancellation of certain uses, and label modifications for other uses to mitigate risk

B. Use and Usage Profile

The following is information on the currently registered uses of DDVP. A detailed table of food and feed uses, or uses which require tolerances or tolerance consideration, is contained in Appendix A.

Pesticide type/target pests:	Dichlorvos (2, 2-Dichlorovinyl dimethyl phosphate), also known as DDVP, is an organophosphate insecticide. Target pests are flies, gnats, mosquitoes, chiggers, ticks, cockroaches, armyworms, chinch bugs, clover mites, crickets, cutworms, grasshoppers, and sod webworms.
Mode of Action:	Inhibition of cholinesterase.
Formulations:	Granules for bait, liquid, resin impregnated, ready to use sprays and foggers.
Methods of Application:	Applied with ready to use aerosol spray cans, spray equipment, wall mounted foggers, and through slow release from impregnated materials, such as resin strips and pet collars.
Use Sites:	DDVP is registered to control insect pests in agricultural sites, commercial, institutional and industrial sites; in and around homes; and on pets. DDVP is also used in greenhouses; mushroom houses; storage areas for bulk, packaged and bagged raw and processed agricultural commodities; food manufacturing/processing plants; animal premises; and non-food areas of food-handling establishments. It is also registered for direct dermal pour-on treatment of cattle and poultry. DDVP is not registered for direct use on any field grown commodities.
Application Rates:	The maximum rate is 2.0 gm ai/1000 cu. ft. for liquid formulations in greenhouses and warehouses; and 0.09 lb ai/1000 cu. ft. for

	impregnated material.
Annual Usage in the U.S.:	Approximately 54% used for commodities in bulk storage, distribution warehouses and processing plants; 28% for livestock and poultry; and 15% for Pest Control Operator/structural use.
Related Pesticides:	DDVP is closely related to naled and trichlorfon, which are members of the organophosphate class of pesticides. Naled and trichlorfon both metabolize or degrade to DDVP in food, water, or the environment.
Tolerances	Currently, there are 27 tolerances listed in 40 CFR §108.235 for DDVP on agricultural (food and feed) crops and animal commodities. See Table 1 for a complete list of the DDVP tolerances.

III. Links to the DDVP Risk Assessments

Please refer to Appendices J and K for the Human Health and Ecological Risk Assessments for DDVP, dated June 20, 2005, and June 22, 2006, respectively, for details on the risks associated with the use of DDVP. These documents are also available in the public docket EPA-HQ-OPP-2002-0302, located on-line in the Federal Docket Management System (FDMS) http://www.regulations.gov.

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 submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical grade) data to support reregistration of products containing DDVP as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support interim reregistration of products containing DDVP once the use deletions and label amendments discussed above become effective. Additional data are required to confirm this determination.

The Agency has completed its assessment of the dietary (both food and drinking water), residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient DDVP. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient DDVP, the Agency has sufficient information on the human health and ecological effects of DDVP to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing DDVP will be eligible for reregistration provided that (i) label amendments are made to reflect the use deletions, use amendments, and other measures identified in the registrant’s May 9, 2006 terms and conditions letter, and (ii) any additional measures needed to reduce cumulative risks

are adopted. Label changes and language are listed in Section V. Appendix A provides a detailed table of those uses eligible for reregistration. Appendix B identifies generic data the Agency reviewed as part of its interim determination of reregistration eligibility of DDVP, and lists the studies the Agency found acceptable and that satisfy the data requirement. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data or additional data requirements necessary to confirm the decision presented here.

Because the Agency has not yet addressed the potential cumulative risk for all of the organophosphates, this reregistration eligibility decision does not fully satisfy the requirements for reassessment of the existing DDVP food residue tolerances as called for by FQPA. When the Agency has addressed potential organophosphate cumulative risks, DDVP tolerances will be reassessed. At that time, the Agency will also meet the FQPA requirements and make a final decision on the reregistration eligibility determination for DDVP. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.4 of this document.

B. Public Comments and Responses

During the public comment period on the revised ecological risk assessment, which closed on June 30, 2005, the Agency received comments from AMVAC Chemical Corporation, Beyond Pesticides, Natural Resources Defense Council, and Cereal Food Processors, Inc. These comments in their entirety are available in the public docket EPA-HQ-OPP-2002-0302, located on-line in the Federal Docket Management System (FDMS) http://www.regulations.gov. During the public comment period on the human health assessment, which closed on December 11, 2000, the Agency received comments from the Norwegian Agricultural Inspection Service, Pesticide Applicators Education Program, Natural Resources Defense Council (NRDC), AMVAC Chemical Corporation, University of Georgia Entomology Department, North American Miller's Association, California Pistachio Commission, Fumigation Service & Supply, Inc., U.S. Department of Agriculture (USDA), and California Department of Pesticide Regulation. The Agency's responses to substantive comments for both comment periods are available in memoranda in the public docket. It is important to note that the Agency's responses to the public comments reflected the Agency's position at the time that the responses were written. This DDVP IRED supersedes previous Agency responses to public comments.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with DDVP. This assessment is for this individual organophosphate and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as a common biochemical interaction of organophosphate pesticides with cholinesterase which may lead to a myriad of cholinergic effects. The Agency will finalize the

cumulative risk assessment and risk management decisions for the entire class of organophosphates shortly.

DDVP is closely related to naled and trichlorfon, which are also members of the organophosphate class of pesticides. Naled and trichlorfon both metabolize or degrade to DDVP in food, water, or the environment. Therefore, FQPA requires OPP to estimate aggregate risk from all sources of DDVP, including DDVP derived from naled and trichlorfon. The current assessment addressed the risks posed by DDVP resulting from the uses of DDVP, naled, and trichlorfon.

The Agency has made an interim conclusion that tolerances for DDVP meet the FQPA safety standards and that the risk from aggregate exposure (from food, drinking water, and residential sources) is within the DDVP "risk cup." The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Determination of Safety to U.S. Population (Including Infants and Children)

The Agency has made an interim decision that the established tolerances for DDVP, with label amendments and changes as specified in this IRED document, meet the safety standards under the FQPA amendments to Section 408(b)(2)(D) and 408(b)(2)(c) of the FFDCA, and that there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or any other subgroup, from the use of DDVP. The safety determination considers factors such as the toxicity, use practices and exposure scenarios, and environmental behavior of DDVP.

In determining whether or not infants and children are particularly susceptible to toxic effects from DDVP residues, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The Agency evaluated the hazard and exposure data to determine if the FQPA10X safety factor should be retained, reduced, or removed. In doing so, the Agency concluded that the FQPA Safety Factor for DDVP can be reduced to 1X, except for certain scenarios, for which the FQPA factor is retained at 3X to account for the lack of a NOAEL. The exposure scenarios that have retained a 3X FQPA Safety Factor due to a lack of a NOAEL are: short-term incidental oral; short-, intermediate-, and long-term dermal; short- and intermediate-term inhalation of vapors; and short- and intermediate-term inhalation during application. In the case of DDVP, the Agency has concluded that the FQPA Safety Factor should be reduced based on the lack of pre- and/or postnatal susceptibility resulting following exposure to DDVP, the lack of residual uncertainties for pre- and/or postnatal toxicity, and the fact that the DDVP food, drinking water, and residential assessments are not expected to underestimate exposure. For more details on the DDVP FQPA Safety Factor, refer to the Human Health Risk Assessment, dated June 22, 2006 (Appendix J).

c. 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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on DDVP, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, DDVP may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

FQPA stipulates that when determining the safety of a pesticide chemical EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the Agency concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism. These may be found on EPA's website at http://www.epa.gov/pesticides/cumulative.

DDVP is a member of the organophosphate (OP) class of pesticides. EPA considers organophosphates to express toxicity through a common biochemical interaction with cholinesterase and, consequently the organophosphate pesticide risks are considered as a group. EPA published the final guidance that it now uses for identifying substances that have a common mechanism of toxicity (FR 64(24) 5796-5799, February 5, 1999), "Proposed Guidance for Cumulative Risk Assessment for Chemicals that Have a Common Mechanism of Toxicity." This document was made available for public comment in the Federal Register (65 FR 40644, June 30, 2000) and the Agency presented this approach to the FIFRA/FQPA Science Advisory Panel

in late September, 2000. The revised methods, based on SAP's review, were used to conduct preliminary and revised cumulative risk assessments for organophosphate pesticides in 2002 (US EPA, 2002) and can be found at http://www.epa.gov/scipoly/sap/2002/index.htm. The revised cumulative risk assessment for OPs, (US EPA, 2002a) can be found on the Agency's web site http://www.epa.gov/pesticides/cumulative/rra-op/. It assesses the cumulative effects of exposure to multiple OPs, including DDVP.

Once the aggregate, single chemical assessments are completed for all the individual organophosphates, the Agency will issue the final cumulative risk assessment for these compounds. For purposes of this interim decision, EPA has considered risks for only DDVP and its degradates.

2. Tolerance Summary

A tolerance summary and interim tolerance reassessment decision is presented for DDVP in Table 1 below. Currently there are 27 tolerances listed in 40 *CFR* §180.235 for DDVP on agricultural (food and feed) crops and animal commodities. DDVP residues are currently expressed in terms of the parent compound only, with the exception of cucumbers, lettuce, mushrooms, and tomatoes, which are expressed as naled. The registrants are not supporting tolerances for several crops and animal commodities, including cucumbers, lettuce, radishes, and tomatoes. These tolerances will be proposed to be revoked. EPA will propose to raise the tolerances for fat, meat, and meat byproducts of cattle, goats, horses, and sheep were raised to harmonize with the Codex maximum residue limit (MRL).

The tolerances in 40 *CFR* §180.235 for nonperishable packaged, bagged or bulk raw food and for packaged or bagged nonperishable processed foods (formerly in 40 *CFR* §185.1900) do not refer to specific commodities.

Table 1. Tolerance Reassessment Summary for DDVP.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.235(a)(1)*			
Cattle, fat	**0.02(N)**	**0.05**	EPA will propose to raise the tolerance to harmonize with the Codex maximum residue limit (MRL).
Cattle, meat	**0.02(N)**	**0.05**	
Cattle, mbyp	**0.02(N)**	**0.05**	
Cucumbers	**0.5** [1]	**Revoke**	The registrant is not supporting use of DDVP on this commodity. Tolerance has been revoked.
Eggs	**0.05(N)**	**0.05**	
Goats, fat	**0.02(N)**	**0.05**	EPA will propose to raise the tolerance to harmonize with the Codex maximum residue limit (MRL).
Goats, meat	**0.02(N)**	**0.05**	
Goats, mbyp	**0.02(N)**	**0.05**	
Horses, fat	**0.02(N)**	**0.05**	EPA will propose to raise the tolerance to harmonize with the

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Horses, meat	**0.02(N)**	**0.05**	Codex maximum residue limit (MRL).
Horses, mbyp	**0.02(N)**	**0.05**	
Lettuce	**1.0** [1]	**Revoke**	The registrant is not supporting use of DDVP on this commodity. Tolerance has been revoked.
Milk	**0.02(N)**	**0.05**	EPA will propose to raise the tolerance to harmonize with the Codex maximum residue limit (MRL).
Mushrooms	**0.5** [1]	**0.5**	The tolerance should be revised to be expressed in terms of DDVP.
Poultry, fat	**0.05(N)**	**0.05**	
Poultry, meat	**0.05(N)**	**0.05**	
Poultry, mbyp	**0.05(N)**	**0.05**	
Radishes	**0.5**	**Revoke**	The registrant is not supporting use of DDVP on this commodity.
Raw agricultural commodities, nonperishable, bulk stored regardless of fat content (post-H)	**0.5**	**4.0**	The required residue data showed that a higher tolerance is needed. EPA will propose to raise the tolerance. *[Raw agricultural commodities, nonperishable, bulk stored]*
Raw agricultural commodities, nonperishable, packaged or bagged, containing 6 percent fat or less (post-H)	**0.5**		The required residue data showed that a higher tolerance is needed. EPA will propose to raise the tolerance. *[Raw agricultural commodities, nonperishable, packaged and bagged]*
Raw agricultural commodities, nonperishable, packaged or bagged, containing more than 6 percent fat (post-H)	**2.0**	**4.0**	
Sheep, fat	**0.02(N)**	**0.05**	EPA will propose to raise the tolerance to harmonize with the Codex maximum residue limit (MRL).
Sheep, meat	**0.02(N)**	**0.05**	
Sheep, mbyp	**0.02(N)**	**0.05**	
Tomatoes (pre- and post-H)	**0.05** [1]	**Revoke**	The registrant is not supporting use of DDVP on this commodity.
Tolerances Listed Under 40 CFR §180.235(a)(2)			
Edible swine tissue [2]	**0.1**	**Revoke**	Residue data have been required and not submitted.
Tolerances Listed Under 40 CFR §180.235(a)(3)			
Packaged or bagged nonperishable processed food	**0.5**	**4.0**	The required residue data showed that a higher tolerance is needed, and the tolerance should be moved

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
			to §180.235(a)(1). EPA will propose to raise the tolerance. *[Processed food, nonperishable, packaged or bagged]*
Tolerances to be Proposed Under 40 CFR §180.235(a)			
Soybean, hulls	**--**	**15.0**	Soybean hulls have been added to the Agency's list of regulated processed commodities since DDVP tolerances were set.
Aspirated grain fractions	**--**	**20.0**	Aspirated grain fractions have been added to the Agency's list of regulated processed commodities since DDVP tolerances were set. The tolerance is required when residues in the aspirated grain fractions are greater than the residues in soybean grain residues.

N Negligible residues

* Concurrently with the revocation of the tolerance for edible swine tissue in §180.235(a)(2) and the moving of the tolerance for packaged or bagged nonperishable processed food in §180.235(a)(3), §180.235(a)(1) should be redesignated §180.235(a).

[1] Residues expressed as naled. Another registrant has expressed interest in supporting the tolerance on tomato. However, data have been required and not submitted.

[2] Resulting both from its use as an anthelmintic in swine feed and as an insecticide applied directly to swine; prescribed by 21 CFR 558.205 as a feed additive in swine, with a tolerance of 0.1 ppm for residues of DDVP in edible swine tissue listed in 21 CFR 556.180.

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of DDVP in/on various commodities. The Codex MRLs are expressed in terms of DDVP *per se* and are based on residues likely to be found at harvest or slaughter. The Codex MRL and the U.S. tolerance expressions are compatible. A comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 2.

The following conclusions can be made regarding efforts to harmonize U.S. tolerances with Codex MRLs: (i) compatibility between the U.S. tolerances and Codex MRLs exists for milks, mushrooms, meat (from mammals other than marine mammals), and poultry meat; and (ii) incompatibility of the U.S. tolerances and Codex MRLs remains at present for cereal grains because of differences in good agricultural practices. However, the difference between the U.S. tolerance and Codex MRL for cereal grains is relatively small and unlikely to result in trade concerns in international commerce.

Table 2. Codex MRLs and Applicable U.S. Tolerances for DDVP

Commodity	MRL (mg/kg)	Reassessed U.S. Tolerance, ppm	Recommendation
Cereal grains	5	4.0	
Meat (from mammals other than marine mammals)	0.05*	0.05	Compatibility exists
Milks	0.02 (*)	0.02	Compatibility exists
Mushrooms	0.5	0.5	Compatibility exists
Poultry meat	0.05	0.05	Compatibility exists
Wheat bran, Unprocessed	10	--	
Wheat flour	1	--	
Wheat germ	10	--	
Wheat wholemeal	2	--	

1 (*) = At or about the limit of detection.

D. Regulatory Rationale

The Agency has determined that products containing DDVP will be eligible for reregistration provided that the use deletions, use amendments, worker protections, and label language amendments included in the IRED and in the registrant's May 9, 2006, terms and conditions letter for the DDVP registration are implemented.

1. Human Health Risk Management

a. Aggregate Risk Mitigation (food, drinking water, and residential exposure)

As discussed in the revised human health risk assessment (Appendix J), upon implementation of the use deletions, use amendments, and the labeling amendments reflected in the DDVP registrant's May 9th, 2006, letter to EPA, all aggregate (food, drinking water, and residential) risks of concern from use of DDVP will have been addressed; therefore, no further risk mitigation will be necessary for this interim reregistration eligibility decision.

The preliminary human health risk assessment indicated the possibility of drinking water and inhalation exposures of concern from the degradation of trichlorfon into DDVP from trichlorfon turf use. However, since the preliminary risk assessment was written, the registrant for trichlorfon submitted soil dissipation data which indicated that, under predominant soil pH conditions, the actual rate at which trichlorfon degrades into DDVP is significantly lower than assumed in the preliminary risk assessment. As a result, the Agency does not believe that there will be significant drinking water or inhalation exposures to DDVP from the use of trichlorfon on turf. As noted below, confirmatory data in the form of a turf transferable residue (TTR) study will be required from the trichlorfon registrant to verify that the revised assessment of drinking water and inhalation exposure is accurate.

b. Occupational Risk Mitigation

As discussed in the revised human health risk assessment (Appendix J), upon implementation of the use deletions, use amendments, worker protections, and labeling amendments reflected in the DDVP registrant's May 9th, 2006, letter to EPA, the occupational risks of concern from use of DDVP will have been addressed. No further mitigation is necessary.

2. Ecological Risk Management and Mitigation

As discussed in the ecological risk assessment attached as Appendix K, the following potential risks of concern were identified by Agency screening-level modeling:

- For use on turf, the chronic level of concern (LOC) was exceeded for birds, and the chronic and acute endangered species LOCs were exceeded for certain mammalian species. Turf use modeling also resulted in acute, acute endangered species, and chronic LOC exceedences for freshwater invertebrates.

- For the flying insect exposure scenario, the chronic level of concern (LOC) was exceeded for birds, and the chronic and acute endangered species LOCs were exceeded for certain mammal species.

- For the bait exposure scenario, acute risk and acute endangered species LOCs were exceeded for birds. Chronic risk from bait use could not be assessed due to insufficient data.

As noted above, the registrant has requested that all uses on lawns, turf, and ornamentals be deleted from its registration; therefore, the above-referenced risks from the turf use scenarios will not occur. Regarding the remaining two uses for which ecological concerns were identified, flying insect spray and granular bait use, modeling for both uses predicts only small exceedences of the risk quotients (RQs). For the flying insect exposure scenario, most of the chronic RQs were below 5, with a high of 8.3 for 15 g short grass-eating mammals. It is important to note also that the exposure assumptions for the flying insect risk estimate represents an extreme worst case scenario: the maximum application rate was assumed to be applied 75 times per year. For the large majority of users, such year-round insect control regimens at the maximum treatment levels are not necessary. Moreover, even for climates where target insect infestations are a year-round problem, it is unlikely that treatments will continue uninterrupted every 3 to 5 days for an entire year.

For the granular bait use, the highest estimated RQ was just under 1 for 20 g birds; the rest of the estimated RQs were below 0.2. Given these very low exceedences in the Agency's screening level modeling at maximum use rate, the Agency does not believe that this use of DDVP presents a risk of concern. Therefore EPA is not requiring additional mitigation measures.

3. Other Labeling Requirements

In order to be eligible for reregistration, DDVP use and user safety information also needs to be included in the labeling of all end-use products containing DDVP. For the specific label statements and a list of additional data requirements necessary to confirm this decision, refer to Section V of this RED document.

4. Threatened and Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered 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 that may affect any particular species, EPA uses basic toxicity and exposure data developed for REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will take into consideration risk mitigation measures that are being implemented as a result of this IRED.

For the remaining outdoor uses of DDVP flying (insect and granular bait), the Agency's level of concern for Federally listed threatened and endangered species were exceeded for endangered bird species and small mammals. There also may be the potential for indirect adverse effects for some listed species that are dependent on this taxonomic group. These findings are based on EPA's screening level assessment and do not constitute a may affect finding under the Endangered Species Act.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species may result in limitations on use of DDVP, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of DDVP "may effect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). EPA is not requiring specific DDVP label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Program.

5. General Risk Mitigation

DDVP end-use products may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing DDVP specific to Federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a

product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) must be adopted.

V. What Registrants Need to Do

The Agency has determined that DDVP is eligible for reregistration provided (i) label amendments are made to reflect the use deletions, use amendments, and other measures identified in the registrant's May 9, 2006, terms and conditions letter, as well as this IRED, and (ii) any additional measures needed to reduce cumulative risks are adopted. The Agency intends to issue Data Call-Ins (DCIs) for generic (technical or manufacturing-use grade) data and product-specific data. Generally, registrants will have 90 days from receipt of a generic DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. Table 3 below presents the additional generic data the Agency intends to require for DDVP to be eligible for reregistration. For product-specific DCIs, registrants will have eight months to submit data and amend labels. In order for products containing DDVP to be eligible for reregistration, all product labels must be amended to incorporate the specific changes and language presented in Table 4 below. Table 4 also describes how the required language should be incorporated.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of DDVP has been reviewed and determined to be complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are included in the generic DCI for this IRED.

Table 3. Confirmatory Data Requirements for the Reregistration of DDVP

Data Requirement	New OPPTS Guideline Number (GLN)	Old Guideline Number
Storage Stability The reregistration requirements for storage stability data are not fulfilled. Information pertaining to the storage intervals and conditions of samples of the following commodities must be submitted: packaged and bagged raw agricultural commodities and processed food; bulk stored raw agricultural commodities; milk; eggs; and meat, fat, and meat byproducts of dairy cows and poultry. Alternatively, the registrant may demonstrate that there are sufficient residue data which are supported by storage stability data to support all registered uses of DDVP.	**860.1380**	**171-4e**
Magnitude of Residues: Swine The reregistration requirements for data pertaining to this guideline topic are not completely fulfilled. A dermal magnitude of the residue study must be submitted for swine. No additional data are required for milk and edible tissues of ruminants, and for eggs and edible tissues of poultry.	**860.1480**	**171-4j**

In addition, a confirmatory exposure study will be required for trichlorfon based on the DDVP risk assessment. A TTR study (GDLN 875.2500**)** with analyses for trichlorfon and DDVP in the turf and in the toddler breathing zone above the turf (18") is requested to confirm

the exposure estimates in this document. The study must be conducted at an appropriate pH (approx. 7). The air concentrations of DDVP must be expressed in mg/L. A field dissipation study may be substituted, provided it meets these requirements. A DCI for this confirmatory data will be sent to the trichlorfon registrant.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, labeling on manufacturing-use products (MUP) should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the specific language presented in Table 4 below.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g) (2) (B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response Form provided for each product. The Agency intends to issue a separate product-specific Data Call-In outlining specific data requirements.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in the IRED. The specific changes and language required are presented in Table 4 below.

Except for pest strips, 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. Please refer to "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

For large pest strips (80 gram and 65 gram), the registrant shall stop distributing product with old labels on April 15, 2007, (or 4 months after EPA approves their new labels, which ever is later); supplemental distributors shall have until December 31, 2007, to sell any old labeled product. As of January 1, 2008, the registrant and its supplemental distributors may sell only pest strips with the new label language. After December 31, 2007, the Registrant will reclaim any old labeled product from its distributors or end use registrants.

For small pest strips (16 gram, 10.5 gram, and 5.25 gram) the new label language is effective as of the date EPA approves the changes described above. The existing stocks time frames will be established per the "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

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

Table 4: Summary of Labeling Changes for DDVP

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into: (1) Dry formulations for use in impregnated dispensers, impregnated resin dog and flea collars, and dry bait formulations: (2) The following impregnated resin pest strip products: 80, 65, 16, 10.5 and 5.25 grams (3) Ready to Use aerosol and total release fogger products intended for commercial use; (4) Liquid formulations for the following agricultural/commercial uses: farm buildings, (farmyards), manure treatments on farm premises, dairy and farm premises, feed lots, including barns, feeding areas, shelters and stables, dairy barns (including milk rooms), equipment and barnyards, livestock feeding areas, pens, poultry droppings, poultry houses (equipment and yards), greenhouses (non-food), mushroom houses, beef cattle, poultry, dairy cattle, goats, horses (including ponies), sheep, swine and turkeys, and; (5) Liquid formulations for use only in commercial application equipment such as conventional or ULV fogging equipment (space treatment) for warehouses, silos, mushroom houses, greenhouses (non-food) bulk bins and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities and non-food feed areas processing/manufacturing plants. "Not for formulation into: (1) Products intended for use by residential consumers that contain more than .5% a.i. DDVP; (2) Ready to Use (RTU) total release fogger products intended for use on residential sites; (3) Aerosol products intended to be used as crack and crevice or space sprays on residential sites; (4) Liquid formulations intended for use with hand held fogging or hand held smoke generator equipment; (5) Products intended for use in tobacco houses; (6) Products intended for use in the following types of food/feed manufacturing establishments: bottling plants (including wineries, breweries, soft drinks, frozen food/feed (including pizza and ice cream plants; (7) Products intended for use in the following food/feed processing establishments: meat, poultry and seafood slaughtering and/or packing plants (including edible fats and oils), frozen food/feed plants (including fruit and vegetables), dairy product plants (including milk processing plants);	Directions for Use

	(8) Products intended for use on lawns, turf, or ornamentals."	
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	"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 IRED and Agency Label Policies	"This product is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
PPE Requirements Established by the IRED[1] for liquid formulations (excludes Ready to Use aerosol products containing 5% or less a.i. DDVP)	"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, applications and other handlers must wear: - long-sleeve shirt, - long pants, - shoes and socks, and - chemical-resistant gloves - A NIOSH-approved 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, -- an organic-vapor removing cartridge or canister with any N,R,P, or HE prefilter.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the IRED for Ready to Use (RTU) Aerosol products containing 5% or less a.i. DDVP and products	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." Applicators and other handlers must wear:	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

formulated as a granular baits.	- long-sleeve shirt, - long pants, - shoes and socks, - chemical resistant gloves	
PPE Requirements Established by the IRED for Ready to Use pest strips and collars	PPE not required	
User Safety Requirements for all products requiring PPE (see above)	"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 for all Formulations	None Required	
User Safety Recommendations	All products: "User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." All products requiring PPE: "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards Statements for products labeled for outdoor uses	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish, birds, and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate."	Precautionary Statements under Environmental Hazards
Environmental Hazards for Products labeled for Indoor Use that are packaged in containers	"ENVIRONMENTAL HAZARDS" "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 Pollution Discharge Elimination System	Precautionary Statements under Environmental Hazards

equal to or greater than 5 gallons or 50 lbs	(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."	
Restricted-Entry Interval (REI), Early Entry PPE and Ventilation Requirement for products with use directions for use within the scope of the Worker protection Standard for agricultural pesticides	"NOTIFICATION: Before the start of the application, notify workers of the application by warning them orally and by posting fumigant warning signs at all entrances to the building. The signs must bear the skull and crossbones symbol and state: (1) "DANGER/PELIGRO," (2) "Building under fumigation, DO NOT ENTER/NO ENTRE," (3) the date and time of fumigation, (4) "DDVP {or use brand name} Fumigant in use," and name, address, and telephone 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 posting and removal." "Do not apply this product to a greenhouse or mushroom house that is attached to another structure, including another greenhouse or mushroom house, unless the greenhouse or mushroom house to be treated is entirely sealed off from the other structures." "A trained pesticide handler with immediate access to the PPE that this labeling requires for applicators must maintain constant visual or voice contact with any handler who is applying this product in a greenhouse or mushroom house or who enters the treated building before the ventilation is complete to perform any handling task." "Entry (including early entry that would otherwise be permitted under the WPS) by any person -- other than a correctly trained and equipped handler who is performing a handling task permitted by the WPS and wearing the personal protective equipment required for handlers -- is PROHIBITED in the entire greenhouse or mushroom house (entire enclosed structure/building) from the start of application until ventilation is complete in the greenhouse or mushroom house. Ventilation is complete *either* when 24 hours have elapsed following application and the building has been opened and aired *or* when a direct-indication short-term concentration monitoring device (e.g. Draeger tube) indicates that the DDVP air concentration is equal to, or less than 0.050 ppm (50% of the OSHA PEL). A trained pesticide handler with immediate access to the PPE that this labeling requires for applicators must maintain constant visual or voice contact with any handlers entering the treated building before the ventilation is complete." **"For Greenhouses:** If ventilation is complete before 12 hours have elapsed following application (e.g., Draeger tub reading), then a restricted-entry interval of 12 hours is in effect. Do not enter or allow workers to enter during the restricted entry interval of 12 hours. Early entry as permitted by the Worker Protection Standard is permitted *provided:* • the fumigant warning sign is removed, and • the following personal protective equipment is worn: coveralls, shoes and socks, and waterproof gloves."	Agrigultural Use Reqirements Box

	"For Mushroom Houses: If ventilation is complete before 18 hours have elapsed following application (e.g., Draeger tub reading), then a restricted-entry interval of 18 hours is in effect. Do not enter or allow workers to enter during the restricted entry interval of 18 hours. Early entry as permitted by the Worker Protection Standard is permitted *provided:* • the fumigant warning sign is removed, and • the following personal protective equipment is worn: coveralls, shoes and socks, and waterproof gloves."	
Entry Restrictions for products having occupational uses on the label not subject to the WPS (applies to aerosols applied as a space spray, fog or smoke)	"NOTIFICATION: Before the start of the application, post fumigant warning signs at all entrances to the building. The signs must bear the skull and crossbones symbol and state: (1) "DANGER/PELIGRO," (2) "Building under fumigation, DO NOT ENTER/NO ENTRE," (3) the date and time of fumigation, (4) "DDVP {or use brand name} Fumigant in use," and name, address, and telephone number of the applicator. The signs must be located prominently at each entrance, using a sign size and letter size that makes the sign clearly legible. All signs must be removed after the ventilation is complete and before routine entry by unprotected persons is permitted. "Entry by any person -- other than a correctly trained and equipped handler who is performing a task related to ventilation or air concentration monitoring and who is wearing the personal protective equipment required for handlers -- is PROHIBITED in the entire enclosed structure/building from the start of application until ventilation is complete. Ventilation is complete *either* when 24 hours have elapsed following application and the building has been opened and aired *or* when a direct-indication short-term concentration monitoring device (e.g. Draeger tube) indicates that the DDVP air concentration is equal to, or less than 0.050 ppm (50% of the OSHA PEL)."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Entry Restrictions for products having occupational uses on the label that are only applied as a surface spray.	***Entry Restriction for non-WPS uses applied as a surface spray:*** "Do not enter or allow others to enter until sprays have dried."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.

General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing specified PPE may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	Liquid Formulations: "Use in hand held fogger or hand held smoke generator equipment is prohibited." "Use in residential sites as a crack and crevice or space spray is prohibited" "Use on Lawns, turf or ornamentals is prohibited". Pest Strips (80 and 65 g): "For use in unoccupied areas; not for use in homes except garages, attics, crawl spaces, and sheds occupied for less than 4 hours per day. Also for use in boathouses, museum collections, animal buildings, and milk rooms, or enclosed areas thereof, occupied for less than 4 hours per day. For use in unoccupied areas such as trash dumpsters, catch basins, bulk raw grain bins, storage bins, insect traps, enclosed utility boxes, and storage units. Also for use in non-perishable packaged and bagged and bulk stored processed and raw agricultural commodities (including soybeans, corn, grains, cocoa beans and peanuts). Also for use in the following unoccupied structures, provided they are unoccupied for more than 4 months immediately following placement of a pest strip: vacation homes, cabins, mobile homes, boats, farm houses, and ranch houses." Pest Strips (16, 10.5, and 5.25 g): "Within homes, use only in closets, wardrobes, and cupboards. Also for use in storage units, garages, attics, crawl spaces, boathouses, museum collections, garbage cans, trash dumpsters, animal buildings, milk rooms, catch basins, bulk raw grain, and storage bins."	Directions for Use
End Use Products Intended for Residential Use		

Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application." Pest Strips (80 and 65 g): "For use in unoccupied areas; not for use in homes except garages, attics, crawl spaces, and sheds occupied for less than 4 hours per day. Also for use in boathouses, museum collections, animal buildings, and milk rooms, or enclosed areas thereof, occupied for less than 4 hours per day. For use in unoccupied areas such as trash dumpsters, catch basins, bulk raw grain bins, storage bins, insect traps, enclosed utility boxes, and storage units. Also for use in non-perishable packaged and bagged and bulk stored processed and raw agricultural commodities (including soybeans, corn, grains, cocoa beans and peanuts). Also for use in the following unoccupied structures, provided they are unoccupied for more than 4 months immediately following placement of a pest strip: vacation homes, cabins, mobile homes, boats, farm houses, and ranch houses." Pest Strips (16, 10.5, and 5.25 g): "Within homes, use only in closets, wardrobes, and cupboards. Also for use in storage units, garages, attics, crawl spaces, boathouses, museum collections, garbage cans, trash dumpsters, animal buildings, milk rooms, catch basins, bulk raw grain, and storage bins."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	Liquids applied as surface sprays: "Do not allow people or pets to enter the treated area until sprays have dried."	Directions for use under General Precautions and Restrictions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

APPENDIX A: Dichlorvos Use Patterns Eligible For Reregistration

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Agricultural commodities (bulk storage of nonperishable raw and processed agricultural commodities including raw grains, corn, soybeans, cocoa beans, and peanuts)			
Premise treatment	20% Impr	10.5 g of product/ 50-100 cu. ft or 80 g of product/ 900-1200 cu. Ft	Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr]		Use in kitchens, restaurants, or areas where food/feed are prepared or processed, use in food/feed processing or food/feed manufacturing areas of food/feed processing and food/feed manufacturing plants are prohibited.
	20% Impr		Use in kitchens, restaurants, or areas where food is prepared or served and use in edible product areas of food processing plants are prohibited.
Greenhouses (not containing food commodities)			
Fog application	0.37 lb/gal EC	0.004 lb/1,000 cu. ft	Applications may be made using a cold aerosol generator. Hand held foggers are no longer permitted.
Mushroom houses			
Fog application [hand-held fogger is no longer permitted]	50% FIC	2% finished spray [6.25 oz/10,000 cu.ft]	Applications may be made in 1,1,1-trichloroethane using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed. A 1-day PHI has been established for mushrooms.
		2% finished spray [10 oz/10,000 cu.ft] 5 g/10,000 cu.ft	Applications may be made in deodorized base kerosene using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed. A 1-day PHI has been established for mushrooms.
	0.37 lb/gal EC	0.004 lb/1,000 cu.ft	Applications may be made using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed.
Brush on /coarse spray	2 lb/gal EC	0.00125 lb/100 sq ft	Coarse spray or paint on walls, around doors, ventilators & cracks before mushrooms come into production. Use as 0.5% solution – 1 pint of 0.5% solution per 100 sq ft., up to 10 days before crop emerges on soil beds. Do not spray inside walls after mushrooms appear on beds. After mushrooms appear, spray only the outside of the building.
Food-handling establishments (including households; restaurants; theaters; food processing plants; industrial plants; and warehouses)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Indoor treatment Directed spray application	4 lb/gal EC	0.5% finished spray	Applications may be made with deodorized base oil or water using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas while food is exposed is prohibited
Indoor treatment Remote Fog Application	20% PrL	2.5 g/1000 cu. ft.	Application made by timer when buildings are unoccupied. Building should be closed and ventilation kept to a minimum. Lock all entrances, and do not allow unprotected workers to enter the building when being treated.
Food-handling establishments (including theaters; food processing plants; industrial plants; and warehouses)			
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	0.37 lb/gal EC 1.59 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 2 lb/gal SC 8.39 lb/gal SC	1% finished spray [1 gal/64,000 cu.ft]	Fogging or misting applications may be made with deodorized base oil or water using fogging or misting equipment to treat indoor areas. Applications are to be made when the plants are not in operation. Food should be removed and food-handling equipment covered prior to application or washed with suitable cleaner and potable water after application.
Food-handling establishments [including areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage, and enclosed processing systems (mills, dairies, edible oils, syrups), and serving areas]			
Indoor crack and crevice treatment	0.25 lb/gal EC 0.5 lb/gal EC	0.1% finished spray	Applications may be made in water or oil and may be applied by directing small amounts into crack and crevices, in points between different elements of construction, and between equipment legs and bases. Applications in food areas other than crack and crevice treatments are prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)]			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Indoor treatment Directed spray application	0.37 lb/gal EC 1.59 lb/gal EC 1.15 lb/gal SC 2 lb/gal SC 8.39 lb/gal SC	0.5% finished spray	Applications may be made with deodorized base oil or water using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas while food is exposed are prohibited.
	4.48 lb/gal SC [	0.5% finished spray	Applications may be made with deodorized base oil using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in food/feed handling areas of food/feed handling establishments, restaurants or other areas where food is commercially prepared or served and use to treat non-perishable bagged or bulk raw or processed commodities is prohibited.
	10 lb/gal SC	0.5% finished spray	For use in warehouses, silos, bulk bins, and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities. Applications may be made with deodorized base oil using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use of this product in food processing plants, food-handling areas of restaurants, or areas where food is prepared or served, and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of food, water, food containers, or cooking utensils is prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)]			
Indoor spot treatment	0.25 lb/gal EC 0.5 lb/gal EC	0.1% finished spray	Applications may be made in water or oil and may be applied as a coarse spray or with a paint brush to areas where pests hide (baseboard areas, around water pipes, surfaces behind and beneath sinks, lockers, tables, pallets, and similar areas). Applications may be repeated as needed. Use of this product in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas where food is exposed are prohibited.

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
	1.16 lb/gal EC [	0.5% finished spray	Applications may be made in water and may be applied to areas where pests hide (around baseboards, cracks, walls, door and window frames and localized areas of floors). Use of this product in food processing plants, food-handling areas of restaurants, or areas where food is prepared or served, and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of food, water, food containers, or cooking utensils is prohibited.
	0.5% RTU	0.5% spray	Applications may be made with a pump sprayer to areas where pests hide (dark corners of room and closets, cracks and crevices in walls, behind and beneath sinks, stoves, refrigerators, cabinets, washing machines, cupboards, bookcases, and around baseboards). Use of this product in food areas of food-handling establishments, restaurants, or other areas where food is commercially prepared or processed and use in serving areas where food is exposed or while facility is operating are prohibited.
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	4.48 lb/gal SC	1% finished spray [1 gal/64,000 cu.ft]	Fogging or misting applications may be made with deodorized base oil using fogging or misting equipment to treat indoor areas. Use in bottling plants, food contact areas or meat slaughter, and/or packing plants or in frozen food plants is prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)] (continued)			
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	10 lb/gal SC	1% finished spray [1 gal/64,000 cu.ft]	For use in warehouses, silos, bulk bins, and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities. Fogging or misting applications may be made with deodorized base oil using fogging or misting equipment to treat indoor areas. Use in bottling plants, food contact areas or meat slaughter, and/or packing plants or in frozen food plants is prohibited. When using in food processing, handling, and storage areas: (I) applications may be made only during times when plant is not in operation and no food products are exposed; if bulk, unpackaged food is exposed, it must be removed or covered prior to treatment; (ii) all food processing surfaces should be covered during treatment or thoroughly cleaned before using.
Indoor premise treatment	0.5% PrL	0.5% spray	Use as a space spray is prohibited. Applications may be applied to areas where pests hide (cracks, around baseboards, cabinets, walls, and woodwork) and repeated as necessary. Use of this product in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of utensils, food, water, and foodstuffs prohibited.
	20% Impr	10.5 g of product/ 50-100 cu. ft	Use in kitchens, restaurants, or areas where food/feed are prepared or processed, use in food/feed processing or food/feed manufacturing areas of food/feed processing and food/feed manufacturing plants are prohibited.
Animal Uses (Premises)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, loafing pens, pig pens, poultry houses, hog barns, stables, and other farm buildings)			
Premise treatment Directed spray application	1 lb/gal EC	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to all exterior and interior surfaces, treating window sills, around doors, fences, and ledges or as a directed spray to floors, baseboards, crack and crevices in wall, and along base of walls. Applications may be made using water- or oil-based sprays; applications may be repeated as necessary. A 1-day preslaughter interval (PSI) has been established.
	2 lb/gal EC	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using water; applications may be repeated as necessary. Animals must be removed prior treatment. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited.
	0.37 lb/gal EC 2 lb/gal EC 4 lb/gal EC	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using water; applications may be repeated as necessary. Animals may be present during treatment. Contamination of water, feed or foodstuffs, milk or milking utensils is prohibited.
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Premise treatment Directed spray application	1.16 lb/gal EC 1.59 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using diesel oil or water; applications may be repeated as necessary. Direct treatment of animals or humans and contamination of water, feed or foodstuffs, milk or milking utensils are prohibited.
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	2 lb/gal EC	1% finished spray [0.5 qt/8,000 cu.ft] or 0.5% finished spray [1 qt/8,000 cu.ft]	Fog applications may be made using diesel oil. Animals must be removed prior to treatment. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited.
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	0.37 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC	1% finished spray [0.5 qt/8,000 cu.ft] or 0.5% finished spray [1 qt/8,000 cu.ft]	Fog applications may be made using diesel oil. Animals must be removed prior to treatment. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited. Contamination of water, feed or foodstuffs, milk or milking utensils is prohibited.
Premise treatment	1% G	0.04 oz/1,000 sq.ft	Bait applications may be made to clean floor areas, ground areas outside enclosures, window sills, or other areas where flies congregate. Applications are to be made in such a manner that stock cannot come into contact with bait.
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)			
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	1 lb/gal EC	1% finished spray [0.5 qt/8,000 cu.ft]	Fog applications may be made with animals present, provided a direct animal treatment of DDVP has not been made in the past 8 hours. Applications may be made using water or deodorized kerosene. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings.

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Animal buildings (including horse barns, calf parlors, hog parlors, stables, poultry houses, tack rooms, and dog kennels)			
Premise treatment	20% Impr	10.5 g of product/ 50-100 cu. ft	Contamination of water, food or foodstuffs, milk or milking equipment is prohibited. Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr	10.5 g of product/ 50-100 cu. ft	Contamination of water, food or foodstuffs, milk or milking equipment is prohibited.
Milk rooms (including bulk storage rooms)			
Premise treatment	20% Impr	10.5 g of product/ 50-100 cu. ft	Contamination of milk or milking equipment is prohibited. Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr	10.5 g of product/ 50-100 cu. ft	Contamination of milk or milking equipment is prohibited.
Feed lots, stockyards, corrals, and holding pens			
Outdoor premise treatment	1 lb/gal EC		Applications may be made as an overall mist spray to fences, feed bunkers, shade areas, spillage areas, building walls, and other areas where flies congregate. Applications may be made in water using a mist blower or similar equipment at 3- to 14-day intervals.
	0.37 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC]	0.5% finished spray [5 gal/A] 0.2 lb/A	Applications may be made as an overall mist spray to fences, feed bunkers, spillage areas, and building walls. Applications may be made in diesel oil or water using a mist blower or similar equipment. Animals may be present during treatment.

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Poultry houses			
Premise treatment	0.37 lb/gal EC 1 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC [5481-200]	0.5% finished spray [1 qt/1,000 sq.ft] Not specified on the 2 lb/gal EC [5481-73] product label	Applications may be made to manure, window sills, exterior walls, interior walls, feed room floors, and walkways. Only crack and crevice treatments are permitted for indoor use and applications are to be made out of reach of poultry (EPA Reg. No. 5481-41 only).
	1% G [5481-9]	0.04 oz/1,000 sq. ft	Bait applications may be made to droppings under cages, on walkways, window sills, alley ways, and other areas where flies congregate. Applications are to be made out of reach of birds.
Direct Animal Uses			
Cattle (beef and dairy)			
Animal mist spray treatment	1 lb/gal EC [5481-41]	1% finished spray [2 fl. oz/animal/day]	Application may be made in water as an atomized spray uniformly distributed over each animal. Do not wet the skin.
	2 lb/gal EC [5481-73]	0.5% finished spray [4 fl. oz/animal/day]	Application may be made in water as an atomized spray uniformly distributed over each animal. Application more than once per day and application to calves less than 6 months of age are prohibited.

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
	0.37 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC [1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC	1% finished spray [2 fl. oz/animal/day]	Application may be made in deodorized base oil or water as an atomized spray uniformly distributed over each animal. Do not wet the hide. Application of more than 2 fl. oz. per animal per day and application to calves less than 6 months of age are prohibited. A 1-day PSI has been established (EPA Reg. Nos. 5481-204 and 5481-220 only).
Cattle (beef and dairy) (continued)			
Animal face paint treatment	1 lb/gal EC	0.5% bait slurry [1 tsp/face]	Applications may be made to the animal's forehead daily for 14 days and thereafter as needed.

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
	0.37 lb/gal 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC	1% bait slurry [3 mL/face]	Application is to be made as a 6-inch line to the animal's forehead with a paint brush.
Cattle (beef and dairy) (continued)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Manure treatment	0.37 lb/gal EC 1 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC 10 lb/gal SC	0.5% finished spray [2 qt/100 sq.ft] or 1% finished spray [1 qt/100 sq.ft]	Applications may be made in water to control maggots in manure piles and garbage dumps.
Poultry			
Manure treatment	1 lb/gal EC [5481-41]	0.5% finished spray [2 qt/100 sq.ft]	Applications may be made in diesel oil or deodorized kerosene to control flies and maggots in poultry droppings.
Animal Uses - Oral Dosing (Drug Use)			
Swine			
Feed treatment	N/A [3]	12.5-20.6 mg/kg body weight	Application is to be made by mixing active ingredient into feed and may be repeated in 4-5 weeks.
Wide Area and General Outdoor Treatment			
Outdoor areas (including outside picnic areas, patios, and eating areas of drive-in restaurants)			
Outdoor spray application	2 lb/gal SC	0.5-1% finished spray	Applications may be made in deodorized spray base oil and repeated monthly or as needed.
Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
Outdoor spray application	1 lb/gal EC	0.5% finished spray [1 qt/1,000 sq. ft]	Applications may be made in water and repeated as needed. Direct use on animals and contamination of feed, foodstuffs, or water are prohibited.
Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses) (continued)			
	0.37 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC 8.39 lb/gal SC		
Outdoor spray application	10 lb/gal SC	0.5% finished spray [1 qt/1,000 sq. ft]	Applications may be made in diesel oil or water and repeated as needed. Direct use on animals or humans and contamination of water, food, food containers or cooking utensils are prohibited.
Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses) (continued)			

Site Application Type	Formulation	Application Rate, ai	Use Directions and Limitations
	0.37 lb/gal EC 1.16 lb/gal EC 1.59 lb/gal EC 2 lb/gal EC 4 lb/gal EC 1.15 lb/gal SC 4.48 lb/gal SC		
Outdoor fogging application [Hand-Held Foggers are no longer permitted]	8.39 lb/gal SC 10 lb/gal SC	1% finished spray [5-10 pt/A] or 0.05-0.1 lb/A	Fogging or misting applications may be made with diesel oil or water using fogging or misting equipment to treat outdoor living areas, picnic areas, backyard areas, patios, loading docks, outdoor latrines, parking areas, refuse areas around service stations, open air drive-ins, ice cream stands, and garbage collection and disposal areas. Use in areas where food or feed crops are growing is prohibited.
Catch basins			
Outdoor treatment	20% Impr	One strip	One strip (10.5 or 80 g of product) is to be suspended 10 inches above water level for control of mosquitoes breeding in catch basins.

APPENDIX B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision for DDVP

GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

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

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

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

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of DDVP

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	40798101
830.1600	61-2A	Description of materials used to produce the product	All	40798101
830.1620	61-2B	Description of production process	Al	40798101
830.1670	61-2B	Formation of Impurities	All	40798101
830.1700	62-1	Preliminary Analysis	All	40798102
830.1750	62-0	Certification of Limits	All	40798102
830.1800	62-3	Analytical Method	All	40798102
830.6302	63-2	Color	All	40798103
830.6303	63-3	Physical State	All	40798103
830.6304	63-4	Odor	All	40798103
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	40798103, 41232401, 43890401
830.6367	63-17	Storage Stability		40798103
830.6320	63-20	Corrosion Characteristics		40798103
830.7000	63-12	pH	All	40798103
830.7050	None	UV/Visible Absorption	All	
830.7200	63-5	Melting Point	All	
830.7220	63-6	Boiling Point	All	40798103
830.7300	63-7	Density	All	40798103
830.7550	63-11	Partition coefficient, shake flask method	All	40798103
830.7840	63-8	Solubility	All	40798103
830.7950	63-9	Vapor Pressure	All	40798103
ENVIRONMENTAL TOXICITY				
850.2100	71-1A	Avian Acute Oral Toxicity – Quail	ALL	00160000, 40818301
850.2100	71-1A	Avian Acute Oral Toxicity – Duck	ALL	00160000
850.2200	71-2A	Avian Dietary Toxicity – Quail	ALL	00022923
850.2200	71-2B	Avian Dietary Toxicity – Duck	ALL	00022923
850.2300	71-4A	Avian Reproduction – Quail	ALL	43981701
850.2300	71-4B	Avian Reproduction – Duck	ALL	44233401
850.1075	72-1A	Fish Toxicity Bluegill	ALL	40094602
850.1075	72-1B	Fish Toxicity Bluegill – TEP	ALL	43284701
850.1075	72-1C	Freshwater Fish Toxicity Rainbow Trout	ALL	40098001
850.1075	72-1D	Freshwater Fish Toxicity Rainbow Trout – TEP	ALL	43284702
850.1010	72-2A	Freshwater Invertebrate Toxicity	ALL	40098001
850.1075	72-3A	Estuarine/Marine Toxicity – Fish	ALL	43571403
850.1025	72-3B	Estuarine/Marine Toxicity – Mollusk	ALL	43571404
850.1035	72-3C	Estuarine/Marine Toxicity – Shrimp	ALL	43571405
850.1300	72-4	Freshwater Invertebrate Toxicity – Chronic	ALL	43890301
	72-3D	Estuarine/Marine Toxicity – Fish, TEP	ALL	43571406
	72-3E	Estuarine/Marine Toxicity – Mollusk, TEP	ALL	43571407
	72-3F	Estuarine/Marine Toxicity – Shrimp, TEP	ALL	43571408
850.1350	72-4B	Estuarine/Marine Invertebrate Life	ALL	43854301

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
		Cycle		
850.1400	72-4	Freshwater Fish Early-Life Stage	ALL	43788001
850.3020	141-1	Honey Bee Acute Contact	ALL	00036935
850.5400	122-2	Aquatic Plant Growth	ALL	40228401=40098001
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	ALL	00005467, 45805701, 45805702, 45805703, 45842301
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	ALL	00005467
870.1300	81-3	Acute Inhalation Toxicity – Rat	ALL	00137239
870.2400	81-4	Primary Eye Irritation - Rabbit	ALL	00146921
870.2500	81-5	Primary Skin Irritation	ALL	00146920
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	ALL	41004701
870.6100		Subchronic Neurotoxicity Study in Hens	ALL	41004702
870.3700	83-3A	Developmental Toxicity – Rat	ALL	41951501
870.3700	83-3B	Developmental Toxicity – Rabbit	ALL	41802401
870.3800	83-4	2-Generation Reproduction – Rat	ALL	42483901
870.4100	83-1A	Chronic Feeding Toxicity Study – Rat	ALL	
870.4100	83-1B	Chronic Feeding Toxicity Study - Non-rodent	ALL	41593101
870.4200	83-2B	Carcinogenicity Mice	ALL	00057695, 00632569, 40299401
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	ALL	40299401
870.6100	82-5A	Acute Delayed Neurotoxicity - Hen	ALL	43433501, 41004702
870.6200	81-8	Neurotoxicity Screening Battery	ALL	42958101, 42655301
870.6300	83-6	Developmental Neurotoxicity	ALL	46153302, 46239801
870.7485	85-1	General Metabolism	ALL	41228701, 41839901
870.7600	85-3	Dermal Penetration and Absorption	ALL	41435201
870.8223		Time Course of Cholinesterase Inhibition in Preweaning and Adult Wistar Rats/870.8223	ALL	46153303
Non-Guideline		Preliminary Developmental Neurotoxicity - Rat	ALL	46153301
Non-guideline	Human Studies	Multiple Oral Dosing on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers	ALL	44248801
		Cholinestrase Inhibition Following Oral Administration to Healthy Male Volunteers	ALL	44416201
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	ALL	41723101
835.2240	161-2	Photodegradation - Water	ALL	43326601
835.2410	161-3	Photodegradation - Soil	ALL	43642501
835.4100	162-1	Aerobic Soil Metabolism	ALL	41723102
835.4200	162-2	Anaerobic Soil Metabolism	ALL	43835701
835.1240	163-1	Leaching/Adsorption/Desorption	ALL	41723103, 40034904, 41354105
835.6100	164-1	Terrestrial Field Dissipation	ALL	44297701, 44386701

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations	
RESIDUE CHEMISTRY					
860.1000	170-1	Reduction of Residue			
		Dried Beans	A,B	42910701	
		Cocoa Beans	A,B	42910701	
		Coffee Beans	A,B	42910701	
		Tomato	A,B	42910701	
		Meat, Eggs, Pasteurized Milk	A,B	42910701	
		Degradation - Packaged and Bagged Raw and Processed Commodities	A,B	42858201	
		Degradation - Bulk Stored Raw and Processed Commodities	A,B	42903801	
860.1300	171-4A	Nature of Residue – Plants	A,B	00013545, 00074844	
860.1300	171-4B	Nature of Residue – Livestock	A,B	00013546, 00066696, 00117261, 00117262, 00126462, 00126463, 42721601, 42951701	
860.1340	171-4C	Residue Analytical Method – Plants	A,B	00042702, 00042704, 00042706, 00047472, 00049086, 00049971, 00049975, 00051556, 00074706, 00074777, 00107572, 00115993, 00117747, 00118115, 00139845	
860.1340	171-4D	Residue Analytical Method - Livestock	A,B	00042702, 00042704, 00049086, 00049087, 00049975, 00060469, 00060470, 00060472, 00074706, 00115939, 00115993, 00117257, 00117747, 00118113, 00118592, 00118639, 00140392	
860.1380	171-4E	Storage Stability	A,B	00074776, 00076809, 00140392, 43377701, **Data Gap**	
860.1500	171-4K	Crop Field Trials			
		Radishes	A,B	00118572, 00119536	
		Lettuce	A,B	00033139, 00082271, 00118572, 00119536	
		Cucumbers	A,B	00082271, 00107572, 00118572	
		Mushrooms	A,B	00074658, 00117686, 00117690	
		Multiresidue Methods	A,B	42611001	
860.1360	171-4M	Food Handling			
860.1460	171-4I	Grain Processing and Manufacturing Establishments			A,B
		Bulk Stored Raw and Processed Commodities	A,B	00117747, 42916601	
		Bulk stored peanuts	A,B	43003101	

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations	
		Packaged and Bagged Raw and Processed Commodities	A,B	00056593, 00056595, 00056596, 42853701	
		Magnitude of Residue in Meat, Milk, Poultry and Eggs			
860.1480	171-4J	Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep			A,B
		Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A,B	00118639, 00119537, 00139843, 00139844, 43047901, **Data Gap**	
		Magnitude of Residue in Processed Food/Feed			
860.1520	171-4L	Corn, field			A,B
		Cottonseed	A,B	42993501	
		Rice	A,B	42993501	
		Peanuts	A,B	42952601	
		Soybeans	A,B	42993501	
		Wheat	A,B	42993501	
		Wheat	A,B	42993501	
OCCUPATIONAL/RESIDENTIAL EXPOSURE					

APPENDIX C: Bibliography

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 (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

Chemistry Bibliography

40798101 Feiler, W. (1988) DDVP: Product Identity and Composition. Unpublished compilation prepared by Amvac Chemical Corp. 25 p.

40798102 Feiler, W. (1988) DDVP: Analysis and Certification of Product Ingredients. Unpublished compilation prepared by Amvac Chemical Corp. 13 p.

40798103 Feiler, W. (1988) DDVP: Physical and Chemical Characteristics. Unpublished study prepared by Amvac Chemical Corp. 3 p.

41232401 Feiler, W. (1988) Supplement to: Stability of Technical Grade DDVP. Unpublished study prepared by Amvac Chemical Corp. 4 p.

43890401 Marsh, J. (1996) DDVP--Stability: Lab Project Number: 4506-95-0071-AS-001: 4506-95-0071-AS-000: 4506-95-0071-AS. Unpublished study prepared by Ricerca, Inc. 48 p.

Ecological Effects Bibliography

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

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Labo- ratory Studies. By University of California, Dept. of Entomology. UC, Cooperative Extension. (Leaflet 2287; published study.)

00160000

40094602 Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publi- cation 137. US Fish and Wildlife Service, Washington, D.C. 106 p.

40098001 Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p.

40818301 Grimes, J.; Jaber, M. (1988) DDVP: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Project No. 246-102. Unpub- lished study prepared by Wildlife International Ltd. 21 p.

43284701 Jones, F. (1994) DDVP 4-E Emulsifiable Concentrate: Acute Toxicity to Bluegill (Lepomis machrochirus) under Flow-Through Test Conditions: Lab Project Number: J9403007D. Unpublished study prepared by Toxikon Environmental Sciences. 49 p.

43284702 Jones, F. (1994) DDVP 4-E Emulsifiable Concentrate: Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) (sic) under Flow-Through Test Conditions: Lab Project Number: J9403007E. Unpublished study prepared by Toxikon Environmental Sciences. 49 p.

43571403 Jones, F.; Davis, J. (1994) DDVP Technical Grade: Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-through Test Conditions: Lab Project Numbers: J9403007F: J9403007B. Unpublished study prepared by Toxikon Environmental Sciences. 59 p.

43571404 Jones, F.; Davis, J. (1995) DDVP Technical Grade: Acute Effect on New Shell Growth of the Eastern Oyster (Crassostrea virginica): Lab Project Numbers: J9403007H: J9403007B. Unpublished study prepared by Toxikon Environmental Sciences. 63 p.

43571405 Jones, F.; Davis, J. (1994) DDVP Technical Grade: Acute Toxicity to the Mysid (Mysidopsis bahia) Under Flow-through Test Conditions: Lab Project Numbers: J9403007G: J9403007B. Unpublished study prepared by Toxikon Environmental Sciences. 61 p.

43571406 Jones, F.; Davis, J. (1994) DDVP 4-E Emulsifiable Concentrate: Acute

Toxicity to Sheepshead Minnow, Cyprinodon variegatus, Under Flow-through Test Conditions: Lab Project Numbers: J9403003I: J9403007B. Unpublished study prepared by Toxikon Environmental Sciences. 60 p.

43571407 Jones, F.; Davis, J. (1994) DDVP 4-E Emulsifiable Concentrate: Acute Effect on New Shell Growth of the Eastern Oyster (Crassostrea virginica): Lab Project Numbers: J9403007K: J9403007C. Unpublished study prepared by Toxikon Environmental Sciences. 58 p.

43571408 Jones, F.; Davis, J. (1994) DDVP 4-E Emulsifiable Concentrate: Acute Toxicity to the Mysid, Mysidopsis bahia, Under Flow-through Test Conditions: Lab Project Numbers: J9403007J: J9403007B. Unpublished study prepared by Toxikon Environmental Sciences. 60 p.

43788001 Davis, J. (1995) DDVP Technical Grade: Toxicity to Embryos and Larvae of the Rainbow Trout, Oncorhynchus mykiss, Under Flow-Through Conditions: Lab Project Number: J9403007M. Unpublished study prepared by Toxikon Environmental Sciences. 77 p.

43854301 Ward, S.; Davis, J. (1995) DDVP Technical Grade: Chronic Toxicity to the Mysid (Mysidopsis bahia) Under Flow Through Conditions: Lab Project Number: J9407006A. Unpublished study prepared by Toxikon Environmental Sciences. 90 p.

43890301 Ward, G.; Davis, J. (1995) DDVP Technical Grade: Chronic Life-Cycle Toxicity to the Water Flea, Daphnia magna, Under Flow-Through Test Conditions: Lab Project Number: J94030071: J9403007N. Unpublished study prepared by Toxikon Environmental Sciences. 74 p.

43981701 Cameron, D. (1996) DDVP: Bobwhite Quail Dietary Reproduction and Tolerance Studies: Lab Project Number: AVC 2: AVC 2/960139. Unpublished study prepared by Huntingdon Life Sciences Ltd. 324 p.

44233401 Redgrave, V. (1997) Mallard Duck Dietary Reproduction and Tolerance Studies: DDVP: Lab Project Number: AVC 7/961821: AVC 7. Unpublished study prepared by Huntingdon Life Sciences Ltd. 243 p.

Toxicology Bibliography

00005467 Gaines, T.B. (1960) The acute toxicity of pesticides to rats. Toxicology and Applied Pharmacology 2(1):88-99. (Also in unpublished submission received Feb 14, 1961 under PP0299; submitted by Chemagro Corp., Kansas City, Mo.; CDL:090320-Q)

00057695 Blair, D.; Dix, K.M.; Hunt, P.F.; et al. (1974) Two Year Inhalation Exposure of Rats to Dichlorvos Vapour: Group Research Report TLGR.00 .74. (Unpublished study, including letters dated Aug 6, 1974 from E.L. Hobson to L. Axelrod and Aug 8, 1974 from E.L. Hobson to John B. Ritch, received Oct 2, 1974 under unknown admin. no.; prepared by Shell, Ltd. in cooperation

with Sitting- bourne Research Centre, submitted by Shell Chemical Co., Washington, D.C.; CDL:120611-A)

137239 MacDonald, R.; Thorpe, E.; Hendy, R.; et al. (1982) Toxicology of Consumer Products: The Acute (4 H) Inhalation Toxicology of Dichlorvos Vapour in Rats and Mice: External Report SBER.82.008. (Unpublished study received Jan 24, 1984 under 201-125; prepared by Shell Research Ltd., Eng., submitted by Shell Chemical Co., Washington, DC; CDL:252309-A)

00146920 Mallory, V. (1984) Primary Dermal Irritation Study in Rabbits: 83/ EPA: VCR Insecticide: Summary: PH 420-BL-004-84. Unpublished study prepared by Pharmakon Research International, Inc. 2 p.

00146921 Mallory, V. (1984) Primary Eye Irritation Test EPA/82: VCR Insecticide: Summary: PH 421-BL-005-84. Unpublished study prepared by Pharmakon Research International, Inc. 2 p.

00632569

40299401 Chan, P. (1987) NTP Technical Report on the Toxicology and Carcino-genesis Studies of Dichlorvos (CAS No. 62-73-7) in F344/N Rats and B63F1 Mice: (Gavage Studies): NTP TR 342. Draft Technical Report of July, 1987 prepared for public review and comment. US Dept. of Health and Human Services, Public Health Service, Publication No. NIH 88-2598. 239 p.

41004701 Kleeman, J. (1988) 13-Week Gavage Toxicity Study with DDVP in Rats: Final Report: Project ID: HLA 6274-102. Unpublished study pre- pared by Hazleton Laboratories America, Inc. 294 p.

41004702 Beavers, J.; Driscoll, C.; Dukes, V.; et al. (1988) DDVP: An Acute Delayed Neurotoxicity Study in Chickens: Final Report: Project No. 246-103. Unpublished study prepared by Wildlife International Ltd. 86 p.

41228701 Cheng, T. (1989) Metabolism of (Carbon 14)-DDVP in Rats: Project ID HLA 6274-105. Unpublished study prepared by Hazleton Laboratories America, Inc. 322 p.

41435201 Jeffcoat, A. (1990) Dermal Absorption of Dichlorvos in Rats: Lab Project Number: 4615. Unpublished study prepared by Research Triangle Institute. 196 p.

41593101 Markiewicz, V. (1990) A 52-Week Chronic Toxicity Study on DDVP in Dogs: Lab Project Number: 2534/102. Unpublished study prepared by Hazleton Laboratories America, Inc. 431 p.

41802401 Tyl, R.; Marr, M.; Myers, C. (1991) Development Toxicity Evaluation of DDVP Administered by Gavage to New Zealand White Rabbits: Lab Project Number: 60C-4629-30/40. Unpublished study prepared by Research Triangle Institute. 247 p.

41839901 Cheng, T. (1991) Supplement to: Metabolism of carbon 14-DDVP in Rats (Preliminary and Definitive Phases) (...): Lab Project Number: HLA 6274-105-1. Unpublished study prepared by Hazleton Laboratories America, Inc. 89 p.

41951501 Tyl, R.; Marr, M.; Myers, C. (1991) Developmental Toxicity Evaluation of DDVP Administered by Gavage to CD (Sprague-Dawley) Rats: Lab Project Number: 60C-4629-10/20. Unpublished study prepared by Research Triangle Inst. 305 p.

42483901 Tyl, R.; Myers, C.; Marr, M. (1992) Two-Generation Reproductive Toxicity Study of DDVP Administered in Drinking Water to CD (Sprague-Dawley) Rats: Final Report: Lab Project Number 60C-4629-170. Unpublished study prepared by Research Triangle Institute. 1225 p.

42655301 Lamb, I. (1993) An Acute Neurotoxicity Study of Dichlorvos in Rats: Final Report (Text and Summary Data): Lab Project Number: WIL-188003. Unpublished study prepared by WIL Research Labs., Inc. 984 p.

42958101 Lamb, I. (1993) A Subchronic (13 Week) Neurotoxicity Study of Dichlorvos in Rats: Final Report: Lab Project Number: WIL-188004. Unpublished study prepared by WIL Research Labs, Inc. 1199 p.

43433501 Redgrave, V. (1994) DDVP: 28-Day Neurotoxicity in the Domestic Hen: Lab Project Number: AVC 1/921405: RAD 2/942053. Unpublished study prepared by Huntingdon Research Centre, Ltd. 465 p.

44248801 Gledhill, A. (1997) Dichlorvos: A Single Blind, Placebo Controlled, Randomised Study to Investigate the Effects of Multiple Oral Dosing on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers: Lab Project Number: CTL/P/5392: XH6063. Unpublished study prepared by Zeneca Central Toxicology Lab. 52 p.

44416201 Gledhill, A. (1997) Dichlorvos: A Study to Investigate Erythrocyte Cholinestrase Inhibition Following Oral Administration to Healthy Male Volunteers: Lab Project Number: XH5170: Y09341: C05743. Unpublished study prepared by Zeneca Central Toxicology Lab. 104 p.

45805701 Twomey, K. (2002) Dichlorvos (DDVP): Acute Cholinesterase Inhibition Study in Rats (1st Study): Summary Report: Lab Project Number: CO1001: Y09341/004: AR7079. Unpublished study prepared by Central Toxicology Laboratory. 24 p.

45805702 Twomey, K. (2002) Dichlorvos (DDVP): Second Acute Cholinesterase Inhibition Study in Rats: Lab Project Number: CTL/AR7126/REGULATORY/REPORT: AR7126: CTL/AR7126/REG/REPT. Unpublished study prepared by Central Toxicology Laboratory. 67 p.

45805703 Twomey, K. (2002) Dichlorvos (DDVP): Third Acute Cholinesterase Inhibition Study in Rats: Lab Project Number: CTL/AR38/REGULATORY/REPORT: AR7 138: CTL/AR7138/REG/REPT. Unpublished study prepared by Central Toxicology Laboratory. 136 p.

45842301 Moxon, M. (2002) Dichlorvos: Acute Cholinesterase Inhibition Study in Pre-Weaning Rats: Lab Project Number: CTL/AR7147/REGULATORY/REPORT: AR7147: CTL/AR7147/REG/REPT. Unpublished study prepared by Central Toxicology Laboratory. 49 p.

46153301 Milburn, G. (2003) Dichlorovos: Preliminary Developmental Neurotoxicity Study in Rats. Project Number: CTL/RR0885/REGULATORY/REPORT. Unpublished study prepared by Central Toxicology Lab. (Syngenta). 290 p.

46153302 Milburn, G. (2003) Dichlorvos: Developmental Neurotoxicity Study in Rats. Project Number: 86/REGULATORY/REPORT, RR0886, CTL/RR0886/REG/REPT. Unpublished study prepared by Central Toxicology Lab. (Syngenta). 2328 p.

46153303 Milburn, G. (2003) Dichlorvos: Time Course of Cholinesterase Inhibition in Pre-Weaning and Adult Rats. Project Number: CTL/AR7310/REGULATORY/REPORT, AR7310, CTL/AR7310/REG/REPT. Unpublished study prepared by Central Toxicology Lab. (Syngenta). 176 p.

46239801 Milburn, G. (2004) Dichlorvos: Supplemental Developmental Neurotoxicity Study in Rats. Project Number: RR0988, CTL/RR0988/REG/REPT, CTL/RR0988/REGULATORY/REPORT. Unpublished study prepared by Central Toxicology Lab. 1341 p.

Environmental Fate Bibliography

40034904 Pack, D. (1986) Freundlich Adsorption Isotherms of Dichloracetic Acid: Laboratory Project Identificaton: 8614820. Unpublished study prepared by Chevron Chemical Co. 15 p.

41354105 Pack, D. (1987) Supplement to "Estimation of Soil Adsorption Coefficient of NALED from TLC Data": Lab Project Number: MEF0051/8716396A. Unpublished study prepared by Chevron Chemical Co. 4 p.

41723101 Vithala, R. (1990) DDVP--Hydrolysis of C 14 DDVP in Aqueous Solutions Buffered at pH 5, 7, and 9: Lab Project Number: 006/006/ 001/89. Unpublished study prepared by Univ. of Pittsburgh, Center for Hazardous Materials Research. 141 p.

41723102 Vithala, R. (1990) DDVP--Aerobic Soil Metabolism of C 14 DDVP: Lab Project Number: 006/006/004/89. Unpublished study prepared by Univ. of Pittsburgh, Center for Hazardous Materials Research. 7 p.

41723103 Vithala, R. (1990) DDVP--Mobility of Unaged DDVP Using Batch Equilibrium Technique: Lab Project Number: 006/006/008/89. Unpublished study prepared by Univ. of Pittsburgh, Center for Hazardous Materials Research. 70 p.

43326601 Mobley, S. (1994) Aqueous Photolysis of (carbon 14) DDVP (Dichlorvos) in Artificial Light: Lab Project Number: 838: 1611. Unpublished study prepared by PTRL East, Inc. 95 p.

43642501 Misra, B. (1995) Photodegradation of (Carbon-14)-DDVP (Dichlorvos) on Sandy Loam Soil Under Artificial Sunlight Irradiation: Final Report: Lab Project Number: ME 9400184. Unpublished study prepared by Pittsburgh Environmental Research Lab, Inc. 79 p.

43835701 Mobley, S. (1995) Anaerobic Soil Metabolism of (carbon 14)DDVP (Dichlorvos): Lab Project Number: 882: 1847. Unpublished study prepared by PTRL East, Inc. 82 p.

44297701 Leppert, B. (1997) Dichlorvos: Terrestrial Dissipation of DDVP 2-E on Bareground Plot in California...: Final Report: Lab Project Number: 6293-150: SARS-96-CA-72: SARS-96-72. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Covance Lab., Inc. 404 p.

44386701 Leppert, B. (1997) Dichlorvos: Terrestrial Field Dissipation of DDVP 2-E on Bareground Plot in Missouri: Revised Final Report: Lab Project Number: SARS-96-MO-71: CHW 6293-147: SARS-96-71. Unpublished study prepared by Stewart Agricultural Research, Inc. and Corning Hazleton, Inc. 445 p.

Residue Chemistry Bibliography

00013545 Arthur, B.W.; Casida, J.E. (1957) Metabolism and selectivity of O, O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate and its acetyl and vinyl derivatives. Journal of Agricultural and Food Chemistry 5(3):186-191. (Also In unpublished submission received Apr 16, 1965 under 5H1748; submitted by Shell Chemical Co., Washington, D.C.; CDL:22161-C)

00013546 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)

00033139 Shell Chemical Company (1961) ?Residue Data for Vapona on Lettuce: RES-60-6. (Unpublished study received May 26, 1964 under 201- 125; CDL:000814-A)

00033144 Shell Chemical Company (1963) Determination of Vapona^(R)I Insecti- cide & Dichloroacetaldehyde Residues in Cucumbers, Lettuce, Mushrooms,

Spinach & Tomatoes following Application of Vapona Insecticide: RES-63-116. (Unpublished study received May 26, 1964 under 201-125; CDL:000814-F)

00042702 Shell Development Company (1964) Determination of Vapona(R)I Insecticide in Crops and Animal Products: Enzyme Inhibition-Spectrophotometric Method. Method dated Jun 18, 1964. (Unpublished study received Jun 18, 1964 under unknown admin. no.; CDL: 108831-A)

00042704 Citation: Shell Development Company (1964) Determination of Dichloroacetaldehyde Residues in Crops & Animal Tissue: GLC-Electron Capture Method. Method MMS-50/64 dated Jun 19, 1964. (Unpublished study received Jun 19, 1964 under unknown admin. no.; CDL: 108828-A)

00042706 Kiigemagi, U.; Terriere, L.C. (1964) A Tentative Method for the Determination of DDVP (Vapona): Residues in Certain Vegetables. Method dated Jun 24, 1964. (Unpublished study received Jun 24, 1964 under unknown admin. no.; prepared by Oregon State Univ., Dept. of Agricultural Chemistry, submitted by ?; CDL:108825-A)

00047472 Laboratoire de Recherche et D'Applications (1969) Residues in Unwrapped Foodstuffs Purchased from Shops. (Unpublished study received May 1, 1970 under 0H2477; submitted by Shell Chemical Co., Washington, D.C.; CDL:221670-B)

00049086 Shell Chemical Company (1971) Determination of Vapona(R)I Insecticide in Agricultural Products. Analytical method PMS-G-913/69 dated Jul 1, 1969. (Unpublished study received on unknown date under 201-341; CDL:222759-B)

00049087 Shell Development Company (1969) Residue Determination of Dichlorvos Analogs in Animal Feed, Blood, Body Tissue and Excrement, with Specific Reference to Dichlorvos and Its Methyl, Octyl and Dioctyl Analogs. Analytical method MMS-R-201 dated Aug 1969. (Unpublished study received on unknown date under 201- 341; CDL:222759-C)

00049971 U.S. Department of Agriculture (1962) Determination of DDVP Residues on Various Commodities by the Acetylcholinesterase Inhibition (Colorimetric) Method. Method Pr 5e-62 dated Mar 1, 1962. (Agricultural Marketing Service, Stored-Product Insects Laboratory, unpublished study; CDL:221633-H)

00049975 Shell Chemical Company (1966) Determination of Dichloroacetaldehyde Residues in Crops & Animal Tissue, GLC-Electron Capture Method. Analytical method PMS-G-900/66 dated Oct 6, 1966. (Unpublished study received Apr 4, 1967 under 7H2166; CDL:221633-L)

00051556 Power, J.L. (1970) Letter sent to Kenneth A. Hansen dated Jul 15, 1970: Vapona methodology. (U.S. Public Health Service, Food and Drug

Administration, unpublished study; CDL:221675-B)

00056593 Gillenwater, H.B. (1964) Residues on Loose and Packaged Commodities after Exposure to Dichlorvos (DDVP) Aerosol: Project MQ 1-24:3. (Unpublished study received Apr 16, 1965 under 5H1748; submitted by Shell Chemical Co., Washington, D.C.; CDL:221615-Y)

00056595 U.S. Agricultural Marketing Service (1964) Dichlorvos (DDVP) Residues on Packaged Subsistence Items Exposed to Vapor Applications in a 126,000-Cu. Ft. Warehouse Bay. (Market Quality Research Div., Stored-Product Insects Branch, unpublished study; CDL:221615-AA)

00056596 U.S. Agricultural Marketing Service, Stored-Product Insects Branch (1963) DDVP Residues on Packaged Commodities after Exposure to a Relatively Constant Vapor Concentration Applied with DDVP- Impregnated Granules: Project BS 1-51:62. (Unpublished study; CDL:221615-AB)

00060469 U.S. Department of Agriculture (1968) Results of Research on Residues of Dichlorvos in Milk and Body Tissues of Dairy Cows Treated for Fly Control. (Agricultural Research Service, Entomology Research Div., Texas Laboratory; unpublished study; CDL: 221669-H)

00060470 Shell Development Company (1964) Determination of DDVP in Animal Tissue: Enzyme Inhibition-Spectrophotometric Method. Method MMS-30A/64 dated Jul 1964. (Unpublished study received Nov 6, 1969 under 0H2477; CDL:221669-J)

00060472 Shell Development Company (1964) Determination of Dichloroacetaldehyde Residues in Animal Tissue: GLC-Electron Capture Method. Method MMS-50A/64 dated Jun 19, 1964. (Unpublished study received Nov 6, 1969 under 0H2477; CDL:221669-M)

00066696 Potter, J.C.; Loeffler, J.E.; Collins, R.D.; et al. (1973) Carbon- 14 balance and residues of Dichlorvos and its metabolites in pigs dosed with Dichlorvos- 14 C. Journal of Agricultural and Food Chemistry 21(2):163-166. (Also In unpublished submission received May 1, 1975 under 2724-269; submitted by Zoecon Industries, Inc., Dallas, Tex.; CDL:220018-U)

00074658 Interregional Research Project Number 4 (1970) Residue Data on Vapona in Mushrooms. (Reports by various sources; unpublished study received on unknown date under 1E1100; CDL:090860-A)

00074706 Shell Development Company (1960) Determination of Vapona (TM)I Insecticide in Crops and Animal Products: Enzyme Inhibition-spectrophotometric Method. Analytical method MMS-30/60 dated Dec 7, 1960. (Unpublished study received Nov 9, 1964 under 5011-60; submitted by Carmel Chemical Corp., Westfield, Ind.; CDL: 119777-C)

00074658 Interregional Research Project Number 4 (1970) Residue Data on Vapona in

Mushrooms. (Reports by various sources; unpublished study received on unknown date under 1E1100; CDL:090860-A

00074776 Kohn, G.K. (1960) Letter sent to G.S. Hensill dated May 9, 1960: Storage stability of Dibrom and DDVP in fortified extracts of sorghum--seeds and heads. (Unpublished study received May 16, 1960 under 239-1281; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:026977-A)

00074777 Pack, D.E. (1960) Letter sent to J.N. Ospenson dated Feb 1, 1960: Dibrom and DDVP residues--in acetyl cholinesterase method of determining each in the presence of the other. (Unpublished study received May 16, 1960 under 239-1281; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:026877-C)

00074844 Casida, J.E.; McBride, L.; Niedermeier, R.P. (1961) Metabolism of O,O-Dimethyl 2,2-Dichlorovinyl Phosphate (Vapona (R)I or DDVP) in Relation to Residues in Milk and Mammalian Tissues. (Unpublished study received Aug 20, 1962 under PP0330; prepared by Univ. of Wisconsin, Depts. of Entomology and Dairy Husbandry, submitted by California Chemical Co., Richmond, Calif.; CDL: 090358-H)

00076809 Shell Chemical Company (1980) Summary of Residue Data for Dichlorvos in or on Figs. (Compilation; unpublished study, including published data, received May 8, 1981 under 201-125; CDL: 070073-A)

00082271 Interregional Research Project Number 4 (1968) (Residue Study of Dichlorvos on Tomatoes, Lettuce and Cucumbers). (Compilation; unpublished study received on unknown date under 0E0875; CDL: 097531-B)

00107572 Jones, W.; Miles, E.; Hill, K. (1969) Report of Residue Analysis: PCB-69-8. (U.S. Agricultural Research Service, Entomology Re- search Div., Pesticide Chemicals Research Branch, Analytical Investigations; unpublished study; CDL:022406-A)

00115939 Shell Chemical Co. (1972) Residue Data in Reply to EPA's July 10, 1972 Letter of Special Review for Ciovap EC Insecticide. (Compilation; unpublished study received Sep 20, 1972 under 201-244; CDL:000948-A)

00115945 Shell Chemical Co. (1973) Residue Information in Support of Vapona Insecticide Residual Wall Spray Emulsifiable. (Compilation; unpublished study received on unknown date under 201-EX-45; CDL:238131-A)

00115993 Shell Chemical Co. (1966) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Vapona. (Compilation; unpublished study received May 27, 1967 under 7F0623; CDL:090815-A)

00116436 Shell Oil Co. (1962) Letter sent to L. Lykken dated Feb 9, 1962 Results of tests: Valpona residue in cows milk|. (Unpublished study received Feb 23,

1963 under 201-164; CDL:120488-A)

00117257 Shell Chemical Co. (1971) Analysis of Recovery Samples. (Unpub- lished study received on unknown date under unknown admin. no.; CDL:117545-A)

00117261 Block, A.; Panos, A.; Sheridan, J. (1961) Progress Report I on the Digestion of Dimethyl Dichloro Vinyl Phosphate in Cows: Project No. 9304-80-2. (Unpublished study received Sep 6, 1961 under 5609-7; prepared by Evans Research and Development Corp., submitted by Norda Essential Oil & Chemical Co., New York, NY; CDL:120055-A)

00117262 Casida, J.; McBride, L.; Niedermeier, R. (1961) Metabolism of ... Vapona or DDVP in Relation to Residues in Milk and Mammalian Tissues. (Unpublished study received Jun 28, 1961 under 201- 125; prepared by Univ. of Wisconsin, Depts. of Entomology and Dairy Husbandry, submitted by Shell Chemical Co., Washington, DC; CDL:120058-A)

00117686 Shell Chemical Co. (1962) Determination of Residues of Vapona Insecticide in Various Crops|. (Compilation; unpublished study received Apr 2, 1962 under unknown admin. no.; CDL:120065-A)

00117690 Shell Chemical Co. (1963) Determination of Vapona Insecticide Residues in Mushrooms, Banana Peel and Pulp|. (Compilation; unpublished study received May 26, 1964 under 201-136; CDL: 120071-A)

00117747 Shell Chemical Co. (1970) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Vapona Insecticide|. (Compilation; unpublished study received 1970 under 1F1132; CDL:090909-B)

00117686 Shell Chemical Co. (1962) Determination of Residues of Vapona Insecticide in Various Crops. (Compilation; unpublished study received Apr 2, 1962 under unknown admin. no.; CDL:120065-A)

00118113 Shell Chemical Co. (1969) Vapona: Residues in Milk and Other Subjects|. (Compilation; unpublished study received on unknown date under 9F0788; CDL:093096-A)

00118115 Chemagro Corp. (1973) Banasan: Analytical and Residue Information on Bananas. (Compilation; unpublished study received Oct 9, 1973 under 4E1436; CDL:093829-A)

00118169 Smith, F.; Wheeler, H.; Yeomans, A.; et al. (1964) Dichlorvos Residues on Harvested Tomatoes and Leaf Lettuce Grown in the Greenhouse. (Unpublished study received Jun 25, 1964 under unknown admin. no.; prepared by U.S. Agricultural Research Service, Fruit & Vegetable Insects Branch and Pesticide Chemicals Research Branch, submitted by Plant Products Corp., Blue Point Long Island, NY; CDL:123044-A)

00118572 Jones, W.; Miles, E.; Hill, K. (1970) Report of Residue Analysis: Dichlorvos|.

(Unpublished study received Jun 18, 1974 under 1327-36; prepared by U.S. Agricultural Research Service, Entomology Research Div., Pesticide Chemicals Research Branch, Analytical Investigations, submitted by Fuller System, Inc., Woburn, MA; CDL:024527-A)

00118592 Makhteshim Beer-Sheva Chemical Works Ltd. (1972) Divipan (Dichlorvos): Residue Analysis: DS.16.23.32. (Unpublished study received Nov 16, 1973 under 11724-17; submitted by Intex Products, Inc., Greenville, SC; CDL:028033-B)

00118639 Koos, B. (1973) Determination of DDVP Residues in Chicken Eggs and Tissues following Direct Application with Vapona Insecticide Residual Wall Spray Emulsifiable: TIR-26-009-73. (Unpublished study received on unknown date under 201-EX-45; submitted by Shell Chemical Co., Washington, DC; CDL:238130-A)

00119536 Summit Chemical Co. (1969) (Study: DDVP Residue in Tomatoes and Other Selected Crops). (Compilation; unpublished study received Sep 25, 1970 under 6218-13; CDL:007833-A)

00119537 Shell Chemical Co. (1970) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: (Vapona). (Compilation; unpublished study received Nov 5, 1970 under 1F1059; CDL:093372-C)

00126462 Cheng, H.; Tucker, B. (1983) Metabolic Fate of Naled in Chickens after a Single Oral Dose of (Ethyl-1-14C)-naled: File No. 721.14/Naled. (Unpublished study received Mar 9, 1983 under 239-1633; submitted by Chevron Chemical Co., Richmond, CA; CDL: 249713-A)

00126463 Cheng, H.; Tucker, B. (1983) Characterization of 14C in Chicken Tissues and Eggs after Dosing with (Ethyl-1-14C)-Naled for 10 Consecutive Days: File No. 721.14/naled. (Unpublished study re- ceived Mar 9, 1983 under 239-1633; submitted by Chevron Chemical Co., Richmond, CA; CDL:249713-B)

00139843 Marymiller, R.L.; Bramhall, E.L. (1971) Determination of Vapona(R)I Insecticide Residues in Turkeys following Exposure to This Insecticide via Resin Strip Leg Bands: TIR-24-500-71. (Un- published study received Jan 30, 1973 under 201-341; submitted by Shell Chemical Co., Washington, D.C.; CDL:001044-G)

00139844 Brady, U.E. (1972) Determination of Vapona(R)I Insecticide Residues in Turkeys after Exposure of Birds to Vapona Leg Bands. (Unpublished study received Jan 30, 1973 under 201-341; prepared by Univ. of Georgia, Dept. of Entomology, submitted by Shell Chemical Co., Washington, D.C.; CDL:001044-I)

00139845 Shell Development Company (1969) Residue Determination of Vapona(R)I Insecticide in Air, Food and Beverages: GLC-Phosphorus Detector Method.

Method no. MMS-R-222-1 dated Dec 1969. (Unpublished study received Jan 30, 1973 under 201-341; CDL: 001044-J)

00140392 Shell Chemical Co. (1971) The Results of Tests To Determine Whether Vapona Insecticide Residues Are Incurred in Food Products De- rived from Livestock Treated with Vapona, Including a Description of the Analytical Methods Used. (Compilation; unpublished study received Sep 8, 1969 under 9F0788; CDL:091359-A)

42611001 Williams, M. (1992) Multiresidue Methods Testing for DDVP: DEGS Column Chromatography (Method C) and Method D: Lab Project Number: 10029. Unpublished study prepared by Horizon Laboratories, Inc. 125 p.

42721601 Krautter, G. (1993) The Metabolism of (vinyl-1-(carbon 14)) DDVP in the Lactating Goat Following Dermal Application for 3 Consecutive Days: Lab Project Number: 1381: 498. Unpublished study prepared by PTRL East, Inc. 207 p.

42768702 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Food Handling Establishments: Oat Processing Facility: Final Report: Lab Project Number: SARS 92-14A: 40598. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Analytical Bio-Chemistry Labs, Inc. 234 p.

42775901 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Food Handling Establishments: Corn Processing Facility: Lab Project Number: SARS-92-14C: SARS-92-IA-14C: 40628. Unpublished study prepared by Stewart Ag. Research Services, Inc. and ABC Labs, Inc. 191 p.

42853701 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Nonperishable Raw Agricultural Commodities and Processed Foods: Warehouse Storage on Packaged and Bagged Commodities: Final Report: Lab Project Number: SARS-92-16A. Unpublished study prepared by Stewart Agricultural Research Services, Inc., Horizon Labs, Inc., and Analytical Bio-Chemistry Labs, Inc. 493 p.

42858201 Schofield, C. (1993) Half-Life Determination of Dichlorvos in Nonperishable Raw Agricultural Commodities and Processed Foods: Warehouse Storage of Packaged and Bagged Commodities: Final Report: Lab Project Number: SARS-92-16B. Unpublished study prepared by Stewart Pesticide Registration Associates, Inc. 329 p.

42878801 Feiler, W. (1993) Magnitude of Residues for Dichlorvos in Animal Feed Streams of Food Handling Establishments: Oat Processing Facility: Final Report: Supplemental Study of Fines Stream: Lab Project Number: AMV 002 RES: 40658. Unpublished study prepared by ABC Labs. 74 p.

42903801 Schofield, C. (1993) Half-Life Determination of Dichlorvos in Nonperishable Raw Agricultural Commodities and Processed Foods: Bulk Stored Commodities: Final Report: Lab Project Number: SARS-93-17B.

Unpublished study prepared by Stewart Agricultural Research Services, Inc., Horizon Labs., Inc., and Analytical Bio-Chemistry Labs., Inc. 338 p.

42910701 Williams, M. (1993) DDVP Residues in Uncooked and Cooked/Processed Commodities: Meat, Eggs, Dry Beans, Milk, Cocoa Beans, Coffee Beans, and Tomato Paste: Lab Project Number: 10043. Unpublished study prepared by Horizon Laboratories, Inc. 133 p.

42910801 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Food Handling Establishments: Oat Manufacturing Facility: Final Report: Lab Project Number: SARS-92-14B: SARS-92-IA-14B: 40627. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Analytical Bio-Chemistry Labs, Inc. 204 p.

42910901 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Food Handling Establishments: Wheat Manufacturing Facility: Final Report: Lab Project Number: SARS-92-14D: 10038: SARS-92-IL-14D. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Horizon Labs, Inc. 309 p.

42916601 Schofield, C. (1993) Magnitude of Residue for Dichlorvos in Nonperishable Raw Agricultural Commodities and Processed Foods: Bulk Stored Commodities: Lab Project Number: SARS-93-17A. Unpublished study prepared by Horizon Labs., Inc.; Analytical Bio-Chemistry Labs., Inc.; Stewart Agricultural Research Services, Inc. 316 p.

42951701 Krautter, G. (1993) The Metabolism of (vinyl-1-(carbon 14))DDVP in Laying Hens Following Dermal Application for 3 Consecutive Days: Lab Project Number: 1536: 497. Unpublished study prepared by PTRL East, Inc. 204 p.

42952601 Hofen, J.; Warnke, J. (1993) Magnitude of Residue for Dichlorvos in Processed Fraction of Peanuts: Field Test Site and Processing Laboratory: Lab Project Number: SARS-92-13. Unpublished study prepared by Stewart Agricultural Research Services, Inc.; Horizon Labs, Inc. 310 p.

42993501 Hofen, J.; Warnke, J. (1993) Magnitude of Residue for Dichlorvos in Processed Fractions of Raw Agricultural Commodities: Field Corn, Wheat, Rice, Cottonseed and Soybeans: Final Report: Lab Project Number: SARS-93-18: SARS-93-MO-18: 10016. Unpublished study prepared by Horizon Labs, Inc., Analytical Bio-Chemistry Labs, Inc. and Stewart Agricultural Research Services, Inc. 581 p.

43003101 Hofen, J.; Warnke, J. (1993) Magnitude of Residue for Dichlorvos in Food Handling Establishments: Bulk Stored Peanuts: Final Report: Lab Project Number: SARS-92-12: SARS-92-GA-12: 10035. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Horizon Labs, Inc. 309 p.

43037401 March, K.; Noland, P.; Roesel, L.; et al. (1993) Magnitude of the Residue of

Dichlorvos in Milk and Dairy Cow Tissues: Final Report: Lab Project Number: 40872: M-9134-MB. Unpublished study prepared by ABC Labs, Inc. 96 p.

43047901 March, K.; Noland, P.; Chickering, D. (1993) Magnitude of the Residues of Dichlorvos in Eggs and Laying Hen Tissues: Lab Project Number: 40873: M-9133. Unpublished study prepared by ABC Labs., Inc. 102 p.

43377701 Matheson, W. (1993) Amendment #1 of the Analytical Report for Magnitude of Residue for Dichlorvos in Food Handling Establishments: Bulk Stored Peanuts: Lab Project Number: 10035: SARS/92/12. Unpublished study prepared by Horizon Lab., Inc. 10 p.

Exposure Bibliography

45870701 Jacobs, L.; Driver, J.; Pandian, M. (2003) Residential Exposure Joint Venture: National Pesticide Use Survey--Design, Implementation, Analysis Methods and Results: Lab Project Number: 03-REJV-4M-001: 030-REJV-4M-001: 8D. Unpublished study prepared by NFO WorldGroup and infoscientific.com, Inc. 8515 p.

46099001 Jacobs, L.; Driver, J.; Pandian, M. (2003) Residential Exposure Joint Venture National Pesticide Use Survey - Design, Implementation, Analysis Methods and Results. Project Number: 03/REJV/12M/002. Unpublished study prepared by NFO Worldgroup and Infoscientific.com, Inc. 155 p.

APPENDIX D: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2002-0302. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov.

.

The Agency documents in the docket include:

1. Dichlorvos (DDVP) HED Chapter of the Reregistration Eligibility Decision Document (RED)

2. Weight of Evidence Comparison of Human and Animal Toxicology Studies and Endpoints for DDVP

3. Ethical Review of DDVP Human Study

4. Response to AMVAC's pre-Phase 5 error only comments on the DDVP human health effects risk assessments

5. Response to Public Comments on the Dichlorvos (DDVP) Preliminary Risk Assessment

6. Drinking Water Assessment for Dichlorvos (Revised)

7. Summary of HED's Reviews of Outdoor Residential Exposure Task Force (ORETF) Chemical Handler Exposure Studies; MRID 44972201. ORETF Study Numbers OMA001, OMA002, OMA003, OMA004., DP Barcode 261948, memo dated April 30, 2001.

8. Memorandum: Review of Poison Control Center Data Call In. To Joshua First, December 5, 1994. US EPA.

9. Review of Comments on Dichlorvos Incidences. Memo to D. Utterback. May 17, 1996.

10. Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars: Lab Project Number: TR-506. Unpublished study prepared by Zoecon Industries, Inc. 14 p. {OPPTS 875.1500} MRID 45792201.

11. DDVP (Vapona) QUA, Memorandum to D. Pillitt (RD) dated October 2, 1985.

12. Dichlorvos (084001). Anticipated Residues for Dichlorvos resulting from use of Dichlorvos and Naled. June 15, 1998.

12. Dichlorvos (084001). Refined Anticipated Residues and Dietary Exposure and Risk for Residues of Dichlorvos resulting from use of Dichlorvos, Trichlorfon, and Naled. June 7, 2000.

13. Assessment of Exposures of Residents to Dichlorvos Applied as a Total Release Fogger. May 10, 1993.

14. Review of Exposure Monitoring Study for Use of DDVP in Food Processing Establishments, DP Barcode D191571, December 6, 1993.

15. Exposures from Dichlorvos (DDVP) Resin Strips. D246131. March 5, 1998.

16. Re-entry Exposures to Dichlorvos Resulting from Application to Residential Turf and Recreational Areas. D246126. March 16, 1998.

17. Exposures to Dichlorvos (DDVP) from Flea Collars. March 18, 1998.

18. Exposure Assessment for Dichlorvos (DDVP) Applied to Greenhouse and Mushroom Houses. April 22, 1998.

19. Exposure to Dichlorvos resulting from the Use of Bait Products. D246128. April 28, 1998.

20. Inhalation Exposures from Dichlorvos (DDVP) Resin Strips. June 12, 1998.

21. Revised Applicator Exposures to Dichlorvos resulting from Crack and Crevice Use and the Use of Aerosol Products. D261140. April 30, 1998.

22. Revisions of Exposures from Dichlorvos (DDVP) Resin Strips. D250069. September 30, 1998.

23. Exposures to Dichlorvos Resulting from the Use of Bait Products. D251336. January 27, 1999.

24. Response to Comments from EXPOSAC on Exposure Assessment for Dichlorvos (DDVP) from Flea Collars. D 246127. November 6, 1998.

25. Response to EXPOSAC Comments on Exposure Assessment for Total Release Foggers Containing Dichlorvos (DDVP). D251333. December 31, 1998.

26. Revised Applicator Exposures to Dichlorvos (DDVP) Resulting from Dairy Barn and Animal Spray Uses. D251330. January 27, 1999.

27. Response to Comments from the EXPOSAC and Others on Assessment of Re-entry Exposures to Dichlorvos Resulting from Application to Residential Turf and Recreation Areas. D251909. January 28, 1998.

28. Revised Exposure Assessment for Greenhouses and Mushroom Houses. D251337. January 27, 1999.

29. Response to Amvac Comments on HED Interim Risk Assessment for DDVP. D255064. March 17, 1999.

30. Examination of Recent Submissions from Amvac regarding Dichlorvos (DDVP) and Rationale for Not Including Them in the Exposure/Risk Assessment. May 27, 1999.

31. Dislodgeable Foliar Residues and Exposure Assessment for Residential/Recreational Turf Applications of Dichlorvos (DDVP), PC Code 084001, Barcodes D248456, D248596, D255253, August 13, 1999.

32. Calculation Error - Dichlorvos Resin Strips, D257002, August 16, 1999.

33. Dichlorvos (DDVP) Resin Strip Exposure Assessment for Individuals Exposed for a 2 Hour Period, PC Code 084001. July 21, 2000.

34. Revision of Exposure Assessment for DDVP applied to Warehouses and Food Processing Plants. D226572. June 7, 2000.

35. Response to Comments on the Preliminary Risk Assessment (PRA) for Dichlorvos (PC Code 084001, DP Barcode D271993). May 31, 2001.

36. Addendum to Residential Turf Assessment for Dichlorvos (DDVP) PC Code 084001, DP Barcode D288914. March 28, 2003.

37. Review of Protocol for Study Monitoring Indoor Air Concentrations of DDVP Using Pest Strips in Confined and Unoccupied Areas. DP Barcode D288575. March 14, 2003.

38. Exposure Assessment for Workers Applying DDVP to Rail Cars and Stationary Trucks and Subsequently Loading Cargo onto the Treated Vehicles (PC Code 084001, DPBarcode D289191), January 27, 2005.

39. HED's Revision of the Trichlorfon Residential Exposure/Risk Assessment. PC Code 057901. DP Barcode D268125. August 9, 2000.

40. Vapona (DDVP) Exposure Potential to Workers in Mushroom houses in Ventura County, California in 1981. HS-861.

41. Trichlorfon (057901): HED Revised Preliminary Risk Assessment for Trichlorfon. DP Barcode D268728. Case 0104. September 19, 2000.

42. Dichlorvos (DDVP)- Report of the Cancer Assessment Review Committee, March 7, 2000.

43. Benchmark dose analysis of cholinesterase inhibition data in neonatal and adult rats (MRID no. 46688914) following exposure to DDVP PC Code: 084001. DP Barcode DP 328793. TXR No. 0054223 June 9, 2006

44. Qualitative Assessment of Dichlorvos (DDVP) in Drinking Water and Volatilization from Use of Trichlorfon Turf, May 18, 2006

45. Biological and Economic Analysis of Dichlorvos in Greenhouses

46. Biological and Economic Analysis of Residential Indoor Use of Dichlorvos

47. Biological and Economic Analysis of Dichlorvos for Residential Outdoor Pests

48. Biological and Economic Analysis of Dichlorvos for Pet Collars

49. Biological and Economic Analysis of Dichlorvos for Bulk Stored Commodities

50. Biological and Economic Analysis of Dichlorvos in Mushroom Houses

51. Biological and Economic Analysis of Dichlorvos for Food Storage Areas

52. Request for Voluntary Cancellations and Amended Registrations; Letter from Amvac Chemical Corp. to EPA, May 9, 2006

53. Petition to Conclude Special Review, Reregistration, and Tolerance Reassessment Process and to Revoke All Tolerances and Cancel All Registrations for the Pesticide DDVP, Filed June 2, 2006

APPENDIX E: Generic Data Call-In

Note that a Data Call-In (DCI), with all pertinent instructions, will be sent to the registrants.

APPENDIX F: Product Specific Data Call-In

Note that a Data Call-In (DCI), with all pertinent instructions, will be sent to the registrants.

APPENDIX G: EPA's Batching of DDVP 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 DDVP as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (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 that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by 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 a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Ninety eight products were found which contain DDVP as the active ingredient. These products have been placed into twenty batches and a No Batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

Batch 1A: Products listed in this Batch may cite data from Batch 1.

Batch 3: EPA Reg. Nos. 769-632 and 61483-75 may not cite data generated with lower percentage a.i. products within this batch.

Batch 4: EPA Reg. Nos. 5481-73 and 5481-334 may not cite data generated with lower percentage a.i. products within this batch

Batch 10: EPA Reg. No. 2517-37 may not cite data generated with lower percentage a.i. products within this batch.

Batch 13: EPA Reg. No. 769-924 must conduct own primary eye irritation study.

Batch 15: EPA Reg. Nos. 769-640, 5481-9, & 47000-43 may not cite data generated with EPA Reg. No. 769-568.

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	5481-461	98.0
	5481-462	98.0

Batch 1A	EPA Reg. No.	Percent Active Ingredient
	769-629	90.00
	5481-96	93.00
	5481-200	90.00
	19713-353	90.00
	19713-356	90.09

Batch 2	EPA Reg. No.	Percent Active Ingredient
	769-727	50.0
	769-795	50.0
	5481-202	50.0
	47000-137	50.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	655-692	41.76
	769-632	44.50
	5481-204	41.10
	47000-17	44.50
	61483-75	40.20

Batch 4	EPA Reg. No.	Percent Active Ingredient
	769-625	23.70
	769-627	23.70
	769-798	23.70
	2217-291	24.60
	5481-73	25.00
	5481-205	24.62
	5481-334	25.24
	47000-135	23.70
	47000-138	23.68
	51036-55	23.70

Batch 5	EPA Reg. No.	Percent Active Ingredient
	5481-338	18.6
	5481-344	18.6
	5481-348	18.6

	5481-475	18.6

Batch 6	EPA Reg. No.	Percent Active Ingredient
	655-492	18.6
	47000-130	18.5

Batch 7	EPA Reg. No.	Percent Active Ingredient
	2217-463	15.0
	5481-207	15.0
	5481-208	15.0

Batch 8	EPA Reg. No.	Percent Active Ingredient
	769-796	12.50
	5481-41	13.01

Batch 9	EPA Reg. No.	Percent Active Ingredient
	8730-50	10.0
	65458-6	10.0

Batch 10	EPA Reg. No.	Percent Active Ingredient
	2517-37	9.6
	5481-341	9.0
	5481-343	9.0
	5481-346	9.0

Batch 11	EPA Reg. No.	Percent Active Ingredient
	9444-32	7.0
	19713-344	7.0

Batch 12	EPA Reg. No.	Percent Active Ingredient
	1015-68	5.0
	5481-220	5.0
	47000-74	5.0

Batch 13	EPA Reg. No.	Percent Active Ingredient
	769-924	5.37
	6218-57	5.00

	67517-38	4.65

Batch 14	EPA Reg. No.	Percent Active Ingredient
	2517-38	4.7
	5481-342	4.7
	5481-345	4.7
	5481-347	4.7

Batch 15	EPA Reg. No.	Percent Active Ingredient
	769-568	0.47
	769-640	1.00
	5481-9	1.00
	47000-43	1.00

Batch 16	EPA Reg. No.	Percent Active Ingredient
	655-702	0.93
	47000-23	0.50
	47000-52	1.00

Batch 17	EPA Reg. No.	Percent Active Ingredient
	228-103	0.93
	2217-332	1.00
	47000-114	1.00

Batch 18	EPA Reg. No.	Percent Active Ingredient
	19713-306	1.0
	19713-354	1.0

Batch 19	EPA Reg. No.	Percent Active Ingredient
	4-159	0.5
	47000-129	1.0
	47000-136	0.5

Batch 20	EPA Reg. No.	Percent Active Ingredient
	572-246	DDVP: 0.230 Pyrethrin: 0.034 Piperonyl Butoxide: 0.277
	769-797	DDVP: 1.000

		Pyrethrin: 0.300 Piperonyl Butoxide: 0.500
	4866-3	DDVP: 0.500 Pyrethrin: 0.050 Piperonyl Butoxide: 0.100
	47000-108	DDVP: 0.465 Pyrethrin: 0.025 Piperonyl Butoxide: 0.025
	47000-112	DDVP: 1.000 Pyrethrin: 0.010 Piperonyl Butoxide: 0.100

No Batch	EPA Reg. No.	Percent Active Ingredient
	769-628	50.000
	769-644	DDVP: 1.000 Malathion: 1.500
	769-821	4.980
	1327-36	12.740
	5011-49	9.800
	5481-13	0.500
	5481-201	80.000
	5481-203	50.000
	5481-206	20.000
	5481-340	DDVP: 0.500 Pyrethrin: 0.030 Piperonyl Butoxide: 0.060 MGK 264: 0.102
	6218-21	10.000
	6959-98	18.600
	8536-40	4.650
	8536-41	7.440
	19713-357	20.000
	47000-2	DDVP: 0.500 Phenothrin: 0.200 d-trans Allethrin: 0.323
	47000-54	DDVP: 0.500 Pyrethrin: 0.050 Piperonyl Butoxide: 0.100 MGK 264: 0.160 MGK 326: 0.200
	47000-71	18.600
	47000-131	DDVP: 0.500 Pyrethrin: 0.100 Piperonyl Butoxide: 0.400

	51036-5	33.7
	61483-50	DDVP: 5.300 Tetrachlorvinphos: 23.000
	61483-79	19.200
	65458-5	6.980

Appendix H: List of Registrants Sent Data Call-Ins

BONIDE PRODUCTS, INC.		6301 SUTLIFF ROAD	ORISKANY
NUFARM AMERICAS INC.		150 HARVESTER DRIVE SUITE 200	BURR RIDGE
VALUE GARDEN SUPPLY LLC		PO Box 585	ST. JOSEPH
PRENTISS INC		C.B. 2000	FLORAL PARK
VALUE GARDENS SUPPLY, LLC		PO Box 585	SAINT JOSEPH
DOUGLAS PRODUCTS AND PACKAGING COMPANY	JOHN WISE & ASSOCIATES, LTD	PO Box 1295	LIBERTY
FULLER SYSTEM, INC.		PO Box 3053	WOBURN
PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY
SERGEANT'S PET CARE PRODUCTS, INC.	REGGUIDE	509 TOWER VALLEY DRIVE	HILLSBORO
INTAGRA, INC.		16719 IREDALE PATH	LAKEVILLE
AIRE-MATE INC		PO Box 406	WESTFIELD
AMVAC CHEMICAL CORP		4695 MACARTHUR COURT, SUITE 1250	NEWPORT BEA
SUMMIT CHEMICAL CO		235 S KRESSON STREET	BALTIMORE
CESSCO INC		3609A RIVER RD	JOHNS ISLAND
SOIL CHEMICALS CORPORATION		PO Box 782	HOLLISTER
ABERDEEN ROAD COMPANY		PO Box 435	EMIGSVILLE
WATERBURY COMPANIES INC		PO Box 640 129 CALHOUN STREET	INDEPENDENCE
DREXEL CHEMICAL CO		PO Box 13327 1700 CHANNEL AVENUE	MEMPHIS
CHEM-TECH LTD	STEVEN E. ROGOSHESKE	1479 W POND RD	EAGAN
MICRO-FLO COMPANY LLC		530 OAK COURT DRIVE	MEMPHIS
CALIFORNIA DEPT. OF FOOD AND AGRICULTURE		1220 N STREET	SACRAMENTO
KMG-BERNUTH INC		10611 HARWIN DRIVE, # 402	HOUSTON
PLATO INDUSTRIES, LTD	TECHNOLOGY SCIENCES CROUP, INC.	1150 18TH STREET, NW, SUITE 1000	WASHINGTON
PM RESOURCES INC		13001 ST. CHARLES ROCK RD	BRIDGETON

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

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

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

Instructions:

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

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

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

   Document Processing Desk (distribution code)*
   Office of Pesticide Programs (7504P)
   Environmental Protection Agency
   1200 Pennsylvania Ave, NW
   Washington, DC 20460-0001

   * Distribution Codes are as follows:
   (APPL) Application for product registration
   (AMEND) Amendment to existing registration
   (CAN) Voluntary Cancellation
   (EUP) Experimental Use Permit
   (DIST) Supplemental Distributor Registration
   (SLN) Special Local Need
   (NEWCO) Request for new company number
   (NOTIF) Notification
   (PETN) Petition for Tolerance
   (XFER) Product Transfer

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epamail.epa.gov*. If you want these forms mailed or faxed to you, please contact Lois White, *white.lois@epa.gov* or Floyd Gayles, *gayles.floyd@epa.gov*.

If you have any questions concerning how to complete these forms, please contact OPP's ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

    National Technical Information Service (NTIS)
    5285 Port Royal Road

Springfield, VA 22161

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

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: http://npic.orst.edu

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

- Date of receipt
- EPA identifying number
- Product Manager assignment

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

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

APPENDIX J: **Dichlorvos (DDVP) HED Chapter of the Reregistration Eligibility Decision Document (RED)**

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

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

June 22, 2006

MEMORANDUM

SUBJECT: Dichlorvos (DDVP) HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code: 084001, Case #: 0310, DP Barcode: D330262
Regulatory Action: Phase 5 Reregistration
Risk Assessment Type: Single Chemical/Aggregate

FROM: Susan V. Hummel, Chemist, Branch Senior Scientist
Reregistration Branch IV
Health Effects Division (7509C)

and

William Dykstra, Ph. D., Toxicologist
David Hrdy, Biologist
David Jaquith, Industrial Hygienist
Reregistration Branch IV
Health Effects Division (7509C)

THROUGH: Ray Kent, Ph. D., Branch Chief
Reregistration Branch IV
Health Effects Division (7509C)

TO: Eric Olson, CRM #61
Special Review Branch
Special Review and Reregistration Division (7508C)

Attached please find the revised Human Health Risk Assessment for dichlorvos (DDVP). The Risk Assessment uses some endpoints based on human studies, found to be in compliance with the human studies rule. This document has been revised to address error only comments provided by the registrant (AMVAC). Additionally, on May 9, 2006, AMVAC requested voluntary cancellation and/or amendments, through incorporation of terms and conditions to current dichlorvos registrations. These modifications are summarized below:

Voluntary deletion of the following:

Product Types

1. 100 gram (g) pest strip
2. 21 g pest strip (contingent on the granting of registration for 16 g pest strip)
3. Total release fogger

Use Patterns

4. Lawn, Turf, and Ornamentals
5. Crack and Crevice

Application Method

6. Mushroom house hand held fogger
7. Greenhouse hand held fogger
8. Warehouse hand held fogger

Label Amendments

Occupational Exposure -- Applicators

1. Mushroom house Hose End Sprayer -- add coveralls to personal protective equipment requirements.

Occupational -- Post Application

2. Mushroom houses – 18 hour re-entry interval (REI)
3. Greenhouse -- 12 hour REI

Pest Strips

Registrant will split its end use registrations so that there will be one end use label for the large pest strips (65 g & 80 g) and another for the small pest strips (10.5 g, 5.25 g, and a new 16 g)

65 and 80 g pest strips

Label language to read**:**

"For use in unoccupied areas; not for use in homes except garages, attics, crawl spaces, and sheds occupied for less than 4 hours per day.

Also for use in boathouses, museum collections, animal buildings, and milk rooms, or enclosed areas thereof, occupied for less than 4 hours per day.

For use in unoccupied areas such as trash dumpsters, catch basins, bulk raw grain bins, storage bins, insect traps, enclosed utility boxes, and storage units. Also for use in non-perishable packaged and bagged and bulk stored processed and raw agricultural commodities (including soybeans, corn, grains, cocoa beans and peanuts).

Also for use in the following unoccupied structures, provided they are unoccupied for more than 4 months immediately following placement of a pest strip: vacation homes, cabins, mobile homes, boats, farm houses, and ranch houses."

16 g (new), 10.5 g, 5.25 g pest strips

Label language to read:

"Within homes, use only in closets, wardrobes, and cupboards. Also for use in storage units, garages, attics, crawl spaces, boathouses, museum collections, garbage cans, trash dumpsters, animal buildings, milk rooms, catch basins, bulk raw grain, and storage bins."

Table of Contents

1.0 Executive Summary

The Health Effects Division (HED) has conducted a human health risk assessment for the active ingredient dichlorvos (2,2-dichlorovinyl dimethyl phosphate), also known as DDVP, for the purposes of making a reregistration eligibility decision. Cumulative risk assessment considering risks from other pesticides or chemical compounds having a common mechanism of toxicity is not addressed in this document. This risk assessment updates the Phase 3 Preliminary Human Health Risk Assessment, dated August 9. 2000, addresses the Public Comments submitted in accordance with Phase 3 of the Tolerance Reassessment Advisory Committee (TRAC) Organophosphate (OP) Pilot Process, and additional error correction comments on a June 14, 2005 assessment, and uses endpoints based on human studies for some scenarios. The intentional dosing, human toxicity study used in this risk assessment has been reviewed by EPA's Human Studies Review Board (HSRB), on April 5, 2006, as required by EPA's Human Subjects Protections rule, 40 CFR part 26 (effective April 7, 2006). Exposures and risks for all exposure scenarios have been recalculated. Exposure to dichlorvos from the use of naled and trichlorfon (which metabolize to dichlorvos) is included in this document.

1.1 Use and Major Formulations

Dichlorvos is an organophosphate insecticide and fumigant registered for use in controlling flies, mosquitos, gnats, cockroaches, fleas, and other insect pests. Formulations of dichlorvos include pressurized liquids, granulars, emulsifiable concentrates, total release aerosols, and impregnated materials. Dichlorvos is applied with aerosols and fogging equipment, with spray equipment, and through slow release from impregnated materials, such as resin strips and pet collars.

Dichlorvos is registered to control insect pests on agricultural sites; commercial, institutional and industrial sites; and for domestic use in and around homes (i.e., resin strips) and on pets. Dichlorvos is used preplant in mushroom houses, and postharvest in storage areas for bulk, packaged and bagged raw and processed agricultural commodities, food manufacturing/processing plants, animal premises, and non-food areas of food-handling establishments. It is also registered for direct dermal treatment of cattle and poultry, and swine, sheep, and goats.

The mechanism of pesticidal action of dichlorvos is inhibition of cholinesterase. The Agency has determined that the adverse effects caused by dichlorvos that are of primary concern to human health are neurological effects related to inhibition of cholinesterase activity.

1.2 Regulatory History

The Agency initiated a Special Review for pesticide products containing dichlorvos on February 24, 1988, by publishing Position Document 1 (PD 1). At that time, the Agency was concerned that exposure to dichlorvos from registered uses posed an unreasonable carcinogenic risk and that there were inadequate margins of exposure for cholinesterase inhibition and liver effects to exposed individuals. After evaluation of information submitted through the Special Review Process, the Agency conducted another risk assessment for dichlorvos. In 1995, the Agency concluded that dichlorvos posed carcinogenic risks of concern to the general population

from dietary exposure. The Agency also concluded in 1995 that dichlorvos posed risks of concern for cholinesterase inhibition to residents and to individuals mixing, loading, and applying this pesticide, as well as to those reentering treated areas. Subsequently, the Agency issued a Preliminary Determination to Cancel Certain Registrations and Draft Notice of Intent to Cancel the dichlorvos uses which posed the greatest risks, also called Position Document 2/3 or PD 2/3 (60 FR 50338, September 28, 1995). In its 1995 Preliminary Determination (PD 2/3), the Agency concluded that the risks outweighed the benefits for most uses of dichlorvos and, therefore, recommended a variety of measures to reduce those risks. The Agency proposed cancellation of certain uses of dichlorvos and cancellation of other uses unless certain labeling modifications were made to reduce risk.

The PD 2/3 Federal Register Notice provided for a formal comment period, which closed on December 28, 1995. Comments were received, and are contained in a public docket identified as "OPP-30000/56." Major comments to the PD 2/3 were submitted to the Agency by Amvac Chemical Corporation, the Japanese Resin Strip Manufacturer's Association, grower groups, and the general public. Some of the comments contained additional data pertaining to the risks posed by dichlorvos.

The Agency has also identified newer exposure and toxicity data pertaining to dichlorvos that have become available since publication of the Notice of Preliminary Determination to Cancel certain Registrations and Draft Notice of Intent to Cancel (PD 2/3). In addition to the newer data and information described above, the Food Quality Protection Act of 1996 has effectively modified the considerations the Agency uses to assess the risks of pesticides. Therefore, the Agency has re-evaluated the toxicology and exposure databases for dichlorvos to make a determination of potential special susceptibility of infants and children, as mandated by FQPA. In addition, the Agency has reviewed new information pertaining to dietary exposure and performed a refined dietary exposure assessment. The Agency has also refined the occupational and residential exposure assessment for dichlorvos with new information and new methodologies that were previously unavailable.

The following issues pertaining to the ongoing dichlorvos risk assessment were presented to the FIFRA Science Advisory Panel (SAP) on July 28, 1998: (1) the selection of an FQPA safety factor for dichlorvos and (2) how the Agency conducted the resin strip exposure assessment.

This risk assessment has been conducted for dichlorvos in conjunction with the public review and comment process for all of the organophosphate pesticides. The public process for dichlorvos was initiated on December 3, 1998, when the Phase 1 risk assessment was provided to the registrant for "error only" review. In Phase 2 of the OP pilot process, the error correction comments from the registrant were incorporated. On October 11, 2000, the Preliminary Risk Assessment for dichlorvos was issued for public comment. This revision incorporates Agency response to the public comments submitted in Phase 3 of the OP pilot process. Comments on the dichlorvos Preliminary Risk Assessment were received from Amvac, NRDC, and dichlorvos users. Additional exposure analyses were conducted for different sizes of resin strips and for pet collars. Comments were received from a second registrant "error correction" comment period and from the HSRB from an April 5, 2006 meeting.

1.3 Hazard Identification and Dose-Response Assessment

The toxicology database for dichlorvos is complete with respect to the OPPTS Guideline requirements. For acute toxicity, technical dichlorvos was placed in Toxicity Categories II, I and II, respectively, for the oral, dermal and inhalation routes and in Toxicity Category III and IV for eye and dermal irritation, respectively. Dichlorvos did not cause organophosphate induced delayed neurotoxicity (OPIDN) in the hen following single or multiple (28 days) exposures. Following a single oral dose to rats, dichlorvos was associated with a variety of neurological and physiological changes. Subchronic and chronic oral exposures in rats and dogs as well as chronic inhalation exposure in rats resulted in significant decreases in plasma, red blood cell and/or brain cholinesterase activity. The carcinogenic potential of dichlorvos has been classified as "suggestive" under the 1999 Draft Agency Cancer Guidelines and no quantitative assessment of cancer risk is required. There was no evidence of increased susceptibility following *in utero* exposures to rats and rabbits as well as pre/post natal exposure to rats. Also, there was no evidence of abnormalities in the development of the fetal nervous system in the frbrlopmrnysl/neurotoxicity studies submitted to the Agency.

The toxicity endpoints used in this document to assess risks include acute and chronic dietary reference doses (RfDs), and short-, intermediate- and long-term dermal LOAELs and inhalation no observed adverse affect levels (NOAELs). Endpoints based on human studies have been used to assess some scenarios.

Inhibition of cholinesterase activity was the toxicity endpoint selected for acute and chronic dietary, as well as, short term, intermediate term, and long term (chronic) occupational and residential risk assessments. The Uncertainty Factor(s) ranged from 30 to 100 depending on the route and duration of exposures.

The HED dichlorvos team evaluated the hazard and exposure data to determine if the FQPA10x safety factor should be retained, reduced or removed focusing primarily on the following points: 1) the standard developmental and reproductive toxicity studies and the developmental neurotoxicity study submitted to the Agency showed no residual concern for increased susceptibility of rats, or rabbits to *in utero* and/or postnatal exposure to dichlorvos; 2) in single dose (acute) studies with dichlorvos in rats, there were no differences with respect to either RBC or brain cholinesterase inhibition between preweaning and adult rats; 3) in repeated dose studies with dichlorvos in rats, young rats were no more sensitive than adult rats with respect to inhibition of RBC and brain cholinesterase; and 4) sufficient data were available to ensure that the dietary (food and drinking water) and non-dietary (residential) risk assessments do not underestimate potential exposures and risks for infants and children from the use of dichlorvos. Some scenarios used endpoints ased on a LOAEL, and the 3x uncertainty factor used is considered part of the FQPA safety factor.

The dichlorvos team determined that there no residual concerns for increased susceptibility of infants and children. An FQPA safety factor of 1x is considered appropriate.

1.4 Exposure/Risk Assessment and Risk Characterization

Dietary exposure to dichlorvos residues may occur as a result of use of dichlorvos on or at a variety of sites, including mushroom houses, bulk-stored and packaged or bagged nonperishable processed and raw food, commercial food processing plants, direct dermal pour-on treatment to livestock, and livestock premises treatment. Two other pesticides, naled and trichlorfon, degrade to dichlorvos through plant and animal metabolism and other processes. Residues of dichlorvos from the use of naled on crops are included in the dichlorvos dietary exposure assessment. All trichlorfon field crop food uses have been canceled and associated tolerances revoked; therefore, the Agency does not expect measurable dichlorvos residues from use of trichlorfon on field crops. The trichlorfon tolerances on livestock commodities remain; dermal use on beef cattle is supported as an import use. Non-detectable dichlorvos residues in livestock commodities are expected as a result of trichlorfon use, and dichlorvos was not a significant metabolite in the trichlorfon dermal metabolism study. Therefore, dietary (food) exposure to dichlorvos residues resulting from use of trichlorfon is considered negligible for the purposes of this risk assessment.

Most product and residue chemistry data requirements for dichlorvos have been fulfilled. However, the reregistration data requirements for storage stability (Guideline 860.1380), for meat, milk, poultry, and egg studies (Guideline 860.1480), and directions for use (Guideline 860.1200) have not been fulfilled.

Dietary (food only) exposure estimates for dichlorvos have been refined with residue data from USDA's Pesticide Data Program (PDP), FDA surveillance monitoring data and FDA Total Diet Study (TDS) data. Anticipated residues for dichlorvos have been revised to incorporate these residue data. The acute and chronic dietary exposure analyses for dichlorvos (including contribution from naled and negligible contribution from trichlorfon) were conducted using the Dietary Exposure Evaluation Model (DEEM™) software. Acute dietary exposure did not exceed the Agency's level of concern for the 99.9th percentile of the population. Chronic dietary exposure did not exceed 2% of the cPAD for all subpopulations, which is below the Agency's level of concern of 100%.

The Environmental Fate and Effects Division (EFED) evaluated the potential for dichlorvos to contaminate water from the use of dichlorvos, naled or trichlorfon. EFED has limited ground water monitoring data for dichlorvos, naled, and trichlorfon from the states of California and Hawaii in the "Pesticides in Groundwater" database. These data indicate that naled, dichlorvos, or trichlorfon have not been detected in groundwater; however, these data were not targeted to the pesticide use area. Therefore, the SCIGROW model was used to estimate concentrations of dichlorvos, naled, and trichlorfon in groundwater. OPP does not have any surface monitoring data on the concentrations of dichlorvos, naled, or trichlorfon at the present time. Therefore, the Tier II screening models PRZM and EXAMS with the Index Reservoir and Percent Crop Area adjustment (IR-PCA PRZM/EXAMS) were used to estimate surface water concentrations for dichlorvos resulting from the use of naled, trichlorfon and dichlorvos.

Although PDP water monitoring data were available, and all samples had non-detectable residues (LODs ranged from 6 to 22.5 ppt), these data were not considered sufficiently

representative. In the absence of sufficient water monitoring data, estimated drinking water concentrations (EDWCs) of dichlorvos from the use of dichlorvos, naled, and trichlorfon in water were compared with Drinking Water Levels of Comparison (DWLOCs) for acute or chronic systemic toxicity. EDWCs of dichlorvos in ground and surface water were derived from conservative screening level models. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. HED uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water.

Residential and occupational exposure scenarios can be described as acute, short term (1-30 days), intermediate term (1 month to 6 months), and long term or chronic (6 months to a lifetime). The dichlorvos residential exposure scenarios for aerosol spray cans (both homeowner application and post-application) are considered acute exposure scenarios. Lawn post-application from treatment with trichlorfon is considered a short-term exposure scenario. Resin pest strips and pet flea collars are long term exposure scenarios. Occupational exposure scenarios are typically acute or short-term, except for a few intermediate term occupational exposure scenarios, applications in mushroom houses and direct application to livestock.

Exposure assessments for a number of occupational and residential scenarios were derived from limited data from the scientific literature, textbooks, knowledge of cultural practices, and the Residential SOPs (U.S. EPA, 1997a). Other estimates, particularly in the residential environment, were derived from surrogate data from the Pesticide Handlers Exposure Database (PHED, version 1.1), chemical specific data included in the Outdoor Residential Exposure Task Force (ORETF) database, Residential Exposure Joint Venture (REJV) data, and additional chemical specific monitoring data, including biomonitoring of a urinary metabolite, in combination with models and literature studies.

Residential exposure scenarios do not exceed the Agency's level of concern. Residential exposure from the use of the pressurized aerosol has been recalculated due to new data from the Residential Exposure Joint Venture (REJV).

Residential and occupational exposures to dichlorvos may also result from uses of naled and trichlorfon. The only naled residential use is a mosquitocide public health use. For this use, the application rate of naled is very low, and we expect that any dichlorvos formed dissipates rapidly. Further discussion is found in the exposure assessment section of this document. Approximately 25% of trichlorfon is expected to degrade to dichlorvos at the pH of a typical lawn.

None of the aggregate risks exceed our level of concern, considering food, water, and residential exposures, for all residential exposure scenarios. Food and water exposure were very small compared to the residential exposure estimates.

Occupational handler scenarios do not exceed the Agency's level of concern, after voluntary cancellations, addition of additional PPE, and longer reentry intervals (REIs).

1.5 Human Studies

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, listed below, have been determined to require a review of their ethical conduct, and EPA is currently preparing these ethics reviews in accordance with EPA Human Subjects Protections rule, 40 CFR part 26**.**

Gledhill, A., 1997. Dichlorvos: A Single Blind, Placebo Controlled, Randomised Study to Investigate the Effects of Multiple Oral Dosing on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers: Lab Project Number: CTL/P/5392: XH6063. Unpublished study prepared by Zeneca Central Toxicology Lab. 52 p. MRID 44248801.

Emlay, D.; Rudolph, R. (1977) Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars: Lab Project Number: TR-506. Unpublished study prepared by Zoecon Industries, Inc. 14 p. {OPPTS 875.1500} MRID 45792201.

Klonne, D. (1999) Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns: Lab Project Number: OMAOO5: OMAOO1: OMAOO2. Unpublished study prepared by Ricerca, Inc., and Morse Laboratories. 2213 p. (MRID 44972201) (ORETF study)

McDonald, E., 1991. Indoor Fogger Dermal and Inhalation Exposure Study with DDVP: Lab Project Number: 4-02-333. Unpublished study prepared by British Columbia Research Corp. 331 p. MRID 41928801.

The PHED Task Force, 1995. The Pesticide Handlers Exposure Database, Version 1.1. Electronic Database. Task Force members Health Canada, U. S. Environmental Protection Agency, and the National Agricultural Chemicals Association, released February, 1995.

In addition, the Human Subjects Protections rule requires that the Gledhill study – an intentional dosing, human toxicity study on which EPA is relying in this risk assessment – be reviewed by the Human Studies Review Board (HSRB). The Agency presented the Gledhill study to the HSRB at a meeting on April 2 – 4, 2006. The HSRB discussed the Gledhill study extensively during this meeting and has prepared a draft written report summarizing its discussions. The Agency believes that the oral comments of the HSRB and the draft report provided a sufficient indication of the conclusions likely to appear in the HSRB's final report that EPA could confidently move ahead. Accordingly, the Agency has decided to issue this risk assessment prior to receiving the final written report of the HSRB. The Agency will carefully review the HSRB's final report on DDVP prior to issuing its final reregistration eligibility decision to determine whether the HSRB's report contains conclusions that warrant reconsideration of this risk assessment

2.0 Ingredient Profile

Dichlorvos is a chlorinated organophosphorus insecticide, with technical and manufacturing use products registered to Amvac Chemical Corporation and Drexel Chemical Company. Formulations and EPA Reg. Nos. are summarized below in table 2.0.

Table 2.0. Registered Manufacturing-Use Products of Dichlorvos, as described in OPPIN.

Formulation	EPA Reg. No.	Registrant
93% T	5481-96	Amvac Chemical Corporation
98% T [1,2]	5481-461	
98% T [1,2]	5481-462	
90% FI [3]	19713-353	Drexel Chemical Company

[1] Repackaged from an EPA-registered product. We note that there is not another EPA registered product containing 98% dichlorvos. This discrepancy must be cleared up.
[2] OPPIN currently identifies this product as an FI; however, it is correctly identified as a T.
[3] Sequentially transferred from EPA Reg. Nos. 8521-126, 904-396, and 44215-139.
T = Technical Product FI = Formulation intermediate

2.1 Summary of Registered/Proposed Uses

The basic producer of dichlorvos is Amvac Chemical Corporation. According to an OPPIN search, conducted on 6/12/06, there are 98 active end-use products (EPs) registered under FIFRA Section 3 containing dichlorvos, 29 of which are registered to Amvac; there is one Special Local Need (SLN) registration under FIFRA Section 24(c) associated with these Amvac EPs, and one Special Local Need (SLN) registration under FIFRA Section 24(c) associated with another EP. The registered food and feed use patterns of dichlorvos EP labels subject to reregistration are presented in table 2.1. Residential use patterns are discussed in Section 6 of this document. Occupational use patterns are discussed in Section 9 of this document. In addition, Amvac submitted copies of two product labels for the technical formulation (EPA Reg. Nos. 5481-461 and 5481-462) which include directions for use for various sites.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Agricultural commodities (bulk storage of nonperishable raw and processed agricultural commodities including raw grains, corn, soybeans, cocoa beans, and peanuts)			
Premise treatment	20% Impr [5481-338]		Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr [5481-344]	10.5 g of product/ 50-100 cu. ft or	Use in kitchens, restaurants, or areas where food/feed are prepared or processed, use in food/feed processing or food/feed manufacturing areas of food/feed processing and food/feed manufacturing plants are prohibited.
	20% Impr [5481-348]	80 g of product/ 900-1200 cu. ft	Use in kitchens, restaurants, or areas where food is prepared or served and use in edible product areas of food processing plants are prohibited.
Greenhouses (not containing food commodities)			
Fog application [hand-held fogger is no longer permitted]	0.37 lb/gal EC [5481-220]	0.004 lb/1,000 cu. ft	Applications may be made using a cold aerosol generator. Hand held foggers are no longer permitted.
Mushroom houses			
Fog application [hand-held fogger is no longer permitted]	50% FlC [5481-203]	2% finished spray [6.25 oz/10,000 cu.ft]	Applications may be made in 1,1,1-trichloroethane using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed. A 1-day PHI has been established for mushrooms.
		2% finished spray [10 oz/10,000 cu.ft]	Applications may be made in deodorized base kerosene using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed. A 1-day PHI has been established for mushrooms.
	0.37 lb/gal EC [5481-220]	5 g/10,000 cu.ft	
		0.004 lb/1,000 cu.ft	Applications may be made using a cold aerosol generator. Applications may be made twice a week during spawn run; thereafter use as needed.
Brush on /coarse spray	2 lb/gal EC [72-365] (canceled)	0.00125 lb/100 sq ft	Coarse spray or paint on walls, around doors, ventilators & cracks before mushrooms come into production. Use as 0.5% solution – 1 pint of 0.5% solution per 100 sq ft., up to 10 days before crop emerges on soil beds. Do not spray inside walls after mushrooms appear on beds. After mushrooms appear, spray only the outside of the building.
Tobacco Warehouse:			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Space treatment in closed warehouses [Hand-Held Foggers are no longer permitted]	1.59 lb/gal EC [5481-206] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207]	2% finished spray [19-38 fl.oz/10,000 cu.ft] or 10-20 g/10,000 cu. ft	Fogging applications may be made with odorless oil or other non-flammable oil solvents known to be safe for use in tobacco warehouses. Applications may be repeated as needed. Applications may be made only in warehouses storing unfinished tobacco.
	8.39 lb/gal SC [5481-201]		
	0.37 lb/gal EC [5481-220]	0.37 lb/336,000 cu.ft	Fogging applications may be repeated as needed. Applications may be made only in warehouses storing unfinished tobacco.
Food-handling establishments (including households; restaurants; theaters; food processing plants; industrial plants; and warehouses)			
Indoor treatment Directed spray application	4 lb/gal EC [5481-204]	0.5% finished spray	Applications may be made with deodorized base oil or water using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas while food is exposed is prohibited
Indoor treatment Remote Fog Application	20% PrL [47000-71]	2.5 g/1000 cu. ft.	Application made by timer when buildings are unoccupied. Building should be closed and ventilation kept to a minimum. Lock all entrances, and do not allow unprotected workers to enter the building when being treated.
Food-handling establishments (including theaters; food processing plants; industrial plants; and warehouses)			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	0.37 lb/gal EC [5481-220] 1.59 lb/gal EC [5481-206] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 2 lb/gal SC [5481-334] 8.39 lb/gal SC [5481-201]	1% finished spray [1 gal/64,000 cu.ft]	Fogging or misting applications may be made with deodorized base oil or water using fogging or misting equipment to treat indoor areas. Applications are to be made when the plants are not in operation. Food should be removed and food-handling equipment covered prior to application or washed with suitable cleaner and potable water after application.
Food-handling establishments [including areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage, and enclosed processing systems (mills, dairies, edible oils, syrups), and serving areas]			
Indoor crack and crevice treatment	0.25 lb/gal EC [5481-217] 0.5 lb/gal EC [5481-216]	0.1% finished spray	Applications may be made in water or oil and may be applied by directing small amounts into crack and crevices, in points between different elements of construction, and between equipment legs and bases. Applications in food areas other than crack and crevice treatments are prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)]			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Indoor treatment Directed spray application	0.37 lb/gal EC [5481-220] 1.59 lb/gal EC [5481-206] 1.15 lb/gal SC [5481-207] 2 lb/gal SC [5481-334] 8.39 lb/gal SC [5481-201]	0.5% finished spray	Applications may be made with deodorized base oil or water using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas while food is exposed are prohibited.
	4.48 lb/gal SC [5481-202]	0.5% finished spray	Applications may be made with deodorized base oil using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use in food/feed handling areas of food/feed handling establishments, restaurants or other areas where food is commercially prepared or served and use to treat non-perishable bagged or bulk raw or processed commodities is prohibited.
	10 lb/gal SC [5481-200]	0.5% finished spray	For use in warehouses, silos, bulk bins, and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities. Applications may be made with deodorized base oil using a low pressure sprayer to treat localized areas where insects may infest around baseboards, cracks, walls, doors, window frames, and localized areas of floors. Use of this product in food processing plants, food-handling areas of restaurants, or areas where food is prepared or served, and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of food, water, food containers, or cooking utensils is prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)]			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Indoor spot treatment	0.25 lb/gal EC [5481-217] 0.5 lb/gal EC [5481-216]	0.1% finished spray	Applications may be made in water or oil and may be applied as a coarse spray or with a paint brush to areas where pests hide (baseboard areas, around water pipes, surfaces behind and beneath sinks, lockers, tables, pallets, and similar areas). Applications may be repeated as needed. Use of this product in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use in serving areas where food is exposed are prohibited.
	1.16 lb/gal EC [5481-208]	0.5% finished spray	Applications may be made in water and may be applied to areas where pests hide (around baseboards, cracks, walls, door and window frames and localized areas of floors). Use of this product in food processing plants, food-handling areas of restaurants, or areas where food is prepared or served, and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of food, water, food containers, or cooking utensils is prohibited.
	0.5% RTU [5481-240]	0.5% spray	Applications may be made with a pump sprayer to areas where pests hide (dark corners of room and closets, cracks and crevices in walls, behind and beneath sinks, stoves, refrigerators, cabinets, washing machines, cupboards, bookcases, and around baseboards). Use of this product in food areas of food-handling establishments, restaurants, or other areas where food is commercially prepared or processed and use in serving areas where food is exposed or while facility is operating are prohibited.
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	4.48 lb/gal SC [5481-202]	1% finished spray [1 gal/64,000 cu.ft]	Fogging or misting applications may be made with deodorized base oil using fogging or misting equipment to treat indoor areas. Use in bottling plants, food contact areas or meat slaughter, and/or packing plants or in frozen food plants is prohibited.
Nonfood/feed areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)] (continued)			
Indoor treatment Space spray application [Hand-Held Foggers are no longer permitted]	10 lb/gal SC [5481-200]	1% finished spray [1 gal/64,000 cu.ft]	For use in warehouses, silos, bulk bins, and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities. Fogging or misting applications may be made with deodorized base oil using fogging or misting equipment to treat indoor areas. Use in bottling plants, food contact areas or meat slaughter, and/or packing plants or in frozen food plants is prohibited. When using in food processing, handling, and storage areas: (I) applications may be made only during times when plant is not in operation and no food products are exposed; if bulk, unpackaged food is exposed, it must be removed or covered prior to treatment; (ii) all food processing surfaces should be covered during treatment or thoroughly cleaned before using.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Indoor premise treatment	0.5% PrL [5481-340]	0.5% spray	Use as a space spray is prohibited. Applications may be applied to areas where pests hide (cracks, around baseboards, cabinets, walls, and woodwork) and repeated as necessary. Use of this product in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed and use to treat non-perishable bagged and or bulk stored raw or processed agricultural commodities are prohibited. Contamination of utensils, food, water, and foodstuffs prohibited.
	20% Impr [5481-344]	10.5 g of product/ 50-100 cu. ft	Use in kitchens, restaurants, or areas where food/feed are prepared or processed, use in food/feed processing or food/feed manufacturing areas of food/feed processing and food/feed manufacturing plants are prohibited.
Animal Uses (Premises)			
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, loafing pens, pig pens, poultry houses, hog barns, stables, and other farm buildings)			
Premise treatment Directed spray application	1 lb/gal EC [5481-41]	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to all exterior and interior surfaces, treating window sills, around doors, fences, and ledges or as a directed spray to floors, baseboards, crack and crevices in wall, and along base of walls. Applications may be made using water- or oil-based sprays; applications may be repeated as necessary. A 1-day preslaughter interval (PSI) has been established.
	2 lb/gal EC [5481-73] 0.37 lb/gal EC [5481-220]	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using water; applications may be repeated as necessary. Animals must be removed prior treatment. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited.
	2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204]	0.5% finished spray [1 qt/1,000 sq.ft]	Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using water; applications may be repeated as necessary. Animals may be present during treatment. Contamination of water, feed or foodstuffs, milk or milking utensils is prohibited.
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
	1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201]		Applications may be made as a coarse, wet spray to surfaces, treating window sills, doorways, feed storage rooms, and alleyways. Applications may be made using diesel oil or water; applications may be repeated as necessary. Direct treatment of animals or humans and contamination of water, feed or foodstuffs, milk or milking utensils are prohibited.
Premise treatment Directed spray application	10 lb/gal SC [5481-200]	0.5% finished spray [1 qt/1,000 sq.ft]	
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	2 lb/gal EC [5481-73]	1% finished spray [0.5 qt/8,000 cu.ft] or 0.5% finished spray [1 qt/8,000 cu.ft]	Fog applications may be made using diesel oil. Animals must be removed prior to treatment. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited.
Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	0.37 lb/gal EC [5481-220] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201] 10 lb/gal SC [5481-200]	1% finished spray [0.5 qt/8,000 cu.ft] or 0.5% finished spray [1 qt/8,000 cu.ft]	Fog applications may be made using diesel oil. Animals must be removed prior to treatment. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings. Application in areas where animals have received a direct application of DDVP within the past 8 hours is prohibited. Contamination of water, feed or foodstuffs, milk or milking utensils is prohibited.
Premise treatment	1% G [5481-9]	0.04 oz/1,000 sq.ft	Bait applications may be made to clean floor areas, ground areas outside enclosures, window sills, or other areas where flies congregate. Applications are to be made in such a manner that stock cannot come into contact with bait.

Farm buildings (including animal shelters, barns, around feed lots, dairy barns, milk sheds, poultry houses, hog barns, stables, and other farm buildings) (continued)

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Premise treatment Space spray application [Hand-Held Foggers are no longer permitted]	1 lb/gal EC [5481-41]	1% finished spray [0.5 qt/8,000 cu.ft]	Fog applications may be made with animals present, provided a direct animal treatment of DDVP has not been made in the past 8 hours. Applications may be made using water or deodorized kerosene. Prior to application, reduce air movement as much as possible by closing doors, windows, and other openings.
Animal buildings (including horse barns, calf parlors, hog parlors, stables, poultry houses, tack rooms, and dog kennels)			
Premise treatment	20% Impr [5481-338]	10.5 g of product/ 50-100 cu. ft	Contamination of water, food or foodstuffs, milk or milking equipment is prohibited. Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr [5481-344] [5481-348]	10.5 g of product/ 50-100 cu. ft	Contamination of water, food or foodstuffs, milk or milking equipment is prohibited.
Milk rooms (including bulk storage rooms)			
Premise treatment	20% Impr [5481-338]	10.5 g of product/ 50-100 cu. ft	Contamination of milk or milking equipment is prohibited. Use of product where unwrapped food is stored or allowing the strip to come in contact with food or cooking utensils is prohibited.
	20% Impr [5481-344] [5481-348]	10.5 g of product/ 50-100 cu. ft	Contamination of milk or milking equipment is prohibited.
Feed lots, stockyards, corrals, and holding pens			
Outdoor premise treatment	1 lb/gal EC [5481-41]	0.5% finished spray [5 gal/A]	Applications may be made as an overall mist spray to fences, feed bunkers, shade areas, spillage areas, building walls, and other areas where flies congregate. Applications may be made in water using a mist blower or similar equipment at 3- to 14-day intervals.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Poultry houses	0.37 lb/gal EC [5481-220] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201] 10 lb/gal SC [5481-200]	0.2 lb/A	Applications may be made as an overall mist spray to fences, feed bunkers, spillage areas, and building walls. Applications may be made in diesel oil or water using a mist blower or similar equipment. Animals may be present during treatment.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Premise treatment	0.37 lb/gal EC [5481-220] 1 lb/gal EC [5481-41] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-73] [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201] 10 lb/gal SC [5481-200]	0.5% finished spray [1 qt/1,000 sq.ft] Not specified on the 2 lb/gal EC [5481-73] product label	Applications may be made to manure, window sills, exterior walls, interior walls, feed room floors, and walkways. Only crack and crevice treatments are permitted for indoor use and applications are to be made out of reach of poultry (EPA Reg. No. 5481-41 only).
	1% G [5481-9]	0.04 oz/1,000 sq. ft	Bait applications may be made to droppings under cages, on walkways, window sills, alley ways, and other areas where flies congregate. Applications are to be made out of reach of birds.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
		Direct Animal Uses	
Cattle (beef and dairy)			
Animal mist spray treatment	1 lb/gal EC [5481-41]	1% finished spray [2 fl. oz/animal/day]	Application may be made in water as an atomized spray uniformly distributed over each animal. Do not wet the skin.
	2 lb/gal EC [5481-73]	0.5% finished spray [4 fl. oz/animal/day]	Application may be made in water as an atomized spray uniformly distributed over each animal. Application more than once per day and application to calves less than 6 months of age are prohibited.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
	0.37 lb/gal EC [5481-220] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201] 10 lb/gal SC [5481-200]	1% finished spray [2 fl. oz/animal/day]	Application may be made in deodorized base oil or water as an atomized spray uniformly distributed over each animal. Do not wet the hide. Application of more than 2 fl. oz. per animal per day and application to calves less than 6 months of age are prohibited. A 1-day PSI has been established (EPA Reg. Nos. 5481-204 and 5481-220 only).
Cattle (beef and dairy) (continued)			
Animal face paint treatment	1 lb/gal EC [5481-41]	0.5% bait slurry [1 tsp/face]	Applications may be made to the animal's forehead daily for 14 days and thereafter as needed.

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
	0.37 lb/gal [5481-220]		
	1.16 lb/gal EC [5481-208]		
	1.59 lb/gal EC [5481-206]		
	2 lb/gal EC [5481-205]		
	4 lb/gal EC [5481-204]		
	1.15 lb/gal SC [5481-207]		
	4.48 lb/gal SC [5481-202]		
	8.39 lb/gal SC [5481-201]		
	10 lb/gal SC [5481-200]	1% bait slurry [3 mL/face]	Application is to be made as a 6-inch line to the animal's forehead with a paint brush.
Cattle (beef and dairy) (continued)			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
	0.37 lb/gal EC [5481-220] 1 lb/gal EC [5481-41] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-73] [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201]	0.5% finished spray [2 qt/100 sq.ft]	
Manure treatment	10 lb/gal SC [5481-200]	or 1% finished spray [1 qt/100 sq.ft]	Applications may be made in water to control maggots in manure piles and garbage dumps.
Poultry			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Manure treatment	1 lb/gal EC [5481-41]	0.5% finished spray [2 qt/100 sq.ft]	Applications may be made in diesel oil or deodorized kerosene to control flies and maggots in poultry droppings.
Animal Uses - Oral Dosing (Drug Use)			
Swine			
Feed treatment	N/A [3]	12.5-20.6 mg/kg body weight	Application is to be made by mixing active ingredient into feed and may be repeated in 4-5 weeks.
Wide Area and General Outdoor Treatment			
Outdoor areas (including outside picnic areas, patios, and eating areas of drive-in restaurants)			
Outdoor spray application	2 lb/gal SC [5481-334]	0.5-1% finished spray	Applications may be made in deodorized spray base oil and repeated monthly or as needed.
Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses)			
Outdoor spray application	1 lb/gal EC [5481-41]	0.5% finished spray [1 qt/1,000 sq. ft]	Applications may be made in water and repeated as needed. Direct use on animals and contamination of feed, foodstuffs, or water are prohibited.
Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses) (continued)			

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
	0.37 lb/gal EC [5481-220] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201]		
Outdoor spray application	10 lb/gal SC [5481-200]	0.5% finished spray [1 qt/1,000 sq. ft]	Applications may be made in diesel oil or water and repeated as needed. Direct use on animals or humans and contamination of water, food, food containers or cooking utensils are prohibited.

Outdoor areas (including picnic grounds, parking areas, loading docks, refuse areas, garbage collection and disposal areas, around drive-in restaurants, food processing plants, and warehouses) (continued)

Table 2.1. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Dichlorvos (Case 0310).

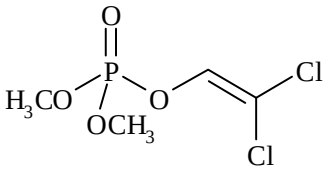
Site Application Type	Formulation [EPA Reg. No.]	Application Rate, ai [1]	Use Directions and Limitations[2]
Outdoor fogging application [Hand-Held Foggers are no longer permitted]	0.37 lb/gal EC [5481-220] 1.16 lb/gal EC [5481-208] 1.59 lb/gal EC [5481-206] 2 lb/gal EC [5481-205] 4 lb/gal EC [5481-204] 1.15 lb/gal SC [5481-207] 4.48 lb/gal SC [5481-202] 8.39 lb/gal SC [5481-201] 10 lb/gal SC [5481-200]	1% finished spray [5-10 pt/A] or 0.05-0.1 lb/A	Fogging or misting applications may be made with diesel oil or water using fogging or misting equipment to treat outdoor living areas, picnic areas, backyard areas, patios, loading docks, outdoor latrines, parking areas, refuse areas around service stations, open air drive-ins, ice cream stands, and garbage collection and disposal areas. Use in areas where food or feed crops are growing is prohibited.
Catch basins			
Outdoor treatment	20% Impr [5481-338] [5481-344] [5481-348]	One strip	One strip (10.5 or 80 g of product) is to be suspended 10 inches above water level for control of mosquitoes breeding in catch basins.

[1] Application rates in brackets refer to amount of finished spray to be applied per listed area.

[2] The product label for EPA Reg. No. 5481-41 prohibits treatment of more than 5 application sites per day and prohibits DDVP applications more than once per week (we note that this is in conflict with use directions for feedlots, stockyards, corrals, and holding pens which allow applications to be made at 3-day intervals). A similar statement was required to be added to the product label for EPA Reg. No. 5481-200. No other products listed in this table bear this restriction.

[3] DDVP is registered for use as an anthelmintic in swine feed; use pattern is defined in 21 CFR §520.600(e)(2).

2.2 Structure and Nomenclature

TABLE 2.2. Test Compound Nomenclature	
Chemical Structure	
Empirical Formula	$C_4H_7Cl_2O_4P$
Common name	Dichlorvos (ISO) or DDVP
Company experimental name	
IUPAC name	2,2-dichlorovinyl dimethyl phosphate
CAS name	2,2-dichloroethenyl dimethyl phosphate
CAS Registry Number	62-73-7
End-use product/EP	Alco, Amvos
Chemical Class	organophosphate
Known Impurities of Concern	none
PC Code No.	084001

2.3 Physical and Chemical Properties

Dichlorvos is a liquid with high vapor pressure at room temperature and is used for fumigation. The high vapor pressure suggests that residues in food and environmental surfaces will dissipate rapidly.

TABLE 2.3. Physicochemical Properties		
Parameter	Value	Reference
Molecular Weight	221.0	
Physical State	liquid	40798103
Boiling point/range	117 C at 10 mm Hg	40798103
pH	~ 4 as 1% aqueous solution	40798103
Specific gravity	1.424 at 25 C	40798103
Water solubility (20 C)	~1.5 g/100 g	40798103
Solvent solubility (temperature not specified)	~0.5% in glycerine; miscible with aromatic hydrocarbons, chlorinated hydrocarbons, alcohols, ketones, and esters. Essentially insoluble in kerosene and aliphatic hydrocarbons	40798103
Vapor pressure (25 C)	0.032 mm Hg at 32 C	40798103
Dissociation constant, pKa	N/A	
Octanol/water partition coefficient, log K_{OW} (25 C)	38.4 log K_{OW} = 1.58	40798103
UV/visible absorption spectrum	N/A	

3.0 Metabolism Assessment

3.1 Comparative Metabolic Profile

A rat metabolism study has been conducted. The overall metabolic profile suggests the involvement of the one-carbon pool biosynthetic pathway as evidenced by the presence of a relatively large amount of radioactivity in the form of expired $^{14}CO_2$ and the presence of dehalogenated metabolites as well as urea and hippuric acid. Plant metabolism studies show that dichlorvos hydrolyzes to dimethyl phosphate and dichloroacetaldehyde, and is incorporated into natural plant constituents. Oral and dermal livestock metabolism studies show that dichlorvos metabolizes to desmethyl dichlorvos in livestock animals. The major environmental degradates were 2,2-dichloroacetic acid, 2,2-dichloroacetaldehyde, desmethyl dichlorvos, and glyoxylic acid.

3.2 Nature of the Residue in Foods

3.2.1. Description of Primary Crop Metabolism

Nature of the Residue - Plants (GLN 860.1300): The reregistration requirements for plant metabolism are fulfilled. The Agency determined that the available data depicting the metabolism of naled in plants are sufficient to delineate the metabolism of dichlorvos in plants because dichlorvos is the initial metabolite of naled. In plants, naled is metabolized to dichlorvos which is hydrolyzed to dimethyl phosphate and dichloroacetaldehyde. Dimethyl phosphate is sequentially degraded to monomethyl phosphate and inorganic phosphates, and dichloroacetaldehyde is converted to 2,2-dichloroethanol which is then conjugated and/or incorporated into naturally occurring plant components. The residue of concern in plant commodities is dichlorvos.

3.2.2 Description of Livestock Metabolism

Nature of the Residue - Animals (GLN 860.1300): The reregistration requirements for animal metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in ruminants and poultry following dermal treatment with dichlorvos have been submitted and evaluated. Because dichlorvos is the initial metabolite of naled, the available metabolism studies reflecting oral dosing of ruminants and hens with naled are sufficient to delineate the metabolism of orally dosed dichlorvos in animals. The residue of concern in animal commodities is dichlorvos.

In the lactating goat treated orally with naled, no naled or dichlorvos was identified in milk (<0.005 ppm) or tissues (<0.05 ppm). Dichloroethanol conjugates and desmethyl-dichlorvos were not identified in milk (<0.05 ppm). Liver and kidney contained up to 0.3 ppm dichloroethanol conjugates and 0.1 ppm desmethyl-dichlorvos; other tissues showed only traces of both of these metabolites.

In laying hens treated orally with naled, the sulfate conjugate of dichloroethanol was the major component (0.1 ppm in fat to 10 ppm in kidney) identified in all tissues. The parent compound, naled, was not identified (<0.01 ppm) in any tissues except gizzard. Naled plus mostly dichlorvos were found in gizzard (0.6 ppm) after 2 hours in singly dosed hens and as a minor metabolite (0.01-0.46 ppm) in tissue samples of multi-dosed hens.

In both lactating goats and laying hens treated orally with naled, naled is initially debrominated to yield dichlorvos. The major pathway is cleavage of dichlorvos to dimethylphosphate and dichloroacetaldehyde. A minor pathway is O-demethylation to form desmethyl-dichlorvos. In part, dichloroacetaldehyde is reduced to dichloroethanol which is conjugated with endogenous sulfate to form the sulfate ester conjugate of dichloroethanol. Dichloroacetaldehyde is dechlorinated and oxidized sequentially to form glyoxal and then glyoxylic acid which is incorporated into amino acids (glycine, alanine, serine, etc.) and proteins.

Metabolism of dichlorvos in ruminants, following dermal exposure, is adequately understood. Dichlorvos is extensively metabolized following dermal exposure. No dichlorvos or primary metabolites of dichlorvos were found in milk or tissues of treated goats, furthermore, incorporation of ^{14}C into endogenous milk (as lactose) and tissue components (as glycerol) of the treated goats was demonstrated.

Metabolism of dichlorvos in poultry, following dermal exposure, is adequately understood. Dichlorvos is extensively metabolized following dermal exposure. Limited amounts of dichlorvos and des-methyl dichlorvos were identified in breast muscle and fat, with the majority of the TRR incorporated into tissue. Radioactivity found in internal tissues accounted for 0.3% of the administered dose.

3.2.3 Description of Rotational Crop Metabolism, including identification of major metabolites and specific routes of biotransformation

Dichlorvos is not registered for field crop uses; therefore no rotational crop data have been required.

3.3 Environmental Degradation

Dichlorvos. A major route of dissipation is volatilization (vapor pressure = 0.032 mm Hg at 32 C). Dichlorvos also appears to degrade through aerobic soil metabolism and abiotic hydrolysis as well, but is secondary to volatilization. Hydrolysis is pH dependant where the half-lives were 11 days at pH 5, 5 days at pH 7 and 21 hours at pH 9. The major degradates were 2,2-dichloroacetic acid, 2,2-dichloroacetaldehyde, desmethyl dichlorvos, and glyoxylic acid. Aerobic soil metabolism data showed a half-life of 10 hours with the major metabolite being 2,2-dichloroacetic acid (62.8% of applied at 48 hours). Other metabolites present at less than 12% of applied were 2,2-dichloroacetaldehyde, and dichloroethanol. Extensive mineralization took place as CO_2 accounted for 60% of applied at 360 hours post-treatment. Due to rapid degradation of dichlorvos leaching/adsorption/desorption data were declared supplemental due to the inability to establish a soil/solution phase equilibrium. However, a soil TLC study (MRID 41354105) indicates that dichlorvos is moderately mobile (K_d's ranging 0.3 to 1.2) based on the

Heiling and Turner's mobility classification. The potential of dichlorvos to leach to ground water is mitigated by its rapid degradation. However, dichlorvos does have the potential to contaminate surface waters because of a low K_{oc} value and high water solubility (10 X 10^3 ppm, or 1%). Substantial fractions of run-off will more than likely occur via dissolution in run-off water rather than adsorption to eroding soil. Dichlorvos should not be persistent in any surface waters due to its susceptibility to rapid hydrolysis.

Naled. Chemical hydrolysis and biodegradation are the major processes involved in the transformation of naled and its degradates in the environment. While direct photolysis in water is not a major degradative pathway for naled, indirect photolysis in the presence of photosensitizer may play an important role in the photodegradation of naled in aqueous media and soils. The degradate dichlorvos does not form under abiotic hydrolysis nor by direct photolysis in water, but forms by indirect photolysis in water and soils. In the presence of photosensitizer in water, as much as 20% of the applied dose of naled can be found as dichlorvos after 1 day, with rapid decline of dichlorvos residues afterwards. Under aerobic conditions, naled mineralizes rapidly to CO_2 and degrades to dichloroacetic acid and dichloroethanol, but dichlorvos is not detected. This is likely to be the result of the rapid degradation and mineralization of any dichlorvos that may form from naled. However, under anaerobic aquatic conditions, dichlorvos can be as high as 15% of the applied naled dose after 1 day. The degradation of dichlorvos, once formed, was slower than that of parent naled. During the first 1-2 days after application of naled, the half-life of dichlorvos was about 0.9 days.

Trichlorfon. Dichlorvos is formed from trichlorfon in both soil and water by aerobic soil metabolism. Environmental fate data indicate that trichlorfon degrades rapidly in aerobic soil ($t_{1/2}$ 1.8 days) under non-sterile conditions; however, in a sterile soil, trichlorfon was stable ($t_{1/2}$ > 40 days). Abiotic hydrolysis studies indicate that trichlorfon degrades rapidly in aqueous media and that the rate of conversion is pH dependent. The estimated half-life of trichlorfon is 31 minutes at pH 9, and 34 hours at pH 7, and 104 days at pH 5. This indicates the stability of trichlorfon under acidic conditions. The maximum amount of dichlorvos formed from trichlorfon by aerobic aquatic metabolism is approximately 56 percent of the amount of trichlorfon originally applied at pH 8.5.

3.4 Summary of Residues for Tolerance Expression and Risk Assessment

Tolerances for residues of dichlorvos are published in 40 CFR 180.235. The current tolerance expression includes only dichlorvos [2,2-dichlorovinyl dimethyl phosphate].

Table 3.6. Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression

Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	dichlorvos	dichlorvos
	Rotational Crop	N/A	N/A
Livestock	Ruminant	dichlorvos	dichlorvos
	Poultry	dichlorvos	dichlorvos
Drinking Water		dichlorvos	Not Applicable

4.0 Hazard Characterization/Assessment

4.1 Hazard Characterization

Dichlorvos is a chlorinated organophosphate pesticide cholinesterase inhibitor, which inhibits plasma, erythrocyte, and brain cholinesterase in a variety of species, but does not cause organophosphate-induced delayed neurotoxicity (OPIDN) in the hen. Concern for potential developmental neurotoxicity arose based on a study in the open literature (Mehl et al, 1994), which reported decreased total brain weight in two litters of guinea pigs from dichlorvos-exposed dams. However, in developmental neurotoxicity studies in rats, decreased brain weight was not associated with gavage doses of dichlorvos administered to pups during PNDs 8-22. In acute and 90-day neurotoxicity studies in rats, there was no neuropathology associated with changes in FOB and motor activity. Subchronic and chronic oral exposures in rats and dogs as well as chronic inhalation exposure in rats resulted in significant decreases in plasma, red blood cell and/or brain cholinesterase activity. Repeated, oral subchronic exposures in male humans were associated with statistically and biologically significant decreases in red blood cell cholinesterase depression.

There was no evidence of increased susceptibility following *in utero* exposure to rats and rabbits as well as pre/post natal exposure to rats in developmental and reproduction studies. The FQPA safety factor was reduced to 1x. Some scenarios used endpoints based on a LOAEL, and the 3x uncertainty factor used is considered part of the FQPA safety factor.

The carcinogenic potential of dichlorvos has been classified as “suggestive” under the 1999 Draft Cancer Guidelines and no quantitative assessment of cancer risk is required. Dichlorvos has been shown to be a direct acting mutagen in *in vitro* mammalian test systems. Dichlorvos seems to also have clastogenic activity in Chinese hamster ovary (CHO) cells *in vitro* with or without metabolic activation. On the other hand, studies showed that dichlorvos was not clastogenic in *in vivo* micronucleus tests.

Inhibition of cholinesterase activity was the toxicity endpoint selected to assess hazards for all acute and chronic dietary reference doses (RfDs), as well as short-, intermediate-, and long-term (chronic) dermal and inhalation occupational and residential risk assessments. The no observed adverse effect levels (NOAELs), lowest observed adverse effect levels (LOAELs), or $BMDL_{10}$s were selected in light of Agency policy on the use of toxicology studies employing human subjects. Therefore, HED selected doses and endpoints for risk assessment based on both human and animal studies.

Table 4.1a Acute Toxicity of Dichlorvos

Guideline No.	Study Type	MRID #(S).	Results	Toxicity Category
8701.1100	Acute Oral	00005467	LD_{50} = 80 mg/kg (M) 56 mg/kg (F)	II
870.1200	Acute Dermal	00005467	LD_{50} = 107 mg/kg (M) $\geq$ 75 mg/kg (F)	I
870.1300	Acute Inhalation	00137239	$LC_{50} \geq$ 0.198 mg/L	II
870.2400	Primary Eye Irritation	00146921	mild irritant	III
870.2500	Primary Skin Irritation	00146920	mild irritant	IV
870.2800	Dermal Sensitization	none	no study available	NA
870.6100	Acute Delayed Neurotoxicity-Hen	41004702	Negative for acute delayed neurotoxicity	NA
870.6200	Acute Neurotoxicity-Rat	42655301	NOAEL = 0.5 mg/kg; LOAEL = 35 mg/kg (changes in FOB, motor activity) no neuropathology	NA

Table 4.1b. Guideline Toxicology Studies for Dichlorvos in Experimental Animals

Guideline No./Study Type	MRID No.	Results
Acute Oral Cholinesterase Inhibition Study (1^{st}) in Adult SD Rats/ 870.1100 (non-guideline)	45805701 Acceptable	ChEI NOAEL (RBC and Brain) = not established ChEI LOAEL (RBC and Brain) = 2.1 mg/kg/day
Acute Oral Cholinesterase Inhibition Study (2^{nd}) in Adult SD Rats/ 870.1100 (non-guideline)	45805702 Acceptable	ChEI NOAEL (RBC and Brain) = 1 mg/kg ChEI LOAEL (RBC and Brain) = not established
Acute Oral Cholinesterase Inhibition Study (3^{rd}) in Adult Wistar Rats/ 870.1100 (non-guideline)	45805703 Acceptable	<u>RBC Cholinesterase Inhibition</u> NOAEL = 1 mg/kg LOAEL = 5 mg/kg BMD/$BMDL_{10}$ = 1.7/1.3 (M) mg/kg BMD/$BMDL_{10}$ = 1.5/1.2 (F) mg/kg <u>Brain Cholinesterase Inhibition</u> NOAEL = 1 mg/kg LOAEL = 5 mg/kg BMD/$BMDL_{10}$ = 1.6/1.0 (M) mg/kg BMD/$BMDL_{10}$ = 1.6/0.8 (F) mg/kg
Acute Oral Cholinesterase Inhibition Study in Preweaning Wistar Rat Pups/870.1100 (non-guideline)	45842301 Acceptable	<u>RBC Cholinesterase Inhibition</u> ChEI NOAEL (RBC) = not established ChEI LOAEL (RBC) = 1 mg/kg Postnatal day 8 BMD/$BMDL_{10}$ = 1.8/1.3 (M) mg/kg; Postnatal day 8 BMD/$BMDL_{10}$ = 1.5/1.0 (F) mg/kg; <u>Brain Cholinesterase Inhibition</u> ChEI NOAEL (Brain) = 1 mg/kg ChEI NOAEL (Brain) = 5 mg/kg Postnatal day 8 BMD/$BMDL_{10}$ = 1.8/1.5 (M) mg/kg; Postnatal day 8 BMD/$BMDL_{10}$ = 2.2/1.6 (F) mg/kg;
Time Course of Cholinesterase Inhibition in Preweaning and Adult Wistar Rats/870.8223 (Non-Guideline)	46153303 Acceptable	Brain and RBC enzyme activities were maximally inhibited one hour after single dosing in both adult and preweaning female rats. Thereafter, ChE inhibition in both compartments decreased to approximately control levels by 8 hours post dosing.
Repeat Dose Cholinesterase Inhibition Study in Preweaning (PND 18) and Adult (PND 48) Wistar Rats/(Non-Guideline)	46153304 Acceptable	PND18 BMD /$BMDL_{10}$=1.41/1.66 mg/kg/d RBC ChEI (M) PND48 BMD /$BMDL_{10}$=1.31/1.63 mg/kg/d RBC ChEI (M) PND18 BMD /$BMDL_{10}$=0.83/1.47 mg/kg/d RBC ChEI (F) PND48 BMD /$BMDL_{10}$=1.26/1.55 mg/kg/d RBC ChEI (F) PND18 BMD /$BMDL_{10}$=1.40/1.50 mg/kg/d Brain ChEI (M) PND48 BMD /$BMDL_{10}$=0.76/1.46 mg/kg/d Brain ChEI (M) PND18 BMD /$BMDL_{10}$=1.80/2.02 mg/kg/d Brain ChEI (F) PND48 BMD /$BMDL_{10}$=1.26/1.55 mg/kg/d Brain ChEI (F)

Table 4.1b. Guideline Toxicology Studies for Dichlorvos in Experimental Animals

Guideline No./Study Type	MRID No.	Results
Dichlorvos: A single blind, placebo controlled, randomized study to investigate the effects of multiple oral dosing on erythrocyte cholinesterase inhibition in healthy male volunteers (non-guideline)	44248801 Acceptable	RBC cholinesterase inhibition LOAEL = 0.1 mg/kg/day NOAEL = not established
Dichlorvos: A study to investigate erythrocyte cholinesterase inhibition following oral administration to healthy male volunteers (non-guideline)	44317901 Unacceptable	RBC cholinesterase inhibition NOAEL = not determined (missed time of peak effect)
Dichlorvos: A study to investigate the effect of a single oral dose on erythrocyte cholinesterase inhibition in healthy male volunteers (non-guideline)	44248802 Unacceptable	RBC cholinesterase inhibition NOAEL = not determined (missed time of peak effect)
Dermal Absorption/870.7600	41435201 Acceptable	Dermal absorption rate for dichlorvos was estimated to be approximately 11% in 10 hours of exposure.
28-Day Delayed Neurotoxicity-Hen/870.6100	43433501 Acceptable	Cholinesterase inhibition (brain ChEI) NOAEL = 0.1 mg/kg/day LOAEL = 0.3 mg/kg/day No neuropathology.
90-Day Subchronic Oral Toxicity - Rat/870.3100	41004701 Acceptable	NOAEL = 0.1 mg/kg/day LOAEL = 1.5 mg/kg/day (plasma and RBC ChEI)
90-Day Neurotoxicity - Rat/870.6200	42958101 Acceptable	NOAEL = 0.1 mg/day LOAEL = 7.5 mg/kg/day (plasma, red blood cell (RBC) and brain ChEI).
Chronic-Feeding-Dog/870.4100	41593101 Acceptable	NOAEL = 0.05 mg/kg/day LOAEL = 0.1 mg/kg/day (plasma and RBC ChEI in both sexes).
2-Year Inhalation toxicity/ carcinogenicity - Rat/870.4200	00057695, 00632569 Acceptable	$BMD/BMDL_{10}$ = 0.15/0.07 mg/m^3 RBC ChEI (F) $BMD/BMDL_{10}$ = 0.14/0.04 mg/m^3 RBC ChEI (M) $BMD/BMDL_{10}$ = 0.29/0.29 mg/m^3 Brain ChEI (F) $BMD/BMDL_{10}$ = 0.31/0.30 mg/m^3 Brain ChEI (M)
Chronic toxicity/ Carcinogenicity-F344 Rats (NTP study)/870.4300	40299401 Acceptable	NOAEL = Not established LOAEL = 4.0mg/kg/day (plasma and RBC ChEI) Suggestive evidence of carcinogenicity (mononuclear cell leukemia in male rats)
Carcinogenicity-Mouse/870.4200	40299401 Acceptable	NOAEL = Not established LOAEL = 10 mg/kg/day (plasma and RBC ChEI in males)

Table 4.1b. Guideline Toxicology Studies for Dichlorvos in Experimental Animals

Guideline No./Study Type	MRID No.	Results
Developmental Toxicity-Rat/870.3700	41951501 Acceptable	Maternal toxicity NOAEL = 3 mg/kg/day LOAEL = 21 mg/kg/day (clinical signs, decreased body weight gain and reductions in food consumption and efficiency) Developmental toxicity NOAEL = $\geq$ 21 mg/kg/day (HDT)
Developmental Toxicity-Rabbit/870.3700	41802401 Acceptable	Maternal toxicity NOAEL = 0.1 mg/kg/day LOAEL = 2.5 mg/kg/day (mortality, decreased body weight gain at LOAEL) Developmental toxicity NOAEL= $\geq$ 7 mg/kg/day (HDT) ChEI was not measured in main study Range-Finding: Doses were 0, 0.1, 1.0, 2.5, 5.0, 10 mg/kg/day Maternal toxicity ChE NOAEL = 0.1 mg/kg/day ChE LOAEL = 1.0 mg/kg/day
Reproductive Toxicity - Rat/870.3800	42483901 Acceptable	Parental/Systemic NOAEL = 2.3 mg/kg/day LOAEL = 8.3 mg/kg/day (decreased % of females with estrous cycle and increased % of females with abnormal cycling) Offspring NOAEL = 2.3 mg/kg/day LOAEL = 8.3 mg/kg/day (reduced # dams bearing litter, fertility index, pregnancy index and pup weight).
Preliminary Developmental Neurotoxicity - Rat/(Non-Guideline)	46153301 Acceptable	Systemic NOAEL = 7.5 mg/kg/day Maternal Systemic LOAEL = not identified Maternal RBC ChEI NOAEL = 0.1 mg/kg/day Maternal RBC ChEI LOAEL = 1.0 mg/kg/day Maternal Brain ChEI NOAEL = 1.0 mg/kg/day Maternal Brain ChEI LOAEL = 7.5 mg/kg/day Maternal Systemic NOAEL = 7.5 mg/kg/day Offspring Systemic LOAEL = not identified Offspring RBC ChEI NOAEL = 1.0 mg/kg/day Fetuses (GD 22) RBC ChEI LOAEL = 7.5 mg/kg/day Fetuses (GD 22) Brain ChEI NOAEL = 1.0 mg/kg/day Fetuses (GD 22) Brain ChEI LOAEL = 7.5 mg/kg/day Fetuses (GD22) Offspring (Pups) did not demonstrate ChEI during PND 2-22

Table 4.1b. Guideline Toxicology Studies for Dichlorvos in Experimental Animals

Guideline No./Study Type	MRID No.	Results
Developmental Neurotoxicity - Rat/870.6300	46153302 Acceptable (Study RR0886)	Maternal toxicity NOAEL = 7.5 mg/kg/day (HDT) No treatment related effects Developmental toxicity NOAEL= 1.0 mg/kg/day LOAEL = 7.5 mg/kg/day (increases in auditory startle reflex habituation Vmax in PND 23 high dose males in both studies) ChEI was not measured in main study
Developmental Neurotoxicity - Rat/870.6300	46239801 Acceptable (Study RR0988)	Maternal NOAEL is 7.5 mg/kg/day (HDT). A maternal LOAEL was not established. Offspring/developmental NOAEL is 1.0 mg/kg/day (based on study RR0886) and the Offspring/developmental LOAEL is 7.5 mg/kg/day (based on both studies RR0886 and RR0988) with the effect being increases in auditory reflex habituation Vmax in PND 23 high dose males in both studies.
Mutagenicity/Genetic Toxicity Test Guidelines-870.5000	Acceptable	Dichlorvos has been shown to be a direct acting mutagen by common *in vitro* bacterial genetic toxicity assays and in *in vitro* mammalian test systems. Conflicting evidence was seen for clastogenic activity *in vivo*.
Metabolism-Rat/870.7485	41228701 41839901 Acceptable	The overall metabolic profile suggests the involvement of the one-carbon pool biosynthetic pathway as evidenced by the presence of a relatively large amount of radioactivity in the form of expired $^{14}CO_2$ and the presence of dehalogenated metabolites as well as urea and hippuric acid.

4.2FQPA Hazard Considerations

4.2.1 Adequacy of the Toxicity Data Base

The toxicology database for dichlorvos is complete. The FQPA database includes acceptable developmental studies in rats and rabbits, an acceptable 2-generation rat reproduction study, two developmental neurotoxicity studies, and single dose gavage cholinesterase studies in adult and preweaning rats and repeat dose gavage studies in young adult and preweaning rats.

4.2.2 Evidence of Neurotoxicity

There is a concern for neurotoxicity resulting from exposure to dichlorvos. Dichlorvos is a chlorinated organophosphate pesticide cholinesterase inhibitor, which inhibits plasma, erythrocyte, and brain cholinesterase.

4.2.3 Developmental Toxicity Studies

In the rat study (MRID 41951501), the maternal toxicity LOAEL was 21 mg/kg/day based on clinical signs of toxicity, reduced body weight gain, and food efficiency; the maternal NOAEL was 3 mg/kg/day. The developmental LOAEL was not established; the NOAEL was 21 mg/kg/day.

In the rabbit developmental study (MRID 41802401), groups of NZW rabbits (16/dose) received oral administration of dichlorvos (97%) in distilled water at dose levels of 0, 0.1, 2.5, or 7.0 mg/kg/day during gestation days 7 through 19, inclusive. The maternal LOAEL was 2.5 mg/kg/day based on maternal deaths and decreased body weight gain; the NOAEL was 0.1 mg/kg/day. No developmental toxicity was noted; therefore, the NOAEL for developmental toxicity was 7 mg/kg/day.

4.2.4 Reproductive Toxicity Study

In a two generation reproduction study in rats (MRID 42483901), the parental/systemic NOAEL was 2.3 mg/kg/day and the LOAEL was 8.3 mg/kg/day based on a decreased incidence of estrous cycling and increased abnormal cycling in F1 females, reduced water intake in both sexes, and decreased plasma, and RBC ChE activity at all dosage levels in both sexes in both generations. In addition brain ChE was decreased in both sexes at 2.3 mg/kg/day. The NOAEL for brain ChE was 0.6 mg/kg/day and the NOAEL for plasma and RBC ChE depression was less than 0.6 mg/kg/day. The NOAEL/LOAEL for reproductive/offspring toxicity 2.3/8.3 mg/kg/day based on a decrease in the number of dams bearing litters, reduced fertility indices, pregnancy index, and pup body weights on lactation Day 4 in both F1 matings. The offspring were not examined for effects on cholinesterase.

4.2.5 Pre-and/or Postnatal Toxicity

There is no concern for pre- and/or postnatal toxicity resulting from exposure to dichlorvos. There was no evidence for increased susceptibility of the rat and rabbit offspring to prenatal or postnatal exposure to dichlorvos (MRID 41951501, 41802401 and 42483901, respectively) . In both rat and rabbit developmental studies, no developmental effects were observed. In the reproduction study, the parental/systemic NOAEL/LOAEL was 2.3/8.3 mg/kg/day which was identical to the reproductive/offspring NOAEL/LOAEL. In the DNT studies, at doses much higher than used for regulation, increase in auditory startle reflex habituation Vmax in PND 23 high dose males was noted.

4.2.5.1 Determination of Susceptibility

The mode of action for dichlorvos is neurotoxicity through the inhibition of cholinesterase via phosphorylation of the active site of the enzyme. Inhibition of cholinesterase provides the most sensitive endpoint for dichlorvos. There are acute and repeated dosing studies which evaluate cholinesterase inhibition in juvenile and young adult rats. The Agency has completed a benchmark dose (BMD) analysis of these data. The Agency's draft BMD technical guidance indicates that the BMD approach is a preferable alternative to the NOAEL/LOAEL approach (USEPA, 2000). The Office of Pesticide Programs is increasing its use of BMD techniques in its hazard assessments and risk characterizations for use in developing points of departure and in considering relative sensitivity of adult and juvenile animals. BMDs are preferred over the NOAEL/LOAEL as NOAELs/LOAELs are highly dependent on dose selection in that they are limited to the doses included in a study. BMD analysis also considers the entire dose response curve and not just a single point. Moreover, the NOAEL/LOAEL approach does not account for the uncertainty in the estimate of the dose-response. The dichlorvos BMD analysis was developed using the exponential model provided in EPA's OPCum Risk software. The application of the exponential model to cholinesterase data from OPs and *N*-methyl carbamate pesticides has been reviewed by the FIFRA Scientific Advisory Board on multiple occasions. This model and the supporting computer code are publicly available for download, review, and use at www.epa.gov/pesticides/cumulative/EPA_approach_methods.htm.

The Agency calculated the estimated dose to result in 10% inhibition (BMD_{10}) and the lower 95% confidence limit on the BMD_{10} ($BMDL_{10}$). Brain and RBC ChE data from acute dosing to post-natal day 8 (PND8) and young adult rats were extracted from MRID nos. 45805703 and 45842301. The acute $BMDs_{10}$ range from approximately 1.3 mg/kg to 2.0 mg/kg for each compartment, sex and age group. Regarding repeated exposures, brain and RBC ChE data from the repeated dosing studies in juvenile and young adult rat were extracted from MRID nos. 46433201 and 46153304. As described in detail in the Data Evaluation Record (DER) for these studies, the ChE activity measurements in some control groups are unusually high for the laboratory which conducted the repeated exposure study. The registrant, AMVAC, provided historical control values for brain and RBC ChE activity. BMD estimates were developed using both the concurrent and pooled historical control values. It is preferred to evaluate relative sensitivity using concurrent controls however in this case use of the historical control values provides helpful characterization. Overall, for the repeated exposure, the BMDs ranged from approximately 0.5 mg/kg to 1.2 mg/kg when using the historical or concurrent controls and are thus similar between compartments, sexes and age groups.

4.2.5.2 Degree of Concern Analysis and Residual Uncertainties for Pre and/or Post-natal Susceptibility

Based on the BMD analysis summarized above, the dichlorvos risk assessment team has determined that the FQPA Safety Factor can be reduced to **1X** for acute and repeated exposures of dichlorvos. The BMD estimates are similar for juvenile and adult rats, and thus indicates no sensitivity to young animals (Lowit, A., 2006).

4.2.6. Traditional Safety Factors

Any traditional safety factors other than that standard uncertainty factors, the interspecies extrapolation factor, and the intraspecies variability factor, are considered to be FQPA safety factors. For dichlorvos, a LOAEL from a human 21-day oral study is used as an endpoint for short term residential exposure scenarios. The LOAEL to NOAEL factor of 3x is considered to be an FQPA Safety Factor.

4.3 Hazard Identification and Toxicity Endpoint Selection

4.3.1. Acute Reference Dose (aRfD) - General Population

Study Selected: Acute Cholinesterase Study in Rats Non-guideline

MRID: 45805703

Title: Dichlorvos: Third Acute cholinesterase inhibition study in rats; Twomey, K. June 26, 2002.

Executive Summary: In the third acute oral cholinesterase toxicity study in rats (MRID 45805703*)*, groups of 15 male and 15 female Wistar-derived rats were administered single oral doses of dichlorvos (purity of 99.0%) at dose levels of 0 (control), 1 mg/kg, or 5 mg dichlorvos/kg on Day 1 of the study. Nine males were dosed with 35 mg dichlorvos/kg, but due to the severe cholinergic signs, no further dosing at this level was conducted. Two additional groups of 15 females were dosed with 0 or 15 mg dichlorvos/kg as a single oral dose. All animals were observed prior to the start of the study and on Day 1 at time of expected peak effect (30 minutes post dose) for any changes in clinical condition. Body weights were measured at Day 1, 8, and 15. At scheduled termination at 1 hour post dosing, 5/sex/dose animals were sacrificed and brains were removed and weighed. Cardiac blood samples were taken **post mortem** for determination of erythrocyte cholinesterase activity. The cerebellum, cerebral cortex, hippocampus, half and remainder of the brain were dissected out and sent for determination of cholinesterase activity. Dose analysis measurements were acceptable. On day 1

of dosing, severe toxicity in 9 males of the high-dose group (35 mg/kg) was observed. Four of these males were killed for humane reasons within 1 hour of dosing. Those sacrificed and the remaining animals in this group displayed some or all of the following signs: decreased activity, irregular breathing, clonic convulsions, fasiculations, prostration, decreased righting and splay reflexes, and salivation. One female dosed with 15 mg/kg had miosis and fasiculations. There were no meaningful (i.e., miosis) treatment related clinical signs in animals of the 1 or 5 mg/kg dose groups. Body and brain weight comparisons between treated groups of both sexes and their respective controls were not statistically significantly affected. Statistically significant cholinesterase depression occurred at the following doses in blood or brain segments for each sex: cerebellum (males, 35 mg/kg; females, 5 and 15 mg/kg), cortex (males, 5 and 35 mg/kg; females, 5 and 15 mg/kg), hippocampus (males, 35 mg/kg; females, 5 and 15 mg/kg), remainder (males 35 mg/kg; females 5 and 15 mg/kg), half-brain (males, 35 mg/kg; females, 5 and 15 mg/kg), erythrocyte (males, 5 and 35 mg/kg; females, 5 and 15 mg/kg). There was no meaningful cholinesterase depression at 1 mg/kg on erythrocyte or brain segments for both sexes killed at 1 hour post-dosing on day 1 or on day 8 or day 15 in comparison to controls. Due to a lack of cholinesterase inhibition in some animals on day 1, the animals scheduled for cholinesterase measurement on day 8 and 15 were sacrificed.

The LOAEL for erythrocyte and brain cholinesterase inhibition is 5 mg/kg in both sexes.
The NOAEL for erythrocyte and brain cholinesterase inhibition is 1 mg/kg in both sexes.

This acute oral cholinesterase toxicity study is classified **acceptable/non-guideline**. This study **does satisfy** the requirement (modified OPPTS 870.1100; OECD 401) for an acute oral cholinesterase toxicity study on the technical.

Dose and endpoint for establishing the aRfD: A Benchmark Dose Analysis (BMD) was conducted for the dichlorvos cholinesterase inhibition data by RRB4 (Daiss B., 2004). The Agency's BMDS program (Benchmark Dose Software version 1.3.2) was used to derive the $BMDL_{10}$, the estimated dose that results in 10% inhibition of cholinesterase, and the $BMDL_{10}$, the lower 95% confidence interval on the $BMDL_{10}$, for the RBC cholinesterase data. For this analysis, the polynomial continuous model default option of relative deviation was used for the benchmark response (BMR) type, with a corresponding BMR factor of 0.1 used as a basis for BMD and $BMDL_{10}$ derivation.

The $BMDL_{10}$ of 0.8 mg/kg based on Day 1 female brain ChE depression was selected as the lowest value of all the studies available which were analyzed by BMD.

A second BMD analysis was done for dichlorvos to be used in the OP cumulative analysis. This BMD analysis was done using the OPCumRisk software. Similar results were obtained. The decision algorithm and technical details of the "basic" exponential model used in this BMD analysis can be obtained at www.epa.gov/scipoly/sap/2001/september/rpfappendix1.pdf

Uncertainty factor: 100 (10x for interspecies differences and 10x for intraspecies variation).

FQPA Safety Factor: The FQPA Safety Factor has been reduced to 1x, since BMD analysis of studies with pup and adult ChE depression results did not demonstrate any substantial numerical differences in BMDL values (all values were approximately 1 mg/kg) for either RBC or brain cholinesterase.

Comments about Study/Endpoint/Uncertainty Factor: There are no specific issues of concern in the assessment of the rat acute cholinesterase studies.

Acute PAD (General population) = 0.8 mg/kg / 100 = 0.008 mg/kg

4.3.2. Chronic Reference Dose (cPAD)

Study Selected: Chronic Toxicity-Dog 870.4100 (formerly §83-1b)

MRID No. 41593101

Executive Summary: In a chronic feeding study, groups of beagle dogs were administered dichlorvos by capsule for 52 weeks at dose levels of 0, 0.1, 1.0 and 3.0 mg/kg/day. The 0.1 mg/kg/day dose was lowered to 0.05 mg/kg/day on day 22 due to the inhibition of plasma cholinesterase noted after 12 days (plasma cholinesterase was decreased in males (21.1%) and females (25.7%) at week 2 in the 0.1 mg/kg/day group). At time points after week 2, plasma cholinesterase activity was only significantly reduced in males (39.1 to 59.2%) and females (41.0 to 56.7%) in the mid-dose group and in males (65.1 to 74.3%) and females (61.1 to 74.2%) in the high dose group. Although RBC cholinesterase activity was reduced in males (23.6%) and females (50.1%) at week 6 in the low-dose group, this was believed to be an effect on RBC cholinesterase of the higher dose of 0.1 mg/kg/day. Much lower levels of inhibition were observed in this group after week 6. At time points after week 6, RBC cholinesterase activity was only significantly decreased in males (43.0 to 53.9) and females (38.0 to 51.9) in the mid-dose group and in males (81.2 to 86.9%) and females 79.2 to 82.5%) in the high-dose groups. Brain cholinesterase activity was significantly reduced in males (22%) in the mid-dose group and in males (47%) and females (29%) in the high dose group. The NOAEL was 0.05 mg/kg/day and the LOAEL was 0.1 mg/kg/day based on plasma and RBC cholinesterase inhibition in males and females.

Dose and Endpoint for Establishing cRfD: NOAEL = 0.05 mg/kg based on plasma and RBC cholinesterase inhibition in males and females at 0.1 mg/kg/day (LOAEL).

Uncertainty Factor: 100x (10x for interspecies variation, 10x for intraspecies extrapolation)

FQPA Safety Factor: 1x.

Comments about Study/Endpoint/Uncertainty Factor: The human data (discussed in the next section) were not used since RBC cholinesterase inhibition did not demonstrate a steady state (equilibrium) by the end of the study at three weeks, i.e. the inhibition of cholinesterase was progressive and a NOAEL was not achieved. This conclusion was supported by the HSRB.

Chronic PAD = $\frac{0.05 \text{ mg/kg/day}}{100}$ = 0.0005 mg/kg/day

4.3.3. Incidental Oral Exposure (Short Term)

Incidental Oral Exposure: Short-Term (1-30 days)

Study Selected: Subchronic oral toxicity study in human subjects § Non-guideline

MRID No.: 44248801

Executive Summary: In a single blind oral study 6 fasted male volunteers were administered 7 mg of dichlorvos in corn oil (equivalent to approximately 0.1 mg/kg/d) via capsule daily for 21 days. Three control subjects received corn oil as a placebo. Baseline values for RBC cholinesterase activity for each study participant were determined. After dosing started, RBC cholinesterase activity was monitored on days 2, 4, 7, 9, 11, 14, 16, and 18, then on day 25 or 28 post dosing. No clinical signs attributable to administration of dichlorvos was reported. Mean RBC cholinesterase activity was statistically significantly reduced in treated subjects on days 7, 11, 14, 16, and 18. These values were 8, 10, 14, 14, and 16 percent below the pre-dose mean. Under the study conditions, a LOAEL for RBC cholinesterase inhibition was established at 0.1 mg/kg/d. A NOAEL was not established.

Dose and Endpoint for Risk Assessment: The LOAEL of 0.1 mg/kg/d based on statistically significant decreases in RBC cholinesterase inhibition.

Comments about Study/Endpoint: The human study was selected because it is a subchronic study of appropriate duration and is the lowest LOAEL established for RBC cholinesterase inhibition in a repeated oral exposure to dichlorvos. Uncertainty factors account for intraspecies variability (10x). Since the study was conducted in human subjects, there was no need to account for interspecies extrapolation.

FQPA Safety Factor: 3x A 3x for lack of a NOAEL is considered an FQPA safety factor.

Target MOE: 30

4.3.4. Dermal Absorption

Dermal Absorption Factor: The dermal absorption rate for dichlorvos was estimated to be approximately 11% in 10 hours of exposure based on an acceptable dermal absorption study in rats (MRID 41435201).

4.3.5. Dermal Exposure (Acute)

Study Selected: Acute Cholinesterase Study in Rats Non-guideline

MRID: 45805703 (see discussion under Section 4.3.1 Acute Reference Dose)

Target MOE: 100

4.3.6. Dermal Exposure (Short-, Intermediate-, and Long- Term)

Study Selected: Subchronic oral toxicity study in human subjects § Non-guideline

MRID No.: 44248801

Executive Summary: (See discussion above)

Dose and Endpoint for Risk Assessment: The LOAEL of 0.1 mg/kg/d based on statistically significant decreases in RBC cholinesterase inhibition.

Comments about Study/Endpoint: The human study was selected because it is a subchronic study of appropriate duration and is the lowest LOAEL established for RBC cholinesterase inhibition in a repeated oral exposure to dichlorvos. Since the study was conducted in human subjects, there was no need to account for the interspecies extrapolation. Uncertainty factors account for intraspecies variability (10x).

FQPA Safety Factor: 3x A 3x for lack of a NOAEL is considered an FQPA safety factor.

Target MOE: 30

4.3.7. Inhalation Exposure (Acute)

Study Selected: Acute Cholinesterase Study in Rats Non-guideline
MRID: 45805703 (see discussion under Section 4.3.1 Acute Reference Dose)

Target MOE: 100, or 30 if RfC methodology is used. If RfC methodology is used, the interspecies extrapolation factor is reduced from 10x to 3x.

4.3.8. Inhalation Exposure (Short and Intermediate Term)

Study Selected: Subchronic oral toxicity study in human subjects § Non-guideline

MRID No.: 44248801 (See discussion above under dermal exposure)

Comments about Study/Endpoint: The uncertainty factors are the same as discussed above under Dermal Exposure.

4.3.9. Inhalation Exposure (Long Term)

Study Selected: 2-year Rat Inhalation/carcinogenicity870.4200a (formerly §83-2a)

MRID No. 0057695, 00632569

Executive Summary: The critical study for inhalation risk assessment for Dichlorvos is an inhalation carcinogenicity study in rats. Groups of 50/sex/group Carworth rats were exposed to atmospheres containing Dichlorvos vapor for 23 hours/day, 7 days/week at concentrations of 0, 0.05, 0.5, and 5 mg/m^3 equivalent to 0.055, 0.5, and 5.0 mg/kg/day for 2 years. Animals were observed for clinical signs of toxicity, hematology, and clinical chemistry. Plasma, RBC and brain cholinesterase activity were determined at study termination. There were no toxic signs, and no organ weight or organ to body weight changes, or hematological changes attributable to administration of Dichlorvos. Body weights were significantly decreased in mid and high dose males up to study termination, and in high dose females throughout the study. Plasma, RBC, and brain cholinesterase activity were significantly reduced in the mid and high dose groups (76, 72, and 90 and 83, 68, and 90 percent of control in mid dose males and females, and to 38, 4, and 21, and 22, 5, and 16 percent of control in the high dose male and female groups, respectively). RBC cholinesterase activity was reduced to 88 percent of control in the low dose females. The BMD_{10} for RBC cholinesterase inhibition in female rats was 0.15 mg/m^3 and the $BMDL_{10}$ was 0.07 mg/m^3.

Comments about Study/Endpoint: This is the same inhalation study which has been used by the Agency RfD/RfC Work Group in deriving the Reference Concentration (RfC) for Dichlorvos. An Agency RfC document is available on IRIS.

The $BMDL_{10}$ of 0.07 mg/m^3 (or 0.00007 mg/L) was selected for chronic inhalation risk assessment scenarios. Uncertainty factors account for intraspecies variation (10x) and 3x for interspecies variation. (The interspecies extrapolation factor is reduced to 3x when the endpoint is expressed in concentration units (RfC methodology)).

FQPA Safety Factor: 1x

Target MOE: 30

4.3.10. Margins of Exposure

A summary of target Levels of Concern for dichlorvos risk assessment is provided in Table 4.3.10.

Table 4.3.10. Target Levels of Concern (i.e., Margins of Exposure) for Dichlorvos Exposure Scenarios				
Route	**Acute (<1 Day)**	**Short-Term (1-30 Days)**	**Intermediate-Term (1 - 6 Months)**	**Long-Term (> 6 Months)**
Occupational (Worker) Exposure				
Dermal	100	30	30	N/A
Inhalation	100/30*	30	30	N/A
Residential (Non-Dietary) Exposure				
Oral	100	30	N/A	N/A
Dermal	100	30	30	30
Inhalation	100/30*	N/A	N/A	30

*** The higher target MOE is used when the endpoint is expressed in mg/kg/day (for exposure during application). The lower target MOE is used when the endpoint is expressed in concentration units (RfC methodology, used for post-application risk assessment). There is no long term residential inhalation exposure during application.**

For short- and intermediate- term oral and dermal exposures, the uncertainty factor is based on the conventional uncertainty factor of 10X for intraspecies variability. No factor is needed for interspecies extrapolation because the endpoint is based on a human study. A 3x factor for lack of a NOAEL is considered an FQPA safety factor.

For short- and intermediate- term inhalation exposure, the uncertainty factor is based on the conventional uncertainty factor of 10x for intraspecies extrapolation, 3x for the use of a LOAEL. For long term inhalation exposure, the uncertainty factor is based on the conventional uncertainty factor of 10x for intraspecies extrapolation, 3x for interspecies extrapolation (based on air concentrations), The FQPA safety factor is reduced to 1x for residential exposure assessments.

For acute inhalation exposure, the uncertainty factor is based on the conventional uncertainty factor of 100x (10X for interspecies extrapolation and 10x for intraspecies variability), when the endpoint is expressed in mg/kg/day. When the endpoint is expressed in concentration units, the interspecies extrapolation factor is reduced to 3x. The FQPA Safety Factor has been reduced to 1x. The target MOE is 30.

4.3.11. Recommendation for Aggregate Exposure Risk Assessments

Under FQPA, when there are potential residential exposures to the pesticide, aggregate risk assessment must consider exposures from residues in food commodities and drinking water, as well as exposures arising from non-dietary sources (e.g., incidental oral, dermal and inhalation exposures) from the residential scenarios. Since there are residential uses of dichlorvos and the effect is cholinesterase inhibition for all endpoints, aggregation of risk from non dietary sources is required. Since the target MOEs differ, aggregation of risk will be assessed using the aggregate risk index (ARI). The target ARI is 1.

4.3.12. Classification of Carcinogenic Potential

Dichlorvos has been classified as a category C carcinogen based primarily on increased incidences of forestomach tumors in female mice and mononuclear cell leukemia (MCL) in male Fischer 344 rats. Both tumor types have been used at various times to derive q_1^* s for quantitation of cancer risk. After lengthy deliberations and consultations with EPA's Scientific Advisory Panel (SAP) and cancer experts with the National Toxicology Program, HED's Cancer Assessment Review Committee has classified dichlorvos as "suggestive" and not requiring quantitation of cancer risks based on the following rationale:

1) MCL in the male Fischer rat has certain properties in terms of variability and reliability which limit its usefulness for human risk assessment.

2) The forestomach tumors in mice observed at gavage doses causing inhibition of plasma and red blood cell cholinesterase and cholinergic signs, are also limited in their use for human risk assessment.

3) The fact that dichlorvos is only positive by the gavage route and negative by the inhalation route, which is the major route of human exposure, indicates that any classification by the oral route may be limited since localized effects in the forestomach may not be applicable to human risk assessment.

4.4 Summary of Toxicology Endpoint Selection for Dichlorvos

Table 4.4. Summary of Toxicological Doses and Endpoints for Dichlorvos for Use in Dietary and Non-Occupational Human Health Risk Assessments

Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	$BMDL_{10}$ = 0.8 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 1x	**Acute RfD** = 0.008 mg/kg/day **aPAD** = 0.008 mg/kg/day	Rat acute oral cholinesterase studies - RBC and Brain ChE depression. NOAEL = 1 mg/kg/day, LOAEL = 5 mg/kg/day, BMD = 1.6 mg/kg/day for brain ChE depression (F)
Chronic Dietary (All populations)	NOAEL= 0.05 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 1x	**Chronic RfD** = 0.0005 mg/kg/day **cPAD** = 0.0005 mg/kg/day	1-Year Dog study LOAEL = 0.1 mg/kg/day based on Plasma and RBC ChE depression
Short-Term Incidental Oral (1-30 days)	LOAEL= 0.1 mg/kg/day	UF_H= 10x FQPA SF = 3x (UF_L)	**Residential** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Acute Dermal and Acute Incidental Oral	$BMDL_{10}$ = 0.8 mg/kg/day dermal absorption=11%	UF_A = 10x UF_H = 10x FQPA SF = 1x	**Residential** LOC MOE = 100	Rat acute oral cholinesterase studies - RBC and Brain ChE depression. NOAEL = 1 mg/kg/day, LOAEL = 5 mg/kg/day, BMD = 1.6 mg/kg/day for brain ChE depression (F)
Short-, Intermediate- and Long-Term Dermal	Oral study LOAEL= 0.1 mg/kg/day dermal absorption=11%	UF_H = 10x FQPA SF = 3x (UF_L)	**Residential** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Acute Inhalation (1 day)	Oral study $BMDL_{10}$ = 0.8 mg/kg/day (inhalation absorption rate = 100%) Air concentration Equivalent = 0.8 mg/m^3*	UF_A = 10x UF_H = 10x or 3x** FQPA SF = 1x	**Residential** LOC MOE = 100/30**	Rat acute oral cholinesterase studies - RBC and Brain ChE depression. NOAEL = 1 mg/kg/day, LOAEL = 5 mg/kg/day, BMD = 1.6 mg/kg/day for brain ChE depression (F)
Short- and Intermediate-term Inhalation of vapors	Oral study LOAEL= 0.1 mg/kg/day UF=30 Concentration equivalent= 0.35 mg/m^3*	UF_H = 10x FQPA SF = 3x (UF_L)	**Residential** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Short- and Intermediate-Term Inhalation during application	LOAEL= 0.1 mg/kg/day	UF_H = 10x FQPA SF = 3x (UF_L)	**Residential** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Long-Term Inhalation of vapors	$BMDL_{10}$ = 0.07 mg/m^3	UF_A = 10x UF_H = 3x** FQPA SF = 1x	Residential LOC = 30	2-year Rat Inhalation BMD = 0.15 mg/m^3 based on RBC ChE depression (F)
Cancer (oral, dermal, inhalation)	"suggestive" evidence of carcinogenicity not quantifiable under the 1999 Draft Agency Cancer Guidelines			

Table 4.4. Summary of Toxicological Doses and Endpoints for Dichlorvos for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key date (i.e., lack of a critical study). $FQPA_{SF}$ = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = Not Applicable

* Calculation of concentration equivalent $BMDL_{10}$ and LOAEL
Acute Inhalation $BMDL_{10}$
0.8 mg/kg/day x 0.35 kg / 0.34 m^3/day = 0.8 mg/m^3
Short- and Intermediate- term inhalation of vapors LOAEL
0.1 mg/kg/day x 70 kg / 20 m^3/day = 0.35 mg/m^3

**Since the NOAEL is expressed in concentration units (RfC methodology), the interspecies extrapolation factor is 3x (for the acute and long term inhalation scenarios), for a total UF of 30 for acute inhalation and long term inhalation. The residential target MOE is 30 for acute inhalation, since the FQPA safety factor has been reduced to 1. The Residential target MOE is 30 for long term inhalation, since the FQPA safety factor is 1.

4.4 FQPA Safety factor

The HED dichlorvos team evaluated the hazard and exposure data to determine if the FQPA10x safety factor should be retained, reduced or removed focusing primarily on the following points:

- The standard developmental and reproductive toxicity studies and the developmental neurotoxicity study submitted to the Agency showed no residual concern for sensitivity or susceptibility of rats, or rabbits to *in utero* and/or postnatal exposure to dichlorvos;

- In repeated dose studies with dichlorvos in rats, young rats were less sensitive than adult rats with respect to inhibition of RBC cholinesterase; in repeated dose studies with dichlorvos in rats, based on the BMD analysis, there was no difference between young rats and adult rats with respect to inhibition of brain cholinesterase; in repeated dose studies, the BMDs are similar between compartments, sexes and age groups.

- Some exposure scenarios are based on a LOAEL.

- The dietary food exposure assessment utilizes a combination of monitoring data, field trial data, and tolerance level residues. Percent crop treated information is used where available. These data will not underestimate chronic exposures/risks.

- The dietary drinking water assessment (Tier 2 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

- The residential exposure assessment utilizes dichlorvos specific monitoring data, activity specific transfer coefficients and chemical-specific turf transferable residue (TTR) studies for the post-application turf scenario (use of trichlorfon). The refined residential assessment is based on reliable data and is unlikely to underestimate exposure/risk.

The dichlorvos team concluded that the FQPA Safety Factor can be reduced to 1x, except for short term oral and dermal scenarios, for which the FQPA factor is retained at 3x to account for the lack of a NOAEL.

4.5. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on dichlorvos, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, dichlorvos may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Public Health Data

The Agency has conducted a review of reported poisoning incidents associated with human exposure to dichlorvos. The Agency has consulted the following data bases for the poisoning incident data on the active ingredient dichlorvos: (1) the OPP Incident Data System, which contains anecdotal reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992, (2) Poison Control Center Data for 28 organophosphate and carbamate chemicals for the years 1985 through 1992, (3) California Department of Food and Agriculture reports (superceded by the Department of Pesticide Regulation), which contain uniform data on suspected pesticide poisonings collected since 1982, and (4) National Pesticide Telecommunications Network (NPTN), which is a toll-free information service supported by OPP. In addition, the Agency has received public comments regarding poisoning incidences associated with dichlorvos as comments to the Proposed Notice of Intent to Cancel (PD 2/3) and in Phase 3 of the RED process. Specific comments on incidences were received from Amvac Chemical Corporation, the Japanese Resin Strip Manufacturer's association, and two private citizens, Arturo Haran and Eric Levine.

Exposure to dichlorvos has resulted in poisoning incidents. Dichlorvos has widespread use patterns in the home and agricultural environments. Many of these uses (e.g., poultry houses) are atypical of most organophosphates, which make it difficult to compare the risk. According to California data, it appears that a majority of cases involved illnesses to workers indoors that entered a facility previously fumigated with dichlorvos. Often exposure results from inadequate ventilation before persons are allowed in or near the treated area or lack of proper personal protective equipment (PPE).

Dichlorvos can cause systemic illness, including respiratory effects, to individuals who are exposed after fumigation.

5.1 Incident Reports

Incidents with dichlorvos are discussed in a separate review. Blondell, J and Spann, M. 1998. More recent information is available. However, the more recent information is very similar to that reported in 1998, and doesn't change our conclusions (J. Blondell, personal communication with S. Hummel, 1/4/2005).

5.2 Other

The Agency received additional information on poisoning incidents associated with dichlorvos as comments to the PD 2/3 and to Phase 3 of the RED. Specific comments on incidents were received from Amvac Chemical Corporation, the Japanese Resin Strip Manufacturer's Association, and two private citizens, Arturo Haran and Eric Levine. Amvac submitted a review of human incident data for Dichlorvos (Feiler 1995), and the Japanese Resin Strip Manufacturer's Association submitted data on poisoning incidences involving dichlorvos resin strips. Arturo Haran submitted an anecdotal report of health effects and Eric Levine submitted a comment about the

potential carcinogenicity of dichlorvos. The Agency has reviewed this new information (Blondell 1996). The Agency's conclusions are summarized below.

Data reported by the American Association of Poison Control Centers (AAPCC) concerning exposure to single products with dichlorvos often contain other active ingredients. AAPCC reported 21,006 exposures to single products containing dichlorvos. Most of these exposures involve homeowner use products that contained dichlorvos in combination with other insecticides such as propoxur, pyrethrins, or piperonyl butoxide. In these cases involving dichlorvos in combination with other pesticides it is incorrect to attribute any resulting toxicity solely to dichlorvos.

Dichlorvos resin strips account for a very small proportion of total incidents, about 33 cases per year (1% of total incidences). Incident reports involving exposure to resin strips usually do not involve any significant acute symptoms that would require medical treatment (Blondell 1996).

Eric Levine commented on epidemiological evidence linking use of dichlorvos resin strips with childhood cancer. Two epidemiologic studies have reported an association between exposure to dichlorvos resin strips and childhood cancer. These studies by Liess and Savitz (1995) and Davis et al (1993) have been reviewed by the Agency (Blondell 1996). Reviews of these studies have identified biases and confounders that could explain the observed associations. The Agency concludes that the biases are a more likely explanation for the findings of increased cancer than exposure to resin strips. Additional studies that correct for the control of potential biases and problems of exposure determination are needed before an association between dichlorvos and childhood cancer can be established.

A statistically significant excess risk for prostate cancer and dichlorvos exposure was reported in the recent Agricultural Health Study (AHS) by Alavanja et al., (2003). The reported excess risk was based on a small number of cases (n=16) and only seen in the men who had a family history of prostate cancer. The odds ratio reported was 1.75, (75% excess) with confidence interval 1.0-3.06, meaning the risk could be as high as 206%. Dichlorvos was one of seven chemicals positive for prostate cancer among fifty chemicals tested. There is no AHS chemical specific report on dichlorvos at this time. Follow-up studies are planned to examine the interaction effect on family history and genetic susceptibility factors. The AHS is a prospective pesticide epidemiology study that includes over 90,000 certified pesticide applicators and their families from Iowa and North Carolina. Additional analyses will examine dichlorvos findings, as part of the high pesticide exposure event studies and work practices assessments. Dichlorvos is not one of the current National Health and Nutrition Examination Surveys (NHANES) chemicals being examined by the Centers for Disease Control (CDC) National Center for Health Statistics (NCHS).

6.0 Exposure Characterization/Assessment

6.1 Dietary Exposure/Risk Pathway

6.1.1 Residue Profile

The reregistration requirements for plant and livestock metabolism are fulfilled. The Agency determined that the available data depicting the metabolism of naled in plants are sufficient to delineate the metabolism of dichlorvos in plants because dichlorvos is the initial metabolite of naled. In plants, naled is metabolized to dichlorvos which is hydrolyzed to dimethyl phosphate and dichloroacetaldehyde. Dimethyl phosphate is sequentially degraded to monomethyl phosphate and inorganic phosphates, and dichloroacetaldehyde is converted to 2,2-dichloroethanol which is then conjugated and/or incorporated into naturally occurring plant components. The residue of concern in plant commodities is dichlorvos.

Acceptable studies depicting the qualitative nature of the residue in ruminants and poultry following dermal treatment with dichlorvos have been submitted and evaluated. Because dichlorvos is the initial metabolite of naled, the available metabolism studies reflecting oral dosing of ruminants and hens with naled are sufficient to delineate the metabolism of orally dosed dichlorvos in animals. The residue of concern in animal commodities is dichlorvos.

Adequate field trial and processing data are available for the reregistration of dichlorvos, although not all the field trial data are adequately supported by storage stability data, and there is an outstanding data requirement for a dermal study in swine. Finite residues are reported in the field trials, but residues are generally non-detectable in monitoring data. Non-detectable residues were generally reported in livestock tissues, milk, and eggs. Adequate enforcement analytical methods are available in PAM I and II. Dichlorvos is recovered by PAM I Luke multiresidue method (protocol D), provided “early eluter” conditions are used. The Pesticide Analytical Manual (PAM) Vol. II lists a GC method (with flame photometric detection; Method I) for the determination of dichlorvos in plant and animal commodities. An additional GC method (Method II) using electron capture detection is listed for the determination of dichlorvos and naled in plant and animal commodities; this method is also an enforcement method for naled. A GC method using microcoulometric detection is listed as Method A. This method determines total residues of dichlorvos and naled via conversion of naled residues to dichlorvos; however, the method can be modified to determine naled and dichlorvos separately. Data collection methods were similar to the available enforcement methods, and were adequately validated.

Dietary exposure to dichlorvos residues may occur as a result of use on or at a variety of sites, including mushroom houses, warehouses containing bulk-stored and packaged or bagged nonperishable processed and raw food, commercial food processing plants, groceries, direct animal treatment, and livestock premise treatment. As a result, dichlorvos residues may be found in bulk stored and packaged or bagged non perishable processed or raw food. Dichlorvos residues may also be found in mushrooms and in livestock commodities, such as meat, milk, meat byproducts, poultry, and eggs. In addition, a dichlorvos registrant has expressed interest in supporting use on tomatoes.

Two other pesticides, naled and trichlorfon, degrade to dichlorvos through plant and livestock metabolism, and non-biological reactions. The Agency does not expect measurable dichlorvos residues from trichlorfon because all trichlorfon food uses on field crops have been canceled and associated tolerances revoked, and non-detectable residues were found in livestock dermal studies.

Three factors will significantly affect dietary exposure to dichlorvos from registered uses of naled; these include the pre-harvest interval (PHI), the condition and length of storage, and cooking and processing. Plant metabolism studies show that dichlorvos residues are formed 1 to 3 days after treatment with naled; however, dichlorvos residues decline to less than the limit of detection (0.01 to 0.05 ppm) 7 days after treatment. In general, registered uses of naled have PHIs of less than 7 days. Because of the short PHIs for naled products, measurable residues of dichlorvos may be present in the diet from naled treated food. As a result, the dietary (food) exposure assessment for dichlorvos includes residues of dichlorvos resulting from the application of naled.

Dietary exposure estimates for acute and chronic dietary exposure assessments have been refined with residue data from USDA's Pesticide Data Program (PDP), FDA surveillance monitoring data, and FDA Total Diet Study (TDS) data, processing and cooking studies, and percent of crop treated information.

Sources of data to estimate the levels of residues of pesticides in food include the following: tolerances (legal limits), controlled field trial data, Food and Drug Administration (FDA) surveillance and compliance monitoring data, FDA Total Diet Study data (market basket survey based on a random sampling of residues on food in grocery stores), US Department of Agriculture (USDA) Pesticide Data Program (PDP), and USDA/FSIS (Food Safety Inspection Service) livestock monitoring data (Hummel, 1998a, Hummel 2000). The estimated levels of residues can then be adjusted for the effects of processing using processing studies, including commercial processing studies, washing studies, cooking studies, and residue degradation studies. Of these sources, the Agency relied on tolerance levels and field trial data (adjusted for the effects of processing and cooking) to estimate dietary exposure to dichlorvos in the PD 2/3. At the time of the PD 2/3, the monitoring data available for dichlorvos were very limited. In this updated assessment, anticipated residues based on some tolerances plus field trial and monitoring data were used.

(a). ***Field Trial Data***. Data from controlled field trials which reflect currently registered uses are available for mushrooms. Data from direct dermal treatments to cattle and poultry are discussed in the Dichlorvos Registration Standard. Field trial data are available for packaged or bagged food, use in food manufacturing and processing facilities, and for secondary residues in livestock commodities. Adequate field trial data are not available for tomatoes.

(b). ***FDA Surveillance and Compliance Monitoring Data.*** The FDA Surveillance and Compliance Monitoring Program is designed to ensure that pesticide residues do not exceed established tolerances. Naled and dichlorvos are included in the FDA surveillance and compliance monitoring programs. However, dichlorvos is only detected using the Luke method on non-fatty foods, and only when "early eluter" column conditions are used (low column temperature). Thus, the number of samples analyzed for dichlorvos is low compared to the samples analyzed for other

pesticides, although the number of analyses done by FDA that will detect dichlorvos have increased significantly in the last few years. FDA Surveillance and Compliance monitoring data were obtained from FDA for 1990 through 1998. From 1994 through 1998, FDA analyzed over 3000 surveillance monitoring samples for dichlorvos. The limit of quantitation (LOQ) for dichlorvos in fruits and vegetables is approximately 0.01 ppm, and the limit of detection (LOD), approximately 0.003 ppm.

All residues of dichlorvos reported were non-detectable, with the following exceptions: three samples of strawberries (which had low levels of detectable residues of dichlorvos), one sample of red raspberries (0.08 ppm dichlorvos); one tomato sample from Mexico with a trace residue (> LOD, but <LOQ); one sample of garbanzo beans from S. Korea with a trace residue; and 0.03 ppm on one sample of cantaloupe from Honduras. All residues of naled reported were non-detectable, with the following exceptions: 3 samples of strawberries with residues of 0.1, 0.2, and 0.43 ppm naled.

(c). ***FDA Total Diet Study Data (TDS).*** The FDA Total Diet Study Program is designed to measure trends in pesticide residues. Since 1982, approximately four market baskets per year have been collected in a large city in one of four regions of the country. The region of the country in which the market basket samples are collected rotates so that samples are collected in all four regions over one year. FDA summarizes the data expressed as daily intakes for 8 age-sex groups (infants, young children, male and female teenagers, male and female adults, and male and female older persons). Each market basket has consisted of 234-265 individual food items prepared as ready to eat foods (washed and cooked). Individual foods are analyzed separately. Although the TDS includes sampling of meats and poultry, dichlorvos could not be analyzed in these commodities using the TDS analytical methods.

Historically, the Agency has not used FDA Total Diet Study data for exposure assessment purposes because the number of samples is limited (approximately four samples per year of each of 234 - 265 individual food items since 1982), samples are only collected in large cities, and the treatment history is unknown. The TDS does not include minor crops. However, a total of 43 market basket surveys are now available for 1982 - 1996. Among the commodities collected in the TDS, there were approximately 35 non-fatty commodities analyzed which were similar to crackers and cereals, approximately 11 baked goods which were made from flour, sugar, and dried eggs, 4 coffee and 1 tea commodities, plus raisins, prunes, and cooked eggs. These are commodities that are or are produced from 'bulk stored' and 'packaged and bagged' commodities, and may have been treated with dichlorvos closer to the point of consumption than the wheat grain samples collected by USDA in their Pesticide Data Program.

By grouping the commodities (generally along crop group classifications), there were more than 100 samples per group of commodities analyzed. The Agency has used extrapolation among members of crop groups in the past when using monitoring data. For example, monitoring data for oranges could be extrapolated to all citrus (tangerines, tangelos, grapefruit, lemons, and limes), provided the use pattern for citrus is the same.

Dichlorvos is not listed specifically as one of the pesticides recovered in the analyses for the FDA Total Diet Study. However, all of the Total Diet Study samples were analyzed using

temperature programming which would allow detection of "early eluters." Therefore, if dichlorvos is present, it would be detected, and one detectable residue of dichlorvos was reported. The LOD for dichlorvos in total diet samples is 0.001 ppm (personal communication, B. McMahon, FDA).

(d). ***USDA Pesticide Data Program Data.*** The USDA Pesticide Data Program (PDP) collects residue data primarily for fresh fruits and vegetables, plus wheat grain, beef commodities, poultry commodities, and milk. A few canned and frozen commodities have been tested. Samples are collected in terminal markets and large distribution centers. The commodities included in the PDP changes annually. Sampling dates and sites are selected at random following a statistically designed sampling plan. Participating laboratories meet rigorous quality assurance/quality control (QA/QC) criteria including following good laboratory practices (GLP), a check sample program, and confirmation of residue findings. Sampling and analyses are done through a cooperative agreement with nine states and two USDA laboratories. These states represent about 50% of the population of the US and a large percentage of the fresh fruits and vegetables grown in the US. Food commodities collected in the PDP are prepared as normally would be done for consumption, washed and peeled, although not cooked. Canned and frozen commodities are not further cooked before analysis, although they may have been blanched or cooked in the canning or freezing process.

The USDA PDP analyzes for dichlorvos, which would include dichlorvos resulting from naled since the analytical method used generally converts naled to dichlorvos prior to or during the analysis. The LOD for the analyses varied, depending on the laboratory conducting the analyses, and ranged from 3 ppb to 280 ppb. All samples analyzed for dichlorvos had non-detectable residues, except for (1) one peach sample analyzed in 1992, which had a dichlorvos residue of 0.059 ppm; (2) one green bean sample analyzed in 1994, which had a dichlorvos residue of 0.012 ppm; (3) one grape sample analyzed in 1996, which had a dichlorvos residue of 0.003 ppm, which was below the LOQ; (4) one milk sample analyzed in 1996, which had a dichlorvos residue of 0.003 ppm, which was below the LOQ; (5) one pear sample analyzed in 1997, which had a dichlorvos residue of 0.005 ppm, which was below the LOQ; and (5) 15 strawberry samples in 1998, on which the maximum dichlorvos residue was 0.02 ppm. PDP data were used in the dichlorvos dietary exposure assessment for commodities which could be treated with naled, beef commodities, poultry commodities, and for milk. The PDP data on wheat grain were not used, because packaged and bagged commodities made from wheat grain could have been treated again with dichlorvos after the PDP samples would have been collected. The PDP does not analyze for naled because initial method validation indicated that naled is converted to dichlorvos during the analysis. The PDP does, however, identify unknown residues, and would report a residue of naled if found.

(e). ***Processing and Cooking Study Data.*** Residues for raw commodities can be modified by processing factors to account for changes during commercial or other processing and cooking. Processing, cooking and decline (half-life) studies were available for cocoa beans, dry pinto beans, tomato juice, ground roasted coffee beans, raw hamburger meat, raw eggs, and raw whole milk. The resulting cooking factors were used to reduce the Agency's estimate of residues for these commodities and were translated to other commodities based on similarity of cooking time and temperature. Additional cooking studies were available and discussed in the Residue Chemistry Chapter of the Registration Standard. Half-lives of dichlorvos in various commodities

ranged from 0 to over 1,000 hours. The reduction of dichlorvos upon cooking appeared to be related to the length of time and temperature used in cooking. Residues were adjusted based on these cooking factors to obtain the Anticipated Residue Estimate for the cooked commodity.

(f). ***Percent of crop treated data.*** OPP has refined its estimates of dietary exposure for various commodities based on percent of crop treated. The Biological and Economic Analysis Division (BEAD) of OPP provided updated percent of crop treated (% CT) information that were incorporated into the acute dietary (food) exposure analysis as appropriate (Hummel, et. al. 2000). Where a range of percent crop treated estimates are supplied for this analysis, the upper end of that range is assumed for acute dietary (food) exposure analysis, and the typical or average % CT is used for the chronic dietary (food) exposure analysis.

6.1.2 Acute and Chronic Dietary Exposure and Risk

Anticipated residues are a realistic estimate of actual pesticide residues in foods based on available data. Reliable data are available for dichlorvos, including the USDA's PDP data, the FDA Total Diet Study and the FDA monitoring data. These data were not available at the time of the PD 2/3, Notice of Intent to Cancel, published in 1995. Anticipated residues used in the dietary risk assessment are presented in separate memo (Hummel S, Hrdy D, and Sahafayen M, 2000). The methods for deriving anticipated residues for dichlorvos are described below.

(a) ***From Use of Dichlorvos***. All dichlorvos tolerances in 40 *CFR* §180.235 were evaluated as potential sources of dichlorvos residues. For the updated dichlorvos dietary exposure assessment, FDA Total Diet Study data were used for residues resulting from the use of dichlorvos per se, where appropriate, by grouping similar commodities made from grain products, sugar, dried eggs, coffee and tea, and dried fruits. These are summarized below.

Raw Agricultural Commodities. The following uses have been canceled by AMVAC: tomatoes, cucumbers, lettuce, and radishes, and the associated tolerances recommended for revocation. Therefore, these uses are not included in the exposure assessment. One dichlorvos registrant has proposed supporting use on tomatoes, and tomatoes still appears on one product label, EPA Reg. No. 5011-49. No residue data were provided to support this use. No detectable residues of dichlorvos were detected on tomatoes in 1996-1998 in the PDP or from 1994-1998 in the FDA Surveillance Monitoring Program.

Meat, Milk, Poultry and Eggs. Residues in livestock tissues, including milk and eggs, may result from consumption of dichlorvos treated livestock feeds, direct dermal treatments, livestock premise treatments, or from use as a drug in swine. Livestock metabolism studies done at exaggerated rates in ruminants and poultry have demonstrated that oral ingestion of dichlorvos, naled, and trichlorfon by cattle and poultry will not result in detectable residues. This conclusion can be translated to the drug use of dichlorvos in swine. Secondary residues in livestock and poultry from consumption of treated feed fall under category 3 of 40 CFR §180.6(a), having no reasonable expectation of finite residues. Data reflecting dichlorvos direct livestock treatments are discussed in the Residue Chemistry Chapter of the Dichlorvos Registration Standard. Data from direct dermal studies indicate that detectable residues are not expected, except in skin. Residues are non-detectable (<0.01 ppm) in cattle tissue and milk, and non-detectable (<0.05 ppm) in poultry

tissues and eggs. For the PD 2/3 dietary exposure assessment, the Agency used one-half the limit of detection as the residue estimate in both cases.

PDP monitoring data were available for meat (beef and poultry) commodities, and milk. Non-detectable residues of dichlorvos were found in all beef commodities (<0.001 ppm) and poultry commodities (<0.006 ppm), Ratios of dichlorvos residues found in livestock tissues in dermal metabolism studies to residues of dichlorvos found in milk in the livestock dermal metabolism studies were calculated. These ratios were then used with the PDP monitoring data in milk to estimate residues of dichlorvos in livestock tissues (lower than the PDP limit of quantitation for beef commodities). The dietary exposure estimates in poultry commodities are based on the non-detectable residues (<0.006 ppm) reported in PDP monitoring data. A cooking factor of 0.3x was then applied. The dietary exposure estimate for eggs was the non-detectable residue found in cooked eggs in the FDA Total Diet Study.

Bulk Stored, Packaged or Bagged Commodities, Food and Feed Handling Uses. The anticipated residues used in the Dichlorvos PD 2/3 exposure assessment for packaged, bagged or bulk stored food were based on field studies submitted by AMVAC (Hummel 1994b). Residue data were submitted for many commodities. For those commodities where data were not submitted, the Agency translated residue data from similar commodities. For example, data on dry beans are translated to other legumes; data on wheat flour are translated to all flours and meals, etc. In addition, residue data were provided for corn and oats at various points during processing, and for flour, sugar, dried milk, dried eggs, shortening, and baking mix from a treated manufacturing facility. Bulk stored commodities are assumed to be uncovered when treated. Although pesticide labels state that bulk or unpackaged foods should be covered or removed before spraying, it is not possible to assess the effect of covering food since the type of material used in the cover is not specified and the manner in which food is covered would vary considerably. Therefore, food is assumed to be uncovered, which is likely to overestimate residues. Since the proportion of commodities stored in bulk vs. packaged/bagged is unknown, the anticipated residues are based the residues found in packaged/bagged food, because foods are expected to be packaged/bagged closer to the time of consumption.

FDA TDS data were used for the dichlorvos dietary exposure assessment on grain products and sugar, eggs, coffee and tea. In the 43 samples of 126 commodities in which dichlorvos would be detected, only one sample had a detectable residue, one sample of rye bread at 0.01 ppm, which is below the LOQ of 0.03 ppm.

The tolerances in 40 *CFR* §180.235 for nonperishable packaged, bagged or bulk raw food and for packaged or bagged nonperishable processed foods (formerly in 40 *CFR* §185.1900) do not refer to specific commodities. Therefore, the Agency has developed a list of commodities likely to be treated with dichlorvos that are covered by tolerances. Because these tolerances were established to cover residues resulting from use at different sites (for example, wheat could be treated in its raw form in a silo, later as flour, during processing into cake mixes, and finally as a stored packaged commodity), cancellation of any one of the site-specific uses does not necessarily eliminate the risk of a commodity from dichlorvos treatment. The Agency did not combine the residues from different sites in creating the anticipated residues, although the cumulative residues from treating a commodity at different sites were considered in the estimation of percent of crop

treated for the PD 2/3; however, the Agency position has changed. Now we expect that sufficient time will pass between treatments that only the maximum residue from one type of treatment needs to be considered.

(b) ***From Use of Naled.*** All naled tolerances in 40 *CFR* §180.215 were evaluated as potential sources of dichlorvos residues. Anticipated residues are based on either tolerance level equivalents or field trials or monitoring data from FDA (Regulatory monitoring or Total Diet Study) or USDA (PDP). These data sources were used for both acute and chronic dietary exposure estimates. Naled and dichlorvos residue estimates were reduced when data were available to account for the effects of washing, cooking, and processing. In addition, wide area application of naled in mosquito and fly control use could result in residues potentially on all crops in the Agency's DEEM™ software. The Agency did not include all these crops in its estimate of anticipated dichlorvos residues for the chronic dietary exposure assessment. Although it is possible that dichlorvos residues could occur on any raw agricultural commodity from this use of naled, it is unlikely that residues would be found on all commodities. As a result, this inclusion of residues of dichlorvos from all raw crops would present a possible source of overestimation of dietary exposure. A sensitivity analysis was conducted for naled and dichlorvos from naled, done separately from the dichlorvos risk assessment, showing that the mosquito and fly control use was not a substantial source of exposure.

(c) ***From Use of Trichlorfon.*** All trichlorfon tolerances in 40 *CFR* 180.198 were evaluated as a potential source of dichlorvos residues. All tolerances for trichlorfon have been revoked, with the exception of tolerances in beef cattle commodities, which are being retained to cover potential residues from imported meat commodities. In trichlorfon cattle feeding studies, residues of trichlorfon and dichlorvos were non-detectable (<0.05 ppm) in livestock commodities at pre-slaughter intervals of 1, 3, and 7 days (T. Morton, 1999). This would result in residue estimates of the same order of magnitude as those for dichlorvos alone and naled-derived dichlorvos. Measurable residues of dichlorvos from the use of trichlorfon are not expected, because it has no crop tolerances or registered crop food uses (Hummel, 1998b), and non-detectable residues are expected on livestock commodities.

6.1.2.1 Acute Dietary Exposure and Risk

A DEEM™ analysis was performed to estimate acute dietary exposure and risk from dichlorvos; and to estimate dietary exposures and risks for chronic systemic toxicity from residues of dichlorvos (Hummel, S. V., D. Hrdy, M. Sahafayen. 2000). Because dichlorvos residues on food may be derived from use of either dichlorvos or naled, the dietary risk analyses included both dichlorvos and naled-derived dichlorvos. Trichlorfon-derived dichlorvos was considered. All domestic field crop uses of trichlorfon have been canceled. The trichlorfon tolerances have been revoked, except for tolerances in livestock commodities, which were retained as import uses. The DEEM™ analyses were done for all commodities supported for reregistration.

A highly refined acute dietary analysis was performed, which combined the acute exposure from dichlorvos residues resulting from the use of dichlorvos, naled-derived dichlorvos (including residues of naled, which could be converted in the body to dichlorvos), but excluding the naled public health mosquito use (Hummel, et. al. 2000). Residues of dichlorvos from the use of

trichlorfon were estimated to be negligible. For assessing risk use of dichlorvos, anticipated residues based on field trials and monitoring data were used. For assessing risk from naled-derived dichlorvos, anticipated residues based on some tolerances, some field trials, and monitoring data were used. The acute probabilistic dietary analyses used individual food consumption as reported by respondents in the USDA 1989-91 Continuing Survey of Food Intake by Individuals (CSFII) in the DEEM™ software. Results are reported as a percentage of the aPAD for the 99.9th percentile of the population. The % aPAD is calculated as the ratio of the exposure to the aPAD (% aPAD = exposure/aPAD x 100%).

Highly refined anticipated residues which incorporated percent of crop treated (% CT), monitoring data from the PDP, the FDA Surveillance Monitoring Program, the FDA TDS, field trial data, and a few tolerances were used to estimate acute dietary exposure. The acute exposure/risk estimate did not exceed HED's level of concern for either the general US population or any of the sub-populations. The sub-population with the highest exposure was children 1-6 with estimated exposure of 4% of the aPAD (0.000021 mg dichlorvos/kg bwt/day), while the estimated exposure for the U. S. Population was 2% of the aPAD (0.000009 mg dichlorvos/kg bwt/day) at the 99.9th percentile. The results are provided in Table 6.2.1.1.

Table 6.1.2.1. Acute Dietary (Food Only) Tier 3 Exposure and Risk Estimates for Dichlorvos.

Population Subgroup[a]	aPAD, mg/kg	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure, mg/kg	% aPAD[b]	Exposure, mg/kg	% aPAD[b]	Exposure, mg/kg	% aPAD[b]
U.S. pop - all seasons:	0.008	0.000018	0.23	0.000044	0.6	0.000145	1.8
All infants (<1 year):		0.000022	0.28	0.000087	1.0	0.000308	3.8
Children (1-6 years):		0.000034	0.43	0.000076	1.0	0.000334	4.2
Children (7-12 years):		0.000022	0.28	0.000050	0.6	0.000167	2.1
Females (13-50 years):		0.000013	0.16	0.000032	0.4	0.000085	1.1

[a] Population subgroups shown include the U.S. general population, and those of infants, children, and women of child-bearing age.
[b] % aPAD = Exposure (mg/kg) ÷ aPAD (mg/kg) × 100

6.2.1.2. Chronic Dietary Exposure

A refined DEEM™ chronic exposure analysis was conducted using percent crop treated data and anticipated residues to calculate the chronic dietary exposure estimate for the general population and all subgroups (Hummel, et. al. 2000). Anticipated residues were based on monitoring data from the FDA TDS, the FDA Surveillance Monitoring Program, and from the PDP. Therefore, the Agency has high confidence in the residue data used to estimate chronic dietary exposure.

As mentioned above, OPP has refined its estimates of dietary exposure for various commodities based on percent of crop treated. OPP has refined its estimates of dietary exposure for various commodities using processing factors to account for changes in residue levels during commercial or other processing and during cooking.

Highly refined anticipated residues (which also incorporated % CT information, monitoring data from the PDP and the FDA Surveillance Monitoring Program, and field trial data) were used to estimate chronic dietary exposure. The chronic exposure/risk estimate did not exceed HED's level of concern for either the general US population or any of the sub-populations. The resulting risk estimate for all sub-populations and the general US population was below 100% of the cPAD. The sub-population with the highest exposure was children 1-6 with 1% of the chronic population adjusted dose (cPAD) (0.0000013 mg dichlorvos/kg bwt/day), while the estimated risk to the U.S. Population was <1% of the cPAD (0.0000007 mg residue/kg bwt/day). The results are provided below in Table 6.2.1.2.

Table 6.2.1.2. Chronic Dietary (Food Only) Tier 3 Exposure and Risk Estimates for Dichlorvos.

Population Subgroup[1]	cPAD, mg/kg/day[2]	Exposure, mg/kg/day	% cPAD
U.S. Population (total)	0.0005	0.0000007	<1
All infants (< 1 year)		0.0000013	1
Children 1-6 yrs		0.0000013	1
Children 7-12 yrs		0.0000007	<1
Females 13-50 yrs		0.0000003	<1

[1] Population subgroups shown include the U.S. general population, and those of infants, children, and women of child-bearing age, and other, representative populations whose exposure exceeds that of the U.S. general population.

[2] % cPAD = Exposure (mg/kg) ÷ cPAD (mg/kg) × 100

6.2.1.3. Dietary Cancer Risk Estimates

No dietary cancer risks for dichlorvos were estimated. The carcinogenic potential of dichlorvos has been classified as "suggestive" under the 1999 Draft Agency Cancer Guidelines and no quantitative assessment of cancer risk is required. (Diwan, S. 2000).

6.2.2. Uncertainties in Dietary Exposure Assessment

The Agency believes the exposure and risk assessment presented in this document is the most refined to date for acute and chronic dietary exposure to dichlorvos as a result of use of dichlorvos, naled, and trichlorfon. However, there are some uncertainties associated with this exposure assessment as follows:

(a). The dietary exposure analyses relied primarily on monitoring data obtained either "at the farm gate," in the case of FDA surveillance monitoring data, or in regional distribution warehouses for PDP data. Residues potentially present on items purchased at roadside produce stands or farmer's markets are not represented in this analysis. Although cooking data were available and were used, there may be differences in the amount of reduction of dichlorvos residues as a result of cooking.

(b). Samples collected for the FDA Total Diet Study were collected in supermarkets in only four cities per year. Residues found in food in other locations may be different.

(c). Very little monitoring data are available for fumigated commodities. Extensive translation was done from one fumigated commodity to another.

(d). For the commodities for which field trial data were used, the residues of dichlorvos are probably over-estimated. Dichlorvos is expected to dissipate fairly rapidly.

6.2 Water Exposure/Risk Pathway

Dichlorvos residues can be present in ground and/or surface water as a result of use of three pesticides: dichlorvos (DDVP), naled, and trichlorfon (dichlorvos is a degradate of naled and trichlorfon). The Environmental Fate and Effects Division (EFED) discussed the environmental fate of dichlorvos, naled and trichlorfon and evaluated the potential for dichlorvos to contaminate water from these sources (Abdel-Saheb I., 2003, Jones, R. D., 2006). The environmental fate properties of dichlorvos, naled, and trichlorfon are indicators of the potentials of these compounds to migrate to ground or surface water. These fate properties are described below.

6.2.1 Fate Properties of Dichlorvos, Naled, and Trichlorfon

6.2.1.1. Dichlorvos

The major mode of dissipation of dichlorvos is volatilization from soils because dichlorvos has a vapor pressure of 1.2×10^{-2} mm Hg under field conditions. Also, acceptable laboratory studies indicate rapid dissipation through volatilization. Dichlorvos appears to degrade through aerobic soil metabolism and abiotic hydrolysis as well, but these processes are secondary to volatilization. Hydrolysis is pH dependent where the half-lives were 11 days at pH 5, 5 days at pH 7 and 21 hours at pH 9. Aerobic soil metabolism data showed a half-life of 10 hours; 2,2-dichloroacetic acid was the major metabolite. An acceptable soil TLC study indicates that dichlorvos is moderately mobile (K_d's ranging 0.3 to 1.2), based on the Heiling and Turner's mobility classification. The potential of dichlorvos to leach to ground water is mitigated by its rapid degradation. Dichlorvos has the potential to contaminate surface waters because of a low K_{oc} value and high water solubility (10×10^3 ppm, or 1 %). Substantial fractions of run-off will more than likely occur via dissolution in run-off water rather than adsorption to eroding soil. Despite the potential for contamination, dichlorvos should not be persistent in any surface waters due to its susceptibility to rapid hydrolysis and volatilization.

6.2.1.2. Naled

Chemical hydrolysis and biodegradation are the major processes involved in the transformation of naled and its degradates in the environment. Dichlorvos forms from naled by indirect photolysis in water and soil. In the presence of photosensitizer in water, as much as 20% of the applied dose of naled can be found as dichlorvos after 1 day, with rapid decline of dichlorvos residues afterwards. Under anaerobic aquatic conditions, dichlorvos can be as high as 15% of the applied naled dose after 1 day. The degradation of dichlorvos formed from naled under anaerobic conditions is slower (half-life 0.9 days) than under aerobic conditions.

6.2.1.3. Trichlorfon

Dichlorvos is formed from trichlorfon in soil by aerobic soil metabolism, and in water hydrolysis studies. Environmental fate data indicate that trichlorfon degrades rapidly in aerobic soil ($t_{1/2}$ ~ 1.8 days) under non-sterile conditions; however, in a sterile soil, trichlorfon was stable ($t_{1/2}$ > 40 days). Trichlorfon degradation is strongly influenced pH. In the hydrolysis study at 25° C, the trichlorfon degradation half-life was 104 days at pH 5; 34 hours at pH 7; and 31 minutes at pH 9. The maximum measured dichlorvos formed from trichlorfon also varied with pH, with a maximum percentage converted of 2.1% at pH 5; 25% at pH 7; and 52% at pH 9. The formation of dichlorvos from trichlorfon is not a 'hydrolysis reaction' per se, but a dehydrochlorination. The other degradates found in the hydrolysis study are des-methyldichlorvos, and dichloroacetaldehyde, resulting from hydrolysis of dichlorvos directly. There is no acceptable field dissipation study for trichlorfon, because the submitted studies had recovery problems.

6.2.2. Groundwater

EFED has limited monitoring data on the concentrations of dichlorvos, naled or trichlorfon in groundwater. Validated monitoring data for dichlorvos, naled, and trichlorfon are available for the states of California and Hawaii from the Pesticides in Groundwater Database (USEPA 1992). These data indicated that naled, dichlorvos, or trichlorfon have not been detected in groundwater. However, the monitoring studies were not targeted to the pesticide use area. These data are presented in Table 6.2.2a. below.

Table 6.2.2a. Groundwater monitoring data for Dichlorvos, Naled, and Trichlorfon showing number of wells sampled (number of wells with residues) (USEPA 1992)

	Naled	Dichlorvos	Trichlorfon
California	83 (0)	20(0)	280 (0)
Hawaii	3 (0)	7 (0)	

Because the groundwater monitoring data for dichlorvos are limited, EFED used the Tier I **SCI-GROW** screening model to estimate concentrations of dichlorvos in groundwater. This model predicts that dichlorvos, naled, and trichlorfon will not be found in significant concentrations in groundwater. Concentrations of these compounds were calculated based on a maximum annual application rate of 0.2 lb a.i./acre for dichlorvos (wide area treatment), 9.375 lb a.i/acre for naled (the maximum seasonal use rate on Cole crops, 5 applications of 1.87 lb a.i./acre), and 3 times per year at 8.17 lb a.i./acre for trichlorfon (turf). The amount of dichlorvos formed as a degradate of naled was estimated to be 20% of naled. Therefore, a conservative dichlorvos use rate was estimated by using naled's use rate multiplied by 0.20. The amount of dichlorvos formed as a degradate of trichlorfon was estimated to be 56% of trichlorfon, which is the maximum percent of dichlorvos (56%) formed as a trichlorfon degradate determined from the trichlorfon aerobic aquatic metabolism at pH 8.5. The amount of dichlorvos formed as a trichlorfon degradate was estimated by multiplying the maximum application rate for trichlorfon (8.17 lb a.i/acre) by 56%. Because

groundwater concentrations of dichlorvos were estimated using a Tier I screening model, EFED has moderate confidence in the groundwater assessment.

Table 6.2.2b. Estimated Dichlorvos Concentrations in Groundwater.

Source of Dichlorvos Residues	Modeled Groundwater Concentration, µg/L
Dichlorvos Applied 1/week	0.004
Dichlorvos Applied Every Other Day	0.015
Dichlorvos (from Naled)	0.0002
Dichlorvos (from Trichlorfon)	0.01

There may be exceptional circumstances under which groundwater concentrations could exceed the SCI-GROW estimates. However, such exceptions should be quite rare since the SCI-GROW model is based exclusively on maximum groundwater concentrations from studies conducted at sites and under conditions which are most likely to result in groundwater contamination. The groundwater concentrations generated by SCI-GROW are based on the largest 90-day average recorded during the sampling period. Since there is relatively little temporal variation in groundwater concentrations compared to surface water, the concentrations can be considered as appropriate for acute and chronic risk assessment.

6.2.3. Surface Water

Dichlorvos may reach surface water as a result of use of three pesticides: dichlorvos (DDVP), naled and trichlorfon. In the event that all of these pesticides are used in the same use area, then the contribution for each chemical should be incorporated in any risk assessment.

OPP does not have any surface water monitoring data on the concentrations of dichlorvos, naled, or trichlorfon at the present time. Therefore, the Tier II PRZM/EXAMS model was used for dichlorvos, naled and trichlorfon. The turf scenario with the Index Reservoir and Percent Crop Area adjustment (IR-PCA PRZM/EXAMS) was used to estimate surface water concentrations for trichlorfon.

The results from the index reservoir represent potential drinking water exposure from a specific area (Illinois) with specific cropping patterns, weather, soils, and other factors. Use of the index reservoir for areas with different climates, crops, pesticides used, sources of water (e.g. rivers instead of reservoirs, etc), and hydrogeology creates uncertainties. In general, because the index reservoir represents a fairly vulnerable watershed, the exposure estimated with the index reservoir will likely be higher than the actual exposure for most drinking water sources. However, the index reservoir is not a worst case scenario; communities that derive their drinking water from smaller bodies of water with minimal outflow, or with more runoff prone soils would likely get higher

drinking water exposure than estimated using the index reservoir. Areas with a more humid climate that use a similar reservoir and cropping patterns may also get more pesticides in their drinking water than predicted using this scenario.

A single steady flow has been used to represent the flow through the reservoir. Discharge from the reservoir also removes chemical so this assumption will underestimate removal from the reservoir during wet periods and overestimates removal during dry periods. This assumption can underestimate or overestimate the concentration in the pond depending upon the annual precipitation pattern at the site.

The index reservoir scenario uses the characteristics of a single soil to represent the soil in the basin. In fact, soils can vary substantially across even small areas, and this variation is not reflected in these simulations.

The index reservoir scenario does not consider tile drainage. Areas that are prone to substantial runoff are often tile drained. Tile drainage contributes additional water and in some cases, additional pesticide loading to the reservoir. This may cause either an increase or decrease in the pesticide concentration in the reservoir. Tile drainage also causes the surface soil to dry out faster. This will reduce runoff of the pesticide into the reservoir. The watershed used as the model for the index reservoir (Shipman City Lake) does not have tile drainage in the cropped areas.

Turf was used as the site of interest for trichlorfon. General outdoor uses were used as the site of interest for dichlorvos. Eight crops were simulated for naled. The modeling results indicate that all these compounds have the potential to contaminate surface waters by runoff, for short periods of time especially in areas with large amounts of annual rainfall. However, based on its environmental fate characteristics, naled will degrade/dissipate rapidly ($t_{1/2}$ < 1 day), trichlorfon and dichlorvos will persist slightly longer ($t_{1/2}$ 1.4 and ~ 5 days, respectively). Mitigation practices that reduce runoff could be effective in reduction of these chemicals transport into surface waters.

Table 6.2.3a. Estimated Drinking Water Concentrations in Surface Water for Dichlorvos, Dichlorvos from Naled, and Dichlorvos from Trichlorfon use on Turf using Tier II PRZM/EXAMS.

	model EDWCs (µg/L)		
	Dichlorvos[1]	from Naled[2]	from Trichlorfon[3]*
Surface water/ peak (90th percentile annual daily max. for acute exposure analysis)	3.46	33.0	60
Surface water/ 90th percentile annual mean for chronic exposure analysis	0.17	1.83	1.56
use(s) modeled	4 applications @ 0.20 lb ai/acre, spray appl.	5 applications @ 1.87 lb ai/acre, spray appl.	3 applications @ 8.2 lb ai/acre, spray appl.
PCA	0.87		

[1] Dichlorvos from wide area treatment
[2] Naled from treatment of brassica crops
[3] Trichlorfon turf treatment
* Dichlorvos from trichlorfon is adjusted for a 25% conversion at pH 7, a pH typical of soils growing turf.

The maximum amount of dichlorvos formed from naled is approximately 20% of the applied naled. Therefore, a conservative dichlorvos use rate was selected as naled's use rate multiplied by 0.20.

The application rate used on turf for trichlorfon based on 25 percent conversion to dichlorvos adjusted for differences in MW. A maximum of 25% degradation of trichlorfon to dichlorvos was assumed because 25% degradation was the maximum observed in a hydrolysis study at pH 7, a pH typical of soils used to grow turf.

Table 6.2.3b shows the input parameters used in PRZM/EXAMS.

Table 6.2.3b. Input parameters for Dichlorvos, Dichlorvos from Naled, and Dichlorvos from Trichlorfon used in PRZM/EXAMS models.

Chemical	Dichlorvos Information		
	From Naled	From Trichlorfon	Dichlorvos
PC Code for parent chemical	34401	57901	84001
Molecular weight (g/mole)	220.9	220.9	220.9
Solubility (ppm)	10000	10000	10000
Hydrolysis half-life, pH 7 (days)	5.2	5.2	5.2
Soil Photolysis half-life (days)	0.65	0.65	0.65
Aerobic Soil Metabolism half-life (days)	0.42	0.42	0.42
Aerobic Aquatic Metabolism half-life (days)	no data	no data	no data
Soil Organic Carbon Partitioning (K_{oc})(l/kg)	37	37	37
Use	Brassica	Turf	Wide Area Treatment
Application Rate (lb a.i. /acr/yr)	1.87	8.2	0.20
Number Of Applications/year	5	3	4
Interval between appl. (day)	30	7	30
Application Method	Spray	Spray	Spray

6.2.4. Drinking Water Risk Estimates

The Pesticide Data Program (PDP) in USDA-Agricultural Marketing Service has sampled finished drinking water collected after disinfection, and just before distribution to customers, from community water systems in a few states from 2001 through 2004, and raw and finished drinking water from community water systems in a few states in 2004. In 2001, PDP analyzed 214 finished drinking water samples from CA and NY. In 2002 and 2003, PDP sampled 371 and 699 finished drinking water samples, respectively, in CA, CO, KS, NY, and TX. In 2004, PDP sampled raw and finished water from 171 community water systems from MI, NC, OH, OR, PA, and WA. Dichlorvos was one of the analytes. No detectable residues of dichlorvos were found at limits of detection (LOD) of 0.4 - 22.5 pptrillion. Naled and trichlorfon were not among the analytes tested, but PDP would have detected dichlorvos coming from naled and trichlorfon.

The PDP monitoring of water from community water systems does not reflect the drinking water consumed by the population for the following reasons:

- The PDP samples large community water systems in a limited number of states. The sampling sites are not necessarily in dichlorvos, naled, and trichlorfon use areas, and the data may not be reflective of drinking water concentrations in areas of high dichlorvos use.
- The community water systems sampled by PDP are generally deep ground water or surface water systems. The PDP does not sample individual, private wells. Use of the PDP data would not be protective of people whose drinking water source is a private well.

The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for dichlorvos. Therefore, the Agency is presently relying on computer-generated estimated environmental concentrations (EDWCs). The Tier II PRZM/EXAMS model turf scenario with the Index Reservoir and Percent Crop Area adjustment (IR-PCA PRZM/EXAMS) was used to generate EDWCs for surface water and SCI-GROW (an empirical model based upon actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EDWCs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for determining that pesticides residues (and metabolites) in water are not of concern.

For any given pesticide, the SCI-GROW model generates a single EDWC for pesticide concentration in ground water. That EDWC is used in assessments of both acute and chronic dietary risk. It is not unusual for the ground water EDWC to be significantly lower than the surface water EDWCs. The tier II PRZM/EXAMS model provides long duration (up to 36-year) pesticide concentrations in surface water and is mainly used when a refined EDWC is needed.

6.3 Residential (Non-Occupational) Exposure/Risk Pathway

Dichlorvos is registered for several residential uses. Residential handlers may be exposed to dichlorvos during application of dichlorvos in pressurized aerosol spray cans. Residential post application exposure may occur after use of the following products containing dichlorvos: pressurized aerosol spray can, resin pest strips, and pet flea collars. Residential post application exposure to dichlorvos may also occur after lawn treatment with trichlorfon. Residential Exposure and Risk Estimates are summarized in Table 6.3 below. Information sources and major assumptions for each residential scenario are described below, with additional information in the table endnotes. Additional information is available in the referenced documents (Jaquith D., 1993b, Jaquith D 1998a through n, Jaquith D. 1999 through d, Jaquith, D, 2000, and Jaquith, D., 2001 and 2003). Dichlorvos exposure from the use of Naled is covered by the Naled Risk Assessment. Dichlorvos exposure from the use of trichlorfon is included in this document. Although residential bystander exposure could result from the use of naled, both on field crops and as a mosquitocide, any exposure to dichlorvos from the use of naled would be covered by the Naled Risk Assessment.

Residential Scenarios which were evaluated were of acute, short term, or long term duration. A $BMDL_{10}$ of 0.8 mg/kg/day from a rat acute oral cholinesterase study is used for the acute oral, dermal, and inhalation risk assessment. An 11% dermal absorption is assumed for the dermal risk assessment. The target MOE for residential acute risk assessments is 100.

A LOAEL of 0.1 mg/kg/day from a human 21-day oral study is used for short term incidental oral, dermal, and inhalation (during application) risk assessment. An 11% dermal absorption is assumed for the dermal risk assessment. The target MOE for residential short term risk assessments is 30.

A $BMDL_{10}$ of 0.07 mg/m^3 from a 2 year rat inhalation study is used for the long term, post-application inhalation risk assessment. The target MOE for residential long term inhalation risk assessment is 30.

6.3.1 Home Uses

6.3.1.1. Residential Handler

(a). Pressurized Aerosol Spray Can

The exposure assessment for pressurized spray cans was derived from data in the Pesticide Handlers Exposure Database (PHED V1.1) and the Residential SOPs for aerosol application. Residential use of pressurized aerosol product is based on application of 2 ounces from an aerosol can of 0.5 percent dichlorvos (Jaquith 2001; Jaquith 1998f; REJV, 2002). This is an acute exposure scenario.

Pressurized aerosol products containing dichlorvos do not list any clothing requirements; therefore the Agency is assuming that dichlorvos is applied during hot weather when an individual will be wearing the least amount of clothing (i.e., shorts, short sleeve shirt, and shoes). Using the Residential SOPs, unit dermal exposures were 220 mg/lb ai handled, and 1.3 mg / lb ai handled for

inhalation exposure (adjusted for the NAFTA breathing rate of 1.0 m^3/hr, with an absorbed dermal dose of 0.00022 mg/kg/day. Respiratory exposure was estimated to be 1.2 x 10^{-5} mg/kg/day. The total exposure was 2.3 x 10^{-4} mg/kg/day, with an MOE of 3500 (target MOE = 100), which is not of concern.

6.3.1.2. Residential Post-application

(a). Pressurized Aerosol

Post application data from a total release fogger application were used as a surrogate for the post application exposure from pressurized aerosol applications. The total release fogger treatments in the home have been canceled. However the data are still being used to assess the use of the aerosol spray, after adjustment for application rate.

Indoor residential post-application exposures for short term exposure scenarios were derived from a single study measuring the exposures of individuals performing defined activity patterns (20 minute Jazzercise® routine) following the activation of a total release fogger, containing dichlorvos. This study provides a conservative estimate for short term exposure scenarios from indoor applications of dichlorvos (Jaquith 1993b). The multi-phase study measured deposition on whole body dosimeters and (in a separate phase) the urinary concentrations of the metabolite dimethyl phosphate (DMP), a metabolite of dichlorvos. The biomonitoring gave estimates of exposure of 14 μg/kg.

In order to estimate the potential oral exposure from hand to mouth activity of children, the amount of dichlorvos measured on the hands in the passive dosimetry phase was considered to be available for ingestion. The passive dosimetry dose on the hands had to be added because the Jazzercise® routine does not include hand-to-mouth activity. The estimated exposure due to hand to mouth ingestion, was 0.61 μg/kg (Jaquith 1998k), or a total exposure of 15 μg/kg when the potential oral component was included. This is considered to be a short-term exposure scenario. This study only measured exposures to adults; however, exposure to children is expected to be similar to that of an adult.

For post-application exposure and risk estimates from the use of the pressurized aerosol, it was assumed that there would be 2 oz of product (containing 0.5% ai) used in a 1000 sq. ft. house (from the Residential Exposure Joint Venture (REJV) survey (REJV, 2002)). This amount was compared to the amount that was used for a total release fogger, and the ratio used to adjust the amount of the biomonitoring study that was conducted. The MOE was 100, which is not of concern, compared to the target MOE of 30.

(b). Resin Pest Strips

Several sizes of resin pest strips are marketed. The full size, room size strip is 65 or 80 g, containing 12.1 or 14.9 g of dichlorvos, used to treat 1000 ft ^{3}. The full size strip may no longer be used in spaces occupied more than 4 hours per day. Examples of spaces which may not be occupied more than 4 hours per day were attics, crawl spaces, and garages. Other sizes of resin pest strips are the large closet strip, 16 g, containing 3.0 g dichlorvos; the small closet strip, 10.5 g, containing 1.8 g dichlorvos, and the cupboard strip, 5.25 g, containing 0.97 g dichlorvos.

The dichlorvos label for the smaller size resin strips will have these limitations.

"Only available in the following sizes: 16 g (0.56 oz), 10.5 g (0.37 oz), and 5.25 g (0.9 oz) pest strip sizes"

Household use. "Use only in Closets, Wardrobes, and Cupboards. Do not use in areas of a home where people will be present for an extended period of time (e.g., Living Room, Family Room). Do not use in any rooms or closets of rooms where infants, children and the sick or aged are or will be present for any extended period of confinement. Do not use where unwrapped food is stored, or allow the strip to come into contact with food or cooking utensils. Do not allow children or pets to play or sleep in these areas when treatment is in progress."

Storage Units, Attics, Garages, Sheds, and Enclosed Crawl Spaces. "Do not use in areas of a home where people will be present for an extended period of time. [Keep] out of reach of children and pets, in an open space of an enclosed area, away from windows."

The largest pest strip, 100 g, will no longer be registered. The large 80 g and 65 g pest strips will be separated into a separate registration, where the label will state:

"Only available in 65 g and 80 g pest strip sizes."

"DIRECTIONS FOR USE" "For use in unoccupied areas, not for use in homes except garages, attics, crawl spaces, and sheds occupied for less than 4 hours per day.
"Also for use in the following unoccupied structures, provided they are unoccupied for more than 4 months immediately following placement of a pest strip: vacation homes, cabins, mobile homes, boats, farm houses, and ranch houses."

Respiratory exposures resulting from the use of resin pest strips were estimated using a study found in the scientific literature (Collins and DeVries, 1973). Fifteen homes were monitored at various time intervals for a period of 91 days. Air monitoring was done in one place in each of the homes, in the same room with the full sized resin pest strip (80 or 100 g strips). A decay curve measuring the decline of airborne residues was derived for each of these homes. The resulting equations were integrated over a 91 day period and an average concentration was calculated (Jaquith 1998a, 1999d, and 2000). The average air concentration, over this time period was estimated to be 0.015 mg/m^3. Smaller sized resin strips placed in a closet or cupboard would be

expected to have lower concentrations by direct proportion, assuming that the residue of dichlorvos in the air would equilibrate between the closet or cupboard and the room.

Margins of Exposure were calculated for the resin pest strips using the 90 day average air concentration in the house (0.015 mg/m^3) from a 65 -80 g pest strip containing 12.09 - 14.9 g dichlorvos in a 1000 ft^3 room (Collins, R. D. and DeVries, D. M. 1973), and the $BMDL_{10}$ from a chronic rat inhalation study of 0.07 mg/m^3, based on RBC cholinesterase, and 23 hours of exposure. The margins of exposure will vary, depending on the exposure time and the size of the pest strip, as shown in Table 6.3.1.2. below.

Table 6.3.1.2. Exposures/MOEs for dichlorvos resin strips, based on size of resin strip and time exposed

$BMDL_{10}$: 0.07 mg/m^3 for RBC cholinesterase from 2 year rat inhalation study
Exposure duration: 23 hours per day, 7 days a week
90-day average concentrations of 0.015 mg/m^3
Target MOE = 30

Size of Resin Strip	Full size	Closet	Closet	Cupboard
g product	65	16	10.5	5.25
g dichlorvos	12.09	3.0	1.95	0.975
Hours exposed per day	Margin of Exposure (MOE)			
1	110	470	660	1300
2	54	240	330	660
4	**27**	120	170	330
6	**18**	78	110	220
8	**13**	60	83	170
10	**11**	35	67	130
12	**9**	40	55	110
14	**8**	34	48	95
16	**7**	**30**	42	83
18	**6**	**26**	37	74
20	**5**	**24**	33	67
22	**5**	**21**	**30**	60
24	**4**	**20**	**28**	55

The MOEs in table 6.3.1.2 are calculated as follows.

$$\text{MOE} = \frac{0.07 \text{ mg/m}^3}{0.015 \text{ mg/m}^3} \times \frac{23 \text{ hr/day}}{\text{Hr exposed per day}} \times \frac{65 \text{ g dichlorvos in full size strip}}{\text{g dichlorvos in product}}$$

The dichlorvos label has been changed to allow use of resin strips in areas occupied up to 4 hours per day (garages, attics, …) . Although this use would be allowed by the label, there is no expectation that individuals will actually be exposed at this level routinely.

AMVAC has proposed a study to measure air concentrations from use of the smaller resin strips in closets and cupboards. The study has been required by California, but not EPA. A protocol was submitted by the registrant to EPA and reviewed (Jaquith, 2003a). The Agency's comments were provided to AMVAC. Some suggestions were made to improve the study, including diagrams of the houses, placement of the air monitors, and monitoring of fabric in the closets with a closet sized strip. To date, the study has not been submitted to EPA.

(c). Pet Flea Collars

A flea collar is placed on the pet's neck to protect the pet from fleas over the life of the collar. It is expected that the flea collar will be replaced when it is no longer efficacious, which is assumed to be 120 days.

In this assessment, inhalation exposure was estimated for the flea collars, considering them to be a mobile resin strip, because the formulation is similar to the resin strip formulation. A dog collar, containing 2.2 g dichlorvos, would contain (2.2/12.1) or 18 % of the amount of dichlorvos contained in a full sized resin strip. The air concentration in the room with the pet is estimated to average 0.0027 mg/m^3 for 8 hours per day.

In addition, dermal exposure and children's hand-to-mouth exposure assessments were done, using a draft ExpoSAC policy. The calculations for the assessment are shown in the footnote for table 6.3. The dermal exposure was estimated to contribute 0.0011 mg/kg/day and hand-to-mouth exposure was estimated to be 0.0001 mg/kg/day.

Combining the dermal and hand-to-mouth exposure results in an exposure estimate of 0.0012 mg/kg/day, and an MOE of 83. The inhalation MOE is 74, and the total MOE is 39, which is greater than the target MOE of 30, and not of concern.

(d). Lawns and Turf - Post-Application

Dichlorvos from the use of Naled. Naled is used as a mosquitocide, and may result in residues on home lawns. This use was considered in the Naled Risk Assessment.

Dichlorvos from the use of Trichlorfon. Post application exposure to dichlorvos from the use of trichlorfon has been assessed. (Leighton, T., 2000). This is a short-term exposure scenario. Trichlorfon is applied to home lawns at 8.2 lb ai/acre as a granular formulation, which is watered in with 0.25" water. The assessment for dichlorvos from trichlorfon use utilized an environmental fate model to predict residues of a parent and a metabolite, based on the trichlorfon half-life from a trichlorfon turf transferable residue study (TTR) and the dichlorvos half-lives from a turf transferable residue study for dichlorvos. The turf assessment has been modified to assume 25% degradation of trichlorfon to dichlorvos, based on the 25% maximum conversion in a hydrolysis study of trichlorfon at pH 7, a pH typical of home lawns. Trichlorfon degrades less at lower pH's and up to 50% at pH 8.4 (Jones, R. D., 2006).

Hand-to-mouth residues were estimated using the Residential SOPs. Trichlorfon was applied at 8.1 lb ai/A (registered rate is 8.2 lb ai/a). The initial TTR of trichlorfon was 0.0829

$\mu g/cm^2$. Exposure from hand-to-mouth activity for toddlers was added to arrive at total estimated exposure. The maximum amount of dichlorvos was estimated to occur 11 hours after application. (Leighton, 2000). Toddler dermal plus hand to mouth MOEs ranged from 430 to 710, compared to a target MOE of 30.

Inhalation exposure from this scenario could not be assessed, because air concentrations in the breathing zone of toddlers were not provided in the trichlorfon study. For comparison purposes, inhalation estimates from the equivalent dichlorvos dermal exposure is provided in the table. These inhalation exposure estimates are expected to overestimate inhalation exposure because of differences in the application method between dichlorvos and trichlorfon, and because the maximum dichlorvos formed was predicted to occur 11 hours after application. "Wetting in" the trichlorfon granules is expected to reduce the amount of dichlorvos available for volatilization (Jones, R. D., 2006).

A trichlorfon TTR study with analyses for dichlorvos in the turf and in the toddler breathing zone above the turf (18") is being requested to confirm these exposure estimates. The study must be conducted at an appropriate pH (approx. 7). A field dissipation study may be substituted, provided it meets these requirements.

6.3.2 Recreational Uses

The dichlorvos and trichlorfon turf uses could also be recreational uses. They are addressed above in Section 6.3.1 Home uses. The same exposures would be expected for recreational uses as home lawn uses.

6.3.3 Other (Spray Drift, etc.)

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from ground application methods. However, there are no field crop applications employed for dichlorvos. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. On a chemical by chemical basis, the Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift with specific products with significant risks associated with drift.

Table 6.3. Summary of Residential Exposure and Risk Estimates for Dichlorvos

USES	NOTES	EXPOSURE PATTERN[1]	Current Exposure (mg/kg/day)			Current MOE		MOE
			Dermal	Inhalation	Total	Dermal	Inhalation	Total
RESIDENTIAL EXPOSURE All Target MOEs for all Residential Scenarios are 30, except for acute dermal and handler exposure scenarios, where the target MOE is 100.								
RESIDENTIAL HANDLER	2							
(a) Pressurized aerosol spray can	3	Acute	0.00022	0.000012	0.00023	3600	67000	3500
RESIDENTIAL POST-APPLICATION								
(a) Pressurized aerosol (toddler) **Same rate as fogger** **Adjusted rate**	4	Short-term	Dose is 0.90 µg/kg/day based on urinary dimethyl phosphate + incidental oral of 0.038 µg/kg/day		0.00098			100
(b) Resin pest strips **Full size strip 65 g (4 hr exposure)** **Smaller strips (14 hr exposure)** **Closet strip 16 g** **Small Closet strip 10.5g** **Cupboard strip 5.25g**	5	Long-term, Inhalation	 N/A N/A N/A N/A	 0.015 mg/m^3. 0.0048 mg/m^3. 0.0024 mg/m^3 0.0012 mg/m^3.			 27 34 48 95	 27 34 48 95
(c) Pet flea collars **toddler(includes hand-to-mouth)**	6	Long-term	0.0012	0.000949 mg/m^3		83	74	39
(d) Lawns, Trichlorfon use 8.1 lb ai/A Post-application	7	Although inhalation exposure is not assessed, rough estimates were made by comparison with dichlorvos turf study, which we expect to result in an over-estimate of the exposure & risk.						
Toddler - high end		Short-term (adding incidental oral of 0.0004 mg/kg/day	0.00023	not assessed		430	(100)	
Toddler - low end			0.00014	not assessed		710	(150)	

NOTES: The following notes define the assumptions used in calculating the margins of exposure.

Risk is expressed as a Margin of Exposure (MOE)

$$MOE = \frac{NOAEL}{Exposure}$$, where both the NOAEL and the Exposure are expressed in common units

1. Doses and toxicological endpoints for assessment of short term dermal, incidental oral and inhalation (applicator) residential risks are based on an oral LOAEL of 0.1 mg/kg/day from a human 21-day repeated dose study. A dermal absorption factor of 11% was used in assessing risks from dermal exposure. The applicator is assumed to weigh 70 kg. The target MOE for these scenarios is 30 (10x for intraspecies variability, 3x for use of the LOAEL).

   Doses and toxicological endpoints for assessing risks from long-term inhalation of dichlorvos vapors are based on an inhalation $BMDL_{10}$ of 0.07 mg/m^3 from a 2 year rat inhalation study. The target MOE for this scenario is 30 (10x for intraspecies variability, 3x for interspecies extrapolation).

   Acute Dermal and Inhalation endpoints are based on the 0.8 mg/kg/day $BMDL_{10}$ from a rat acute oral cholinesterase study, with an 11% dermal absorption factor for the dermal exposure. The target MOEs are 100 (10x for interspecies extrapolation, and 10x for intraspecies variability)

2. Residential handler assumptions. An average resident applicator weighs 70 kg and has a respiratory volume of 1.0 m^3/hour (NAFTA value for moderate activity). Assume applicator wears short pants, short sleeves, and no gloves.

3. Pressurized aerosol spray - residential handler. Residential use of pressurized aerosol product is based on application of 2 ounces of 0.5 percent dichlorvos pressurized aerosol (0.00063 lb ai). Pressurized aerosol products containing dichlorvos do not have any clothing requirements; therefore EPA is assuming that dichlorvos is applied during hot weather when an individual will be wearing only shorts, short sleeve shirt, and shoes. From the Residential SOPs unit dermal exposures are 220 mg/lb ai handled, and 1.3 mg / lb ai handled for inhalation exposure (after correction for the NAFTA breathing rate). The risk assessment is based on application by a 70 kg resident applicator. (Jaquith, 2001).

   Dermal exposure = 220 mg/lb ai handled x 0.005 x 2 oz/16 oz/lb x 0.11 (dermal absorption factor) ÷ 70 kg = 0.00022 mg/kg/day
   Inhalation Exposure = 1.3 mg/lb ai x 0.000625 lb ai ÷ 70 kg = 1.2 E-5 mg/kg/day
   Total exposure = 0.00022 + 0.000012 = 0.00023 mg/kg/day
   Total MOE = 0.8/0.00023 = 3500

4. Pressurized Aerosol - Post application. The assessment is based on biomonitoring data (urinary excretion of DMP from exposure to dichlorvos) from the use of the Total Release Fogger and represents the total dose to the individual from all routes. To account for children's hand-to-mouth exposure, an estimate of incidental oral exposure was obtained by assuming that all material on hands (from passive dosimetry data) is available for ingestion. (Jaquith, 1998k) The oral exposure from passive dosimetry is added to the dermal exposure from biomonitoring. (Jaquith, 1993b) Children, performing the same activities as adults were considered to have the same exposure as an adult on a mg per kg basis.

   Total Exposure (µg/kg/day) = Biomonitoring Exposure (µg/kg/day) + Hand-to-mouth Exposure (µg/kg)
   15 µg/kg/day + 0.61 µg/kg = 16 µg/kg
   In the biomonitoring study, an average of 1.7 mg dichlorvos was released into a room of 16.8 m^2

   A lower application rate is used for the pressurized aerosol, compared to the total release fogger. The risk assessment is done by using the results of the biomonitoring study, and the ratio of the application rate expected to be used for the pressurized aerosol to the rate that was used in the biomonitoring study.

   The 2 oz application rate for the pressurized aerosol in a typical 1000 sq ft house is from the REJV data.

   Application rate for aerosol = $\frac{2 \text{ oz} \times 0.5\%}{16 \text{ oz} \times 1000 \text{ ft}^2} = 6.2 \times 10^{-7}$ lb/ sq. ft.

   Application rate in biomonitoring study = $\frac{0.77 \text{ g dichlorvos}}{16.8 \text{ m}^2 \times (3.2 \text{ ft/m})^2 \times 454 \text{ g/lb}} = 9.9 \times 10^{-6}$ lb/sq. ft.

   Ratio of application rates = $\frac{6.2 \times 10^{-7} \text{ lb/ sq. ft}}{9.9 \times 10^{-6} \text{ lb/sq. ft}} = 0.063$

   Total Exposure incl. Hand-to-mouth = 15.6 µg/kg/day x 0.063 = 0.98 µg/kg/day

MOE = $\frac{0.1 \text{ mg/kg/day}}{0.00098 \text{ mg/kg/day}}$ = 100 (Target = 30)

5. Resin Strips MOEs were based on the average air concentration (0.015 mg/m^3) in 15 houses over a 90-day period (Collins and DeVries 1973, in Jaquith 1998h) and the $BMDL_{10}$ of 0.07 mg/m^3 from 2 year rat inhalation study. Exposure estimates are adjusted to 14 hours in the house. Exposure estimates for smaller resin strips assume air concentrations are proportional to the weight of the ai in the strip. The target MOE for inhalation exposure is 100.

   MOE (full sized strips) = 0.07/0.015 x 23 hr exposure/14 hr = 8

   Table 6.3.1.2 shows Exposures and MOEs for different exposure times to different sizes of resin pest strips.

6. Inhalation assessment assumes that a flea collar is like a mobile resin strip, and the resident spends 8 hours per day in the room with the pet. The air concentration is obtained by proportion based on the ratio of ai in the collar to the ai in the full sized resin strip. MOEs for many different times of exposure are found in Table 6.3.1.2.

   A full size resin strip of 65 g (12.09 g ai) results in an air concentration of 0.015 mg/m^3. The point of departure (POD) is 0.07 mg/m^3 from 23 hours of exposure. The inhalation exposure is

   0.015 mg/m^3 x $\frac{2.2 \text{ g dichlorvos}}{12.09 \text{ g ai}}$ x $\frac{8 \text{ hr}}{23 \text{ hr}}$ = 0.000949 mg/m^3

   The MOE is 0.07 mg/m^3 / 0.000949 mg/m^3 = 74

   Dermal exposure is estimated as follows from draft ExpoSAC policy
   The amount of dichlorvos available per dog per day is 2.2 g in the collar, divided by the 120 days that the collar is effective, 2.2 g x 1000 mg/g/120 days = 18.3 mg/dog/day.

   The draft ExpoSAC policy assumes 20% of the residue is transferrable, but a carbaryl study (MRID 45792201) showed 2.6% transferrable.

   $\frac{18.3 \text{ mg/dog/day x .026 transferrable}}{5986 \text{ cm}^2 \text{ surface area on a 30 lb dog}}$ = 0.00008 mg/ cm^2 transferrable residue

   A child is assumed to hug a dog and contact 1875 cm^2 of the dog's fur. The dermal absorption is 11%. A toddler is assumed to weigh 15 kg.

   $\frac{0.00008 \text{ mg/ cm}^2 \text{ transferrable residue x 1875 cm}^2 \text{ x .11 dermal absorption factor}}{15 \text{ kg child}}$ = 0.0011 mg/kg/day

   For the hand-to-mouth component, 1 event per hour is assumed. The surface area of a child's hand which goes into the mouth is 20 cm^2 . The child is assumed to play with the dog for 2 hours per day. The saliva extraction factor is 50%.

   $\frac{0.00008 \text{ mg/ cm}^2}{15 \text{ kg child}}$ x $\frac{1 \text{ event/hr x 20 cm}^2 \text{ x 0.5 x 2 hr/day}}{}$ = 0.0001 mg/kg/day

   Combining the dermal and hand-to-mouth exposure results in an exposure estimate of 0.0012 mg/kg/day, and an MOE of 83

7. The calculations for incidental oral and dermal exposure to children playing on turf have been updated to be consistent with the revised Residential SOPs. Activities on the lawn are assumed to start 1 hour or more after spraying, and last 2 hours per day.

   The assessment for dichlorvos from trichlorfon use relied on the dichlorvos half-lives from the same TTR study for dichlorvos, trichlorfon total transferable residues (TTR) residues from a trichlorfon DFR study, and the Residential SOPs. TTRs of dichlorvos were estimated using the calculated half-lives of trichlorfon and dichlorvos (0.53 hours- 3.7 hours). The calculations were done using a spreadsheet-based model developed by EFED to estimate the decay rate of a chemical and its degradate applied to short grass for single or multiple applications. The initial trichlorfon concentration was derived from a Trichlorfon TTR study. A first order decay assumption is used to determine the concentration at each day after initial application based on the concentration resulting from the initial and additional applications. Exposure from hand-to-mouth activity for toddlers was added to arrive at total estimated exposure. (Leighton, 2000). The formulas are presented below. (a) is the exponential form, and (b) is the log transformed versions.

(a) $C_{pT} = C_{pi}e^{-k1T}$

(b) $\ln (C_{pT}/C_{pi}) = k_1T$

For the degradate C_d, $= (k_1C_{pi})e^{-k1T} - e^{-k2T})/(k_2k_1)$
Where:
C_{pT} = parent concentration at time T = day T.
C_{pi} = parent concentration at time T = day zero (0.0138 bcg/cn from trichiorton HR study; MRID 45067201).
k_1 = parent degradation rate constant determined from the trichlorfon TTR study using half life data of 0.93 and 2.5 days (MRID 45067201).
k_2 = DDVP degradation rate constant determined from the DDVP TTR studies using a half life of 0.156 days (MRIDs 44591901, 44610501, and 44794901).

The high end exposure (daily dermal dose) for dichlorvos from trichlorfon, adjusting for 25% conversion to dichlorvos was 0.00019 mg/kg/day. Hand-to-mouth exposure was 0.00004 mg/kg/day, totaling 0.00023 mg/kg/day.

This results in an MOE of $\frac{BMDL_{10}}{\text{Exposure}} = \frac{0.8 \text{ mg/kg/day}}{0.00023 \text{ mg/kg/day}} = 3500$

The inhalation MOEs presented in the table are based on the ratio of the dermal exposure to dichlorvos after treatment of dichlorvos to the dermal exposure to dichlorvos after treatment with trichlorfon. These estimates are expected to overestimate the exposure and risk.

7.0 Aggregate Risk Assessments and Risk Characterization

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require that for establishing a pesticide tolerance "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from all sources. Typically these are dietary (i.e., food, and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate assessment, estimated exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL, LOAEL, BMDL, or PAD), or the risks themselves can be aggregated. When aggregating estimated exposures and risks from various sources, HED considers both the route and duration of exposure. Aggregate risk assessments are typically conducted for acute (1 day), short-term (1-30 days), intermediate-term (30 days to 6 months), and chronic (6 months to lifetime) exposure.

Dichlorvos residues may be present in water and/or food as a result of use of three pesticides: dichlorvos (DDVP), naled, and trichlorfon. Dichlorvos is a degradate of naled and trichlorfon. The Environmental Fate and Effects Division (EFED) evaluated the potential for dichlorvos to contaminate water from these sources. The environmental fate properties of dichlorvos, naled, and trichlorfon are an indicator of the potential of these compounds to migrate to ground or surface water. EFED has limited monitoring data on the concentrations of dichlorvos, naled, or trichlorfon in groundwater. Validated monitoring data for dichlorvos, naled, and trichlorfon are available for the states of California and Hawaii from the Pesticides in Groundwater Database, and from a few other states in the PDP. These data indicated that neither naled, dichlorvos, nor trichlorfon, have been detected in groundwater nor drinking water; however, these data were not targeted to the pesticide use area. OPP does not have sufficient ground or surface water monitoring data on the concentrations of dichlorvos, naled, or trichlorfon at the present time. Therefore, the Tier I screening model SCI-GROW was used to estimate ground water concentrations for naled, trichlorfon and dichlorvos. The Tier II PRZM/EXAMS model was used to estimate drinking water concentrations from surface water.

A probabilistic acute dietary exposure assessment was conducted without the water contribution. The chronic dietary exposure assessment was also conducted without the water contribution. Sufficient water modeling data were available to use for probabilistic assessment if needed.

For residential exposure and risk assessment, deterministic exposure assessments were done. Exposure estimates for a number of occupational and residential scenarios were derived from limited data from the scientific literature, textbooks, and knowledge of cultural practices. Other estimates, particularly in the residential environment, were derived from chemical specific monitoring data, including biomonitoring, in combination with models and literature studies.

The route of exposure which results in the greatest exposure to residents depends on the use pattern. For resident applicators and reentry after use of an aerosol spray, the dermal route of

exposure results in the highest estimated risk. For the pest strip and reentry onto lawns, the inhalation risk is estimated to be the highest. In general, the residential risks are estimated to be much higher than food and water combined.

Drinking Water Levels of Comparison (DWLOCs). For dichlorvos (and most pesticide active ingredients), water monitoring data are considered inadequate to determine surface and ground water drinking water exposure estimates, so model estimates have been used to estimate residues in drinking water (Estimated Drinking Water Concentrations, or EDWCs, see Table 6.2.3a and 6.2.3b). In order to determine if aggregate risks are of concern, HED then calculates drinking water levels of comparison, or DWLOCs. The DWLOC is the maximum amount of a pesticide in drinking water that would be acceptable in light of combined exposure from food and residential pathways. The calculated DWLOCs are then compared to the EDWCs provided by EFED; if model-derived EDWCs exceed the DWLOCs for surface or ground water, there may be a concern for exposure to residues in drinking water.

HED has calculated drinking water levels of comparison (DWLOCs) associated with acute and chronic exposure to dichlorvos in drinking water. These DWLOCs are compared with the estimated drinking water concentrations (EDWCs) of dichlorvos in water.

7.1 Acute Aggregate Risk

The acute aggregate risk estimate to dichlorvos includes exposures from food and drinking water. Although there are several acute residential exposure scenarios, these will be included in the short term aggregate risk assessment because it is highly unlikely that high exposure from food, water, and residential use will co-occur. For the highly refined acute probabilistic dietary exposure analysis, PDP and FDA monitoring data and FDA TDS data were used to the greatest extent possible, along with field trial data, cooking and processing factors, and degradation studies to assess dietary exposures.

The acute DWLOC for dichlorvos includes aggregate exposure from food and water only. The $DWLOC_{acute}$ was calculated for the general population, All Infants, Children (1-6 years) who are the most highly exposed population subgroup, and for females (13-50 years). Acute water exposures and DWLOC calculations are summarized in Table 7.2.4.1. below.

$$DWLOC_{acute}\ (\mu g/L) = \frac{\text{acute drinking water exposure (mg/kg/day) x body weight (kg)}}{\text{Water consumption (L/day) x } (10^{-3}\ mg/\mu g)}$$

where body weight is 70 kg for adults, 60 kg for females (13-50) and 15 kg for children and water consumption is 2 L per day for adults and 1 L per day for children.
acute water exposure = aPAD - acute food exposure
where aPAD is 0.008 mg/kg/day.

Table 7.1. Summary of $DWLOC_{acute}$ Calculations for Dichlorvos.				

DEEM Population Subgroup	Acute Dietary Exposure to Dichlorvos at 99.9th %tile, mg/kg/day	Acute aPAD, mg/kg/day	Allowable Water Exposure, mg/kg/day DWLOC$_{acute}$, µg/L	Maximum EDWC$_{acute}$ µg/L
US Population	0.00014	0.008	280	60
All Infants	0.00031	0.008	120	60
Children (1-6)	0.00033	0.008	120	60
Females (13-50)	0.000085	0.008	240	60

For acute drinking water exposure, the modeled groundwater concentrations of 0.0002 to 0.015 µg/L for dichlorvos resulting from the use of dichlorvos, naled, and trichlorfon are not of risk concern, when compared to the DWLOC$_{ACUTE}$, shown above in Table 7.1. There is no risk concern from the estimated drinking water concentration of dichlorvos in surface water, resulting from the use of dichlorvos, of 3.46 µg/L, from naled, of 33.0 µg/L, nor from trichlorfon, of 60 µg/L.

7.2 Short-Term Aggregate Risk

The short-term aggregate risk estimate includes chronic dietary (food and water) from dichlorvos uses, and acute and short-term non-occupational exposures (i.e., residential/recreational uses).

There are two short-term residential exposure scenarios which could be aggregated with food and water: the application of the aerosol spray and the resulting post-application exposure , and post-application exposure to dichlorvos from turf treatment with trichlorfon. Since the exposures from the aerosol spray and the exposures from treated lawns are so short-lived (a week or less), it is extremely unlikely that an individual would be exposed concurrently. Accordingly, two separate aggregate scenarios are presented. It should be noted that the contribution of food and water to the short-term aggregate risk is considered to be negligible occupying less than one percent of the risk cup. Consequently, the short-term aggregate risk is mainly a result of the residential exposures presented in each of the scenarios.

The first scenario includes the residential use of the aerosol spray can. Exposure from the application of the aerosol spray is considered to be negligible (i.e., an MOE of 3500 was calculated vs. a target MOE of 100) with the majority of the exposure occurring post- application. The MOE calculated from post-application exposures was 100 vs. the target MOE of 30. When these residential exposures are combined (aggregated) with the exposures from food and water and compared to the short-term endpoint, our risk level of concern is not exceeded.

Table 7.2. Short-Term Aggregate Risk and DWLOC Calculations									
Population	***Short*-Term Scenario (post application from spraying with an aerosol can) Target MOE = 30 Short-term LOAEL = 0.1 mg/kg/day**								
	Target Aggregate MOE	**MOE Food[1]**	**MOE residen-tial[2]**	**Aggregate MOE (food and residential)[3]**	**MOE Water[4]**	**Allowable water exposure[5] (mg/kg/day)**	**Ground Water EDWC[6] (ppb)**	**Surface Water EDWC[6] (*ppb*)**	**DWLOC[7] (µg/L)**
Adult Female	30	330000	100	100	43	0.0023	0.01	1.83	69
Child	30	77000	100	100	43	0.0023	0.01	1.83	34

[1] MOE food = [(short or intermediate-term oral NOAEL)/(chronic dietary exposure)] = 0.1mg/kg/day/0.0000003 mg/kg/day for adult females = 330000
= 0.1 mg/kg/day/0.0000013 mg/kg/day = 77000
[2] MOE residential = [(short or intermediate-term oral NOAEL)/(residential exposure)]
[3] Aggregate MOE (food and residential) = 1÷[[(1÷MOE food) + (1÷MOE oral) + (1÷MOE dermal) + (1÷MOE inhalation)]]
[4] Water MOE = 1÷ [[(1÷ Target Aggregate MOE) - (1÷Aggregate MOE (food and residential)]]
[5] Allowable water exposure = Short or Intermediate Term Oral NOAEL ÷ MOE water
[6] The crop producing the highest level was used.
[7] DWLOC(µg/L) = [allowable water exposure (mg/kg/day) x body weight (kg)]
[water consumption (L) x 10-3 mg/µg]
Where body weight = 15 kg for a child, and 60 kg for a woman.

The other scenario involves the post-application exposure to dichlorvos from the use of trichlorfon on turf. As discussed previously, data from trichlorfon are not available to calculate exposures resulting from this use and the Agency has used available data and modeling from dichlorvos to estimate these exposures. The MOEs calculated did not exceed our level of concern (i.e., were greater than our target MOE of 30) and the Agency expects that, given the negligible contribution from food and water, short-term aggregate risks do not exceed our level of concern. Data for the use of trichlorfon on turf will be required to confirm these conclusions.

7.3 Intermediate-Term Aggregate Risk

The intermediate-term aggregate risk estimate includes chronic dietary (food and water) from dichlorvos uses, and intermediate-term non-occupational exposures (i.e., residential/ recreational uses). There are no residential/recreational uses with an intermediate-term exposure scenario. Therefore, intermediate-term aggregate risks were not evaluated.

7.4 Long-Term Aggregate Risk

The long-term aggregate risk estimate for dichlorvos combines chronic exposures from food, drinking water, and long-term residential exposures. There are two long-term residential scenarios: resin strips and pet (flea) collars. While it is possible that an individual could be exposed concurrently to dichlorvos from the use of resin strips, have a pet that wears a dichlorvos collar and consume food and drink water with dichlorvos residues, the probability of these simultaneous exposures is fairly low, especially considering the market share of these residential uses. Consequently, two separate scenarios are discussed for long-term aggregate risk.

The contribution of dichlorvos in food occupies less than one percent of the risk cup for long-term exposure. When potential exposure to water is added, approximately 23 percent of the risk cup is occupied leaving 77 percent (equating to an MOE of 39) for any additional exposures resulting from residential use.

The first scenario considers the pet collar. As discussed previously in this document, the Agency has made a number of conservative assumptions in deriving a risk estimate for this use. Included in these assumptions is that the pet collar acts as a miniature resin strip which results in inhalation exposure proportional to that of larger resin strips and that the pet is in the same room as an individual for 8 hours a day. Additionally, exposures were calculated based on dermal contact (from hugging and petting activities) as well as incidental oral (hand to mouth) exposures exhibited by children. The inhalation MOE is calculated to be 74 and the dermal and incidental oral MOE of 83 for a comined MOE of 39 vs. our target MOE of 30. Therefore, the long-term aggregrate risk does not exceed our level of concern given that this conservative estimate from the pet collar does not exceed the amount left in the risk cup after considering food and water.

The second scenario considers the largest resin strip. The registrant recently voluntarily amended its registration to limit where these strips can be used. No use will be permitted in living areas and the labeling warns of exposure to the strips for more than 4 hours. The Agency believes that given the location of where these strips may be used (e.g., attics, crawl spaces, garages, etc), exposure times will be much less than 4 hours a day and/or that daily exposure (repeated exposure) may not be likely depending on the site of application (e.g., crawl spaces). Consequently, considering the room available in the risk cup after consideration of food and water and that exposures are not expected either daily or for significant periods of time, our risk of concern is not exceeded from this long-term exposure scenario.

7.5 Aggregate Cancer Risk

No aggregate cancer risk assessment is needed. Dichlorvos shows “suggestive” evidence of carcinogenicity under the 1999 Draft Agency Cancer Guidelines. No quantitation is required. No aggregate cancer risk assessment is required.

8.0 Cumulative Risk Characterization/Assessment

Section 408(b)(2)(D)(v) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Dichlorvos is a member of the organophosphate (OP) class of pesticides. Other members of this class of pesticides are numerous and include azinphos methyl, chlorpyrifos, chlorpyrifos-methyl, diazinon, dichlorvos, dicrotophos, dimethoate, disulfoton, methamidophos, methidathion, monocrotophos, naled, oxydemeton-methyl, phorate, phosmet, pirimiphos-methyl, and trichlorfon to name a few. EPA considers organophosphates to express toxicity through a common biochemical interaction with cholinesterase which may lead to a myriad of cholinergic effects and, consequently the organophosphate pesticides should be considered as a group when performing cumulative risk assessments. HED published the final guidance that it now uses for identifying substances that have a common mechanism of toxicity (FR 64(24) 5796-5799, February 5, 1999) “Proposed Guidance of Cumulative Risk Assessment for Chemicals that have a Common Mechanism of Toxicity” was made available for public comment in the Federal Register (65 FR 40644, June 30, 2000 . The Agency presented this approach to the FIFRA/FQPA Science Advisory Panel in late September, 2000. The SAP reviewed revised methods used to conduct a preliminary cumulative risk assessment for organophosphate pesticides in 2002 (US EPA, 2002), found at http://www.epa.gov/scipoly/sap/2002/index.htm.

The Agency has completed a cumulative risk assessment for OPs, (US EPA, 2001) and a revised cumulative risk assessment for OPs, (US EPA, 2002a) which can be found on the Agency's web site http://www.epa.gov/pesticides/cumulative/rra-op/. It assesses the cumulative effects of exposure to multiple OPs, including dichlorvos.

Dichlorvos is closely related to naled and trichlorfon, which are members of the organophosphate class of pesticides. Naled and trichlorfon both metabolize or degrade to dichlorvos in food, water, or the environment. Therefore, FQPA requires OPP to estimate aggregate risk from consumption of food and water, containing dichlorvos derived from naled and trichlorfon and from residential exposure to dichlorvos from the use of those pesticides. The current assessment

addressed only the risks posed by dichlorvos, resulting from the uses of dichlorvos, naled, and trichlorfon.

9.0 Occupational Exposure/Risk Pathway

Risk is expressed as a Margin of Exposure (MOE)

$$MOE = \frac{NOAEL}{Exposure}$$

where both the NOAEL and the Exposure are expressed in the same units (mg/kg/day for dermal or inhalation exposure during application or mg/m^3 for exposure to dichlorvos vapors). Dermal exposures include a dermal absorption factor of 11%, because the exposure is compared to an oral NOAEL. The target MOE for occupational scenarios varies from 30 to 100. (See Table 4.4).

The risk assessment has been changed from previous versions to use the North American Free Trade Agreement (NAFTA) recommended breathing rate of 1.0 m^3/hr rather than the rate recommended in the guidelines or the default breathing rate used in PHED. This change increases the inhalation MOEs, and therefore decreases the estimated risk to occupational and residential handlers. The risk assessment uses the recommended body weight of 70 kg for the acute, short term, and intermediate term risk assessments.

AMVAC has requested voluntary cancellation of the following uses.

Mushroom house, greenhouse, and warehouse hand held fogger
Lawn, Turf, and Ornamental uses
Total release fogger
Crack and Crevice uses

The following label changes will be made:

A Restricted Entry Interval (REI) of 18 hours for mushroom houses, and 12 hours for greenhouse uses.

Toxicological Doses and Endpoints for Occupational Exposure Assessment are presented in Table 9.0. Occupational exposure and risk estimates for applicators are presented in Table 9.1 below. Occupational post-application exposure and risk estimates are presented in Table 9.2 below.

Table 9.0. Summary of Toxicological Doses and Endpoints for Dichlorvos for Use in Occupational Human Health Risk Assessments

Exposure Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dermal	$BMDL_{10}$ = 0.8 mg/kg/day dermal absorption=11%	UF_A = 10x UF_H = 10x	**Occupational** LOC MOE = 100	Rat acute oral cholinesterase studies - RBC and Brain ChE depression. NOAEL = 1 mg/kg/day, LOAEL = 5 mg/kg/day, BMD = 1.6 mg/kg/day for brain ChE depression (F)
Short-, Intermediate- and Long-Term Dermal	Oral study LOAEL= 0.1 mg/kg/day dermal bsorption=11%	UF_H = 10x UF_L = 3x	**Occupational** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Acute Inhalation (1 day)	Oral study $BMDL_{10}$ = 0.8 mg/kg/day (inhalation absorption rate = 100%) Air concentration Equivalent = 0.8 mg/m^3*	UF_A = 10x UF_H = 10x or 3x**	**Occupational** LOC MOE = 100/30**	Rat acute oral cholinesterase studies - RBC and Brain ChE depression. NOAEL = 1 mg/kg/day, LOAEL = 5 mg/kg/day, BMD = 1.6 mg/kg/day for brain ChE depression (F)
Short- and Intermediate-term Inhalation of vapors	Oral study LOAEL= 0.1 mg/kg/day UF=30 Concentration equivalent= 0.35 mg/m^3*	UF_H = 10x UF_L = 3x	**Occupational** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Short- and Intermediate-Term Inhalation during application	LOAEL= 0.1 mg/kg/day	UF_H = 10x UF_L = 3x	**Occupational** LOC MOE = 30	Human 21-day oral study LOAEL = 0.1 mg/kg/day based on RBC ChE depression
Long-Term Inhalation of vapors	$BMDL_{10}$ = 0.07 mg/m^3	UF_A = 10x UF_H = 3x**	**Occupational** LOC = 30	2-year Rat Inhalation BMD = 0.15 mg/m^3 based on RBC ChE depression (F)
Cancer (oral, dermal, inhalation)	"suggestive" evidence of carcinogenicity not quantifiable under the 1999 Draft Agency Cancer Guidelines			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key date (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = Not Applicable

* Calculation of concentration equivalent $BMDL_{10}$ and LOAEL
Acute Inhalation $BMDL_{10}$
0.8 mg/kg/day x 0.35 kg / 0.34 m^3/day = 0.8 mg/m^3
Short- and Intermediate- term inhalation of vapors LOAEL
0.1 mg/kg/day x 70 kg / 20 m^3/day = 0.35 mg/m^3

**Since the NOAEL is expressed in concentration units (RfC methodology), the interspecies extrapolation factor is 3x (for the acute and long term inhalation scenarios), for a total UF of 30 for acute inhalation and long term inhalation.

9.0.1. Mushroom House

(a). Application

Application of dichlorvos to mushroom houses may be made by coarse spray and paint-on applications. Foggers would be permitted if the applicator is outside the mushroom house. The exposures for coarse spray applications were derived from ORETF data. The Outdoor Residential Exposure Task Force (ORETF) has recently completed several surrogate mixer/loader/applicator studies addressing lawn care operators (LCOs). (Bangs, 2001; Jaquith, 2001). The hose-end sprayer scenario from the ORETF studies will be used to estimate exposures to applicators in mushroom houses. Estimates of the surface areas that would be painted or sprayed during dichlorvos application were derived from mushroom culture textbooks and are considered to be conservative (Jaquith 1998d and n). This application scenario is considered to be intermediate term (several months) because a single individual may treat different mushroom houses on different days due to the cyclic nature of mushroom culture.

Coarse Spray and Paint-on Applications. For the coarse spray, data from the ORETF lawn care study were used; protective clothing varied with the application method, and included long pants, long sleeved shirt and gloves, or coveralls plus long pants, long sleeved shirt and gloves. The label does not specify protective clothing needed. Dermal and inhalation exposure and total exposure resulting in an MOE of 46 is not considered to be of concern, compared to the target MOE of 30. If an additional layer of protective clothing were added, the absorbed dermal dose would be cut approximately in half, and the MOE of 88 would be adequate.

(b). Post-application

For reentry exposure, it was assumed that a worker reenters a ventilated mushroom house 12 or 24 hours after treatment and is exposed for 8 hours. This is a short term exposure because workers may be exposed multiple times on subsequent days. The MOE at a 12 hour REI of 23 is less than the target MOE of 30, and is of concern. The MOE at a 24 hour REI of 58 is greater than the target MOE of 30, and is not of concern. AMVAC has submitted an amendment, changing the label REI to 18 hours.

9.0.2. Greenhouse

(a). Application

There are currently no end use product labels with directions for use for greenhouses. However, the technical label for Dichlorvos allows use of up to 2.0 g/1000 cu. ft. Previously, smoke generators were registered, and were considered to result in negligible applicator exposure since the applicator vacates the premises immediately upon activation of the smoke generator. This application scenario is considered to be short term because treatment would not be expected to occur in a given greenhouse more than once a week. The baseline MOE is 46, which is not of concern.

(b). Post-application

The dermal exposure for reentry into greenhouses following the use of dichlorvos was obtained using data from a greenhouse culture textbook, data on turf transferable residues from a chlorpyrifos/dichlorvos study (Goh, K. S., et. al. 1986), and a standard transfer coefficient of 2500 cm^2/hr, from ExpoSAC Policy 003. Inhalation exposure estimates were modeled assuming the initial concentration at the maximum rate, assuming first order kinetics and an air exchange rate from a textbook (Mastalerz, 1977). This is considered to be a short-term exposure scenario (Jaquith, 1998d).

The total daily dermal exposure that would occur after a 2 hour REI is estimated to be 1.2 μg/kg/day. The dichlorvos concentrations available for inhalation exposure were modeled (Jaquith, 1998d), and concentrations depended on the ventilation used. The estimated respiratory component of exposure would be 0.00035 mg/m^3. The resulting MOE with a 2 hour REI of 78 is not of concern, compared to the target MOE of 30. At a 12 hr REI, the total MOE is >650 and is not of concern, compared to the target MOE of 30.

9.0.3. Domestic Animal Premises (food and nonfood) and Direct Animal Sprays, Feedlots, Manure Treatment, Garbage Dumps, and Baits

(a). Application

Dairy barn application and direct application to dairy cattle were used as the reference facility for these exposure assessments (Jaquith 1998l). There are no data addressing the use of dichlorvos in other types of animal facilities. Worker exposure from direct application to animals is based on dairy cattle treatment. Although permitted on product labels, the Agency does not believe that direct application to livestock animals with a handheld sprayer is used. Rather, some type of automated equipment is used to apply dichlorvos directly to animals. Space and premise treatments also help control insects on animals. Since several registered products provide guidance on use with a handheld sprayer, the exposure and risk are estimated here for that application method, which is expected to result in a much higher exposure than automated methods. While some labels indicate that daily application (probably for direct application to cattle) is allowable, the use assessment indicates that the material is applied at 2 week intervals (Dow, M., 1985). This assessment assumes daily applications over several months, and is therefore considered to be an intermediate term scenario.

Cattle. Exposure assessments for direct application to dairy cattle using hand-held sprayers as a surface spray or space spray were conducted using PHED V1.1. Applicators were assumed to be wearing long sleeved shirt, long pants, and gloves. Gloves are not currently required on the label. Absorbed dermal doses were estimated to range from 0.009 to 0.22 μg/kg/day and respiratory doses from 0.008 to 0.039 μg/kg/day, depending on application equipment. These total MOEs would range from 440 to 59000, and are not considered to be of concern.

Poultry. Applicator exposure data for cattle cannot be extrapolated to poultry, because of the different application method and less frequent applications. Individual animals are less likely to be treated directly and the equipment is more likely to be automated. As a result, exposure from

applying dichlorvos to poultry is expected to be much lower than for cattle. Therefore, no separate assessment has been done.

Domestic Animal Premises. Barn sizes were obtained from the dichlorvos Qualitative Use Assessment (QUA) (Dow, M., 1985). Assuming that a worker wears long sleeve shirt, long trousers, shoes and impervious gloves at a minimum, risks from dichlorvos application to domestic animal premises are lower than the risks from direct application to cattle, with total MOEs from 440 to 5900, and do not exceed the Agency's level of concern. Gloves are not currently required on all dichlorvos labels.

Feedlots include stockyards, corrals, holding pens and other areas where large groups of animals are contained. EPA assumes that some type of power sprayer capable of treating a large number of animals in a short time is probably used. A short application time period in an outdoor or partially enclosed area would minimize exposure to less than that of dairy applications.

Manure Treatment. The application equipment used for manure applications may be similar to those used in a dairy barn; however, the application time would probably be less and the treated area would be well ventilated - either outdoors or in a partially enclosed area. The MOE for applicators is expected to be greater than the target MOE for manure use.

(b). Reentry

There are no data addressing potential reentry into animal facilities. Re-entry exposure to animal premises would not be expected to exceed reentry exposure for greenhouses, and would be expected to be considerably less, since animal premises are usually outdoors or well ventilated, where minimal dermal contact is expected.

9.0.4. Food Manufacturing Plant, Warehouse Treatment

(a). Application

Dichlorvos can be applied to warehouses with wall-mounted automatic foggers. Exposure to mixer/loaders through automatic application is expected to be negligible; however, there would still be reentry exposure.

(b). Post-application

In estimating reentry exposure, EPA assumed 24 hours elapsed before reentry is allowed, the label REI; and that workers in food manufacturing plants spend 8 hours per day in the treated area, and 2 hours per day in warehouses. Absorbed dermal exposure was measured for the hands only, which is likely to be the greatest route of dermal exposure, and represents an average of the total exposure measured for three work stations, and was negligible compared to the inhalation exposure. This exposure scenario was considered to be acute due to rapid dissipation of dichlorvos (1 day) and sporadic use. (Jaquith, D., 2000a; Jaquith, D, 1993c).

The dermal exposure estimate is 0.00022 mg/kg/day for food manufacturing plants. The mean air concentration of dichlorvos in a food manufacturing plant is estimated to be 0.053 mg/m^3 , 24 hours after application, which results in an exposure of 0.006 mg/kg/day. The estimated air concentration in a warehouse after a 24 hour REI is 0.074 mg/m^3 . This is an acute exposure scenario with an MOE of 130 (target MOE is 100) for food manufacturing plants, and 650 for warehouses, neither of which is of concern.

9.0.5. Railcars and Trucks

(a). Application

Dichlorvos can be applied to railcars and trucks as a fog or as a surface spray. This is a short term exposure scenario. One to ten railcars or trucks could be treated in a single day. Application with a surface spray would have MOEs of 320, compared to a target MOE of 30, which would not be of concern.

(b). Post-application

In estimating reentry exposure, EPA assumed 6 hours elapsed before reentry is allowed, and that workers could spend 1 hour per truck or railcar and could load 4 railcars or trucks per day. Workers loading rail cars or trucks would not be expected to have dermal exposure to dichlorvos. The air concentration was estimated using initial air concentrations calculated from the application rate, and assuming ventilation similar to a food processing establishment. This exposure scenario was considered to be short term due to rapid dissipation of dichlorvos. (Jaquith, D., 2005). The air concentration 6 hours after treatment is estimated to be 0.018 mg/m^3. The MOE would be 94, which is not of concern, compared to the target MOE of 30. There is considerable uncertainty about the air exchange rate. Under the conditions described, the air exchange rate could be as low as 1/3 per hour.

9.0.6. Insect Traps

Exposure is believed to be negligible since the pesticide is in the form of an impregnated strip in a sealed package, which is opened and the applicator leaves, and the traps are placed in outdoor areas (such as forests) where there is no human exposure.

9.0.7. Occupational Uses of Resin Strips

The dichlorvos label contains the following use patterns and restrictions.

Garbage Cans, Trash Dumpsters, Catch Basins, Utility Enclosures. Keep lid on can and dumpster closed.

Animal Buildings, Milk Rooms. Do not contaminate food, water or foodstuffs. Do not contaminate milk or milking equipment.

Agricultural Commodities: *Bulk Storage of raw grains, corn, soybeans, cocoa beans, and peanuts*. No restrictions.

Reptile Houses and Terrariums. Make sure that the reptiles can not touch or contact the strip.

Exposure to dichlorvos from these use patterns is expected to be small compared to the use of resin strips in homes, provided that workers are in the facilities treated for short periods of time. Refer to table 6.3 for exposure and risk information.

Table 9.1 Occupational Applicator Exposure and Risk Estimates[1]

Scenario	End-note	Duration	# ai/day	Dermal unit exposure	Inhalation unit exposure	Dermal Exposure	Inhalation Exposure	Total Exposure	Dermal MOE	Inhalation MOE	Total MOE
Mushroom house & Greenhouse	2										
- ORETF Hose End Sprayer		Intermediate term	2.6	0.52	0.001	0.00212	0.00004	0.0022	47	2700	46
- ORETF Hose End Sprayer + coveralls		Intermediate term	2.6	0.27	0.001	0.00110	0.00004	0.00061	91	2700	88
Direct animal treatment	3										
- Hand Held Sprayer		Intermediate term	0.092	0.17	0.017	0.000025	0.000023	0.000047	4100	4400	2100
- Backpack Sprayer (471)		Intermediate term	0.092	2.6	0.017	0.000376	0.000023	0.000399	270	4400	250
- Backpack Sprayer (416)		Intermediate term	0.092	0.27	0.017	0.000039	0.000023	0.000062	2600	4400	1600
- Portable Sprayer on Cart		Intermediate term	0.092	0.69	0.052	0.000100	0.000068	0.000168	1000	1500	600
Dairy barns - space spray	4										
- Hand Held Sprayer		Short term	0.033	0.17	0.017	0.000009	0.000008	0.000017	11000	12000	5900
- Backpack Sprayer (471)		Short term	0.033	2.6	0.017	0.000135	0.000008	0.000143	740	12000	700
- Backpack Sprayer (416)		Short term	0.033	0.27	0.017	0.000014	0.000008	0.000022	7100	12000	4500
- Portable Sprayer on Cart		Short term	0.033	0.69	0.052	0.000036	0.000025	0.000060	2800	4100	1700
Dairy barns - surface spray											
- Hand Held Sprayer		Short term	0.053	0.17	0.017	0.000014	0.000013	0.000027	7100	7600	3700
- Backpack Sprayer (471)		Short term	0.053	2.6	0.017	0.000217	0.000013	0.000230	460	7600	440
- Backpack Sprayer (416)		Short term	0.053	0.27	0.017	0.000022	0.000013	0.000036	4400	7600	2800
- Portable Sprayer on Cart		Short term	0.053	0.69	0.052	0.000057	0.000039	0.000097	1700	2500	1000
Rail cars and trucks	5										
- Surface Spray		Short term	0.28	0.67	0.0032	0.00030	0.000013	0.00031	330	7700	320
Feedlots	6	Short term	No data; not expected to exceed dairy barn exposure								
Manure	7	Short term									
Garbage Dumps	8	Short term									

NOTES: The parameters and assumptions used in calculating the margins of exposure are found in the endnotes below

,

Risk is expressed as a Margin of Exposure (MOE)

$$MOE = \frac{NOAEL}{Exposure}$$, where both the NOAEL and the Exposure are expressed in mg/kg/day or mg/m^3

The target MOE for occupational exposure scenarios is 30.

1. Occupational Exposure assumptions. An average worker weighs 70 kg and has a respiratory volume of 1.0 m^3 /hour (NAFTA Value). At a minimum, the following protective clothing was used in the exposure scenarios: gloves, long-sleeve shirt, long pants

2. Mushroom Houses and Greenhouses
   Mushroom Houses - coarse spray. A typical mushroom operation is believed to consist of 10 houses, each with a volume of 30000 ft^3 (850 m^3). The label does not specify protective clothing needed. If an individual treats all 10 houses at a rate of 2 grams per 1000 ft^3 the amount handled in a day would be:

   $$\text{Amount handled (lb ai/day)} = \frac{30000\ ft^3/\text{house} \times 10\ \text{houses/day} \times 2\ g/1000\ ft^3}{454\ g/lb\ ai} = 1.3\ lb\ ai/day$$

   Workers are assumed to be wearing a single layer of clothing and gloves. A second assessment was done for applicators wearing coveralls. Data from the ORETF lawn care study were used (liquid formulation, hose end sprayer).

   AMVAC does not have a coarse spray registered. There was a canceled product, EPA Reg. No. 72-375 that had use directions for the coarse spray or paint-on application to mushroom houses. The use specified 0.25 lb of a 0.5% solution to treat 100 sq ft. If we assume that a typical mushroom house is 6000 sq ft, the amount handled per day would be about1.5 lb ai/day. Thus, the mushroom/greenhouse assessment presented in this table estimates a somewhat higher exposure than what would be expected.

   Greenhouse - The average greenhouse has an estimated volume was 85,000 $ft^{3.}$ A typical operation was assumed to consist of 10 greenhouses which could be treated in a single day. Treatment was estimated to be 3.75 minutes per house or 26 minutes (0.44 hrs) per day. Dichlorvos is applied at the rate of 1.4 grams of active ingredient per 1,000 ft^3. Workers were assumed to be a single layer of clothing and gloves. Treatment would not be expected to occur in a given greenhouse more than once a week, resulting in a short term exposure scenario. Workers are assumed to weigh 70 kg. The unit exposures were 14 mg/lb ai handled for dermal exposure, and 0.19 mg/lb ai handled for inhalation exposure.

   The typical application rate for dichlorvos in a greenhouse is 1.4 g per 1000 ft^3. The amount handled per greenhouse would be:
   Amount handled (lb ai/greenhouse) = 1.4 g ai/1000 ft^3 x 85000 ft^3/greenhouse
   = 120 g ai/greenhouse = 0.26 lb ai/greenhouse
   The amount handled per day would be:
   Amount handled (lb ai/day) = 0.26 lb ai/greenhouse x 10 greenhouses/day = 2.6 lb ai/day

3. Domestic Food/Non-food Animals (non-poultry). Worker exposure from direct application to animals is based on dairy cattle treatment. A one percent solution of dichlorvos is applied with a handheld sprayer. An average herd of dairy cattle consists of 65 head, each requiring 24 seconds to spray, two times per day during treatment. Fly control is required from May to October with application expected to be occurring weekly rather than 2 x per day during this time (26 times per year). Although permitted on product labels, EPA does not believe that direct application with a handheld sprayer is used. Rather, some type of automated equipment is used to apply dichlorvos directly to animals. Space and premise treatments also help control insects on animals. Since several registered products provide guidance on use with a handheld sprayer, the exposure and risk are estimated here for that application method, which is expected to result in a much higher exposure than automated methods. The exposure assessment for direct application to dairy cattle using a handheld sprayer was conducted using PHED V1.1. Applicators were assumed to wear long sleeve shirts, long pants, and gloves.

Domestic Food/Non-food Animals (poultry). Data for cattle cannot be extrapolated to poultry, because of the different application method and less frequent applications. However, individual animals are less likely to be treated directly and the equipment is more likely to be automated. As a result, exposure from applying dichlorvos to poultry is expected to be much lower than for cattle, and no separate assessment is done.

4. Domestic Animal Premises - Dairy Barns. An average dairy barn has the dimensions 30 ft x 100 ft x 9 ft (total area covered is 5,340 ft^2). (Dow, M., 1985). Dichlorvos is applied at two week intervals for 22 weeks, one barn per day. A 1.0 percent solution of dichlorvos is applied using a low pressure hand sprayer at a rate of 0.0115 lb a.i. per 1000 ft^2. A worker wears long sleeve shirt, long trousers, shoes and impervious gloves at a minimum. The unit exposure varies depending on the equipment used.

5. Rail cars and trucks. Calculation is shown for treating 10 rail cars or trucks per day. Dermal absorption is assumed to be 11 percent. Applicators are assumed to wear long sleeve shirts, long pants, gloves, and a respirator (90% protection). Coveralls, although required on some labels, are not included for surface application. An applicator treating 10 rail cars per day handles 0.28 lb ai/day. The dermal unit exposure is 0.67 mg/lb ai, and the inhalation unit exposure is 0.0032 mg/lb ai.

$$\frac{0.28 \text{ lb dichlorvos} \times 0.67 \text{ mg/lb ai} \times 0.11 \text{ (dermal absorpting factor)}}{70 \text{ kg applicator}} = 0.00030 \text{ mg/kg/day}$$

$$\frac{0.28 \text{ lb dichlorvos} \times 0.0032 \text{ mg/lb ai}}{70 \text{ kg applicator}} = 0.000013 \text{ mg/kg/day}$$

6. Feedlots include stockyards, corrals, holding pens and other areas where large groups of animals are contained. EPA assumes that some type of power sprayer capable of treating a large number of animals in a short time is probably used. A short application time period in an outdoor or partially enclosed area would minimize exposure to less than that of dairy applications.

7. Manure. The MOE is expected to be greater than 100 for manure use. Application equipment may be similar to those used in a dairy barn; however, the application time would probably be less and the treated area would be well ventilated - either outdoors or in a partially enclosed area.

8. Garbage Dumps. Exposure at a garbage dump is believed to be less than dairy exposure.

Table 9.2. Summary of Occupational Post-Application Exposure and Risk Estimates for Dichlorvos

USES	NOTES	EXPOSURE PATTERN[1]	Current Exposure (mg/kg/day)		Current MOE		MOE
			Dermal	Inhalation	Dermal	Inhalation	Total
OCCUPATIONAL EXPOSURE	1	Target MOEs for all short term post-application Occupational Scenarios are 30, and for acute post-application scenarios, are 100.					
i. Mushroom house	2						
Reentry (12-hour REI)		Short-term	0.0002	0.044 mg/m^3	450	24	23
Reentry (24-hour REI)		Short-term	0.0002	0.016 mg/m^3	450	66	58
ii. Greenhouse	3						
Reentry (2 hour REI)		Short-term	0.0012	0.00035 mg/m^3	80	3000	78
Reentry (12 hour REI)		Short-term	0.00012	<0.00035 mg/m^3	800	>3000	>650
Reentry (24 -hour REI)		Short-term	<0.00012	<0.00035 mg/m^3	>800	>3000	>650
iii. Food Manufacturing Plant - Reentry (24 hour REI)	4	acute	0.00022	0.053 mg/m^3 (0.006 mg/kg/day)	3600	130	130
iv. Warehouse treatment - Reentry (24 hour REI, 1 hr exposure)	5	acute	0.00022	0.074 mg/m^3 (0.001 mg/kg/day)	3600	800	650
v. Railcars and trucks (8 hr REI)	6	Short-term		0.0187 mg/m^3 (0.0010 mg/kg/day)		94	94

NOTES: The following notes define the assumptions used in calculating the margins of exposure.

1. Risk is expressed as a Margin of Exposure (MOE)

$$MOE = \frac{NOAEL}{Exposure}$$,where both the NOAEL and the Exposure are expressed in mg/kg/day or mg/m^3

The target MOE for all short term post-application occupational exposure is 30, and for all acute post-application scenarios is 100.

Occupational Exposure assumptions. An average worker weighs 70 kg and has a respiratory volume of 1.0 m^3 /hour (NAFTA Value). At a minimum, the following protective clothing was used in the exposure scenarios: gloves, long-sleeve shirt, and long pants. Addition of a respirator to the PPE requirements would reduce estimated inhalation exposure by 90%, which would not change the MOEs by more than a factor of 2.

2. Mushroom Houses - reentry. For reentry exposure, it was assumed that a worker reenters a ventilated mushroom house 12 or 24 hours after treatment and is exposed for 8 hours. The post-application exposures for mushroom houses were derived from a study conducted by the California Department of Food and Agriculture (CDFA) (now the California EPA) in which air and surface residues were measured in mushroom houses where dichlorvos had been applied (Maddy 1981, Jaquith 1998d). This was a limited study measuring surface residues and air concentrations in 2-4 mushroom houses over 24 hours.

   Wipe sampling was only conducted in 2 mushroom houses, preventing any analysis of the distribution of surface residues in these facilities. The highest surface concentration, 0.026 µg/cm^2, was reported 3 hours after application. The last sampling point was at 12 hours after application, when the surface residues averaged 0.007 µg/cm^2. There was no clear trend in the air concentrations. Air samples were collected at 30 minutes, and 1, 3, 6, 12, and 24 hours. Only two samples were taken at the 24 hour sampling period. The air concentrations of dichlorvos averaged 0.022, 0.044, and 0.016 mg/m^3, at 6, 12, and 24 hours after treatment, respectively. The transfer coefficient was obtained from the ExpoSAC policy 003, to be 2500 cm^2/hr. Because of the aeration pattern of mushroom houses, the volatility of dichlorvos, and dissipation of dichlorvos in mushroom houses, this is considered to be a short term exposure scenario. Respirators are not worn during reentry.

   Dermal Exposure (µg/kg/day) = 0.007 µg/cm^2 x 2500 cm^2 /hr x 8 hr/day x 1/70 kg x 0.11 (Absorb)
   = 0.22 µg/kg/day
   = 0.00022 mg/kg/day

   Estimated dermal post-application risk = $\frac{NOAEL}{Exposure} = \frac{0.1\ mg/kg/day}{0.00022\ mg/kg/day} = 450$ (Target MOE = 30, ARI = 450/30 = 15)

   The inhalation risk estimate includes a factor to adjust for the hours of exposure. The endpoint converted to concentration units assumed 24 hours exposure per day. Workers in mushroom houses are exposed for 8 hours.

   Estimated inhalation post-application risk (12 hour REI) = $\frac{NOAEL}{Exposure} = \frac{0.35\ mg/m^3 \times 24hr}{0.044\ mg/m^3\ \ 8\ hr} = 24$ (Target MOE = 30)

   The label REI is now 18 hours.

3. Greenhouse - reentry. The dermal exposure for reentry into greenhouses following the use of dichlorvos was obtained using data from a greenhouse culture textbook, data on turf transferable residues from a chlorpyrifos/dichlorvos turf study (Goh, K. S., et. al. 1986), and a transfer coefficient of 2500 cm^2/hr, from the ExpoSAC Policy 003. Inhalation exposure estimates were modeled assuming the initial concentration at the maximum rate, assuming first order kinetics and an air exchange rate from a textbook (Mastalerz, 1977). This is considered to be a short-term exposure scenario (Jaquith, 1998d).

The dislodgeable foliar residues reported in the Goh study were 0.04 µg/cm^2, 2 - 6 hours after application, and 0.004 µg/cm^2, 10 hours after application of 2 g dichlorvos/1000 ft^3.

The total daily dermal exposure that would occur after a 2 hour REI is estimated to be:

Dermal Exposure (µg/kg/day) = 0.04 µg/cm^2 x 2500 cm^2 /hr x 8 hrs/day x 0.11 (dermal absorption factor) x 1/70 kg = 1.25 µg/kg/day (0.00125 mg/kg/day)

$$\text{Dermal MOE} = \frac{\text{NOAEL}}{\text{Exposure}} = \frac{0.1 \text{ mg/kg/day}}{0.00125 \text{ mg/kg/day}} = 80$$

$$\text{Estimated inhalation post-application risk (2 hour REI)} = \frac{\text{NOAEL}}{\text{Exposure}} = \frac{0.35 \text{ mg/m}^3}{0.00035 \text{ mg/m}^3} \times \frac{24 \text{ hr}}{8 \text{ hr}} = 3000$$

4. Reentry - Food manufacturing plant. Dichlorvos can be applied to food processing facilities with wall-mounted automatic foggers. In estimating reentry exposure to food processing facilities, EPA assumed 24 hours elapsed before reentry is allowed, as required on labels; and that workers spend 8 hours per day on the day following treatment. Dichlorvos is applied at the rate of 2.0 grams active ingredient per 1,000 ft^3 over a period of 125 minutes per application. Hand rinses were done and air concentrations were measured at 0, 3, 6, 10, 22, and 42 hours after application. Dermal exposure was measured for the hands only and represents an average of the total exposure measured for three work stations. Because significant exposure occurs for only one day and occurs sporadically, this is considered an acute reentry scenario and MOEs are calculated using the $BMDL_{10}$ of 0.8 mg/kg for inhibition of rat cholinesterase.

   The dermal exposure calculated in the original review (Jaquith 1993c), 0.00027 mg/kg/day, has been corrected for the application rate (2.0/2.4), resulting in a dermal exposure estimate of 0.00022 mg/kg/day.

   The dermal MOE = 0.8/.00022 = 3600

   Mean air concentrations of dichlorvos in a food handling establishment following treatment using a fogger at 2.4 g ai/1000 ft^3. Means include samples from all sites and two different heights. (Jaquith, D., 2000a; Jaquith, D, 1993c).

Hours After Application	Mean Conc. (mg/m^3)	Conc. Corrected for application rate (mg/m^3)
0	10.0	8.3
3	2.7	2.2
6	0.62	0.52
10	0.37	0.31
22	0.13	0.11
42	0.052	0.043

   An exponential decay curve $C = C_0 \times e^{-kt}$ was fit to the data where C_0 = 0.93 mg/m^3 and k = 0.10 /hour. The corresponding equation for average concentration over the interval from t_1 to t_2 is $C_{avg} = C_0 \times (e^{-kt1} - e^{-kt2}) / k(t_2-t_1)$. For the interval from 24 to 32 hours, the average concentration is 0.053 mg/m^3. The dose on a mg/kg basis is:

Dose (mg/kg) = 0.053 mg/m^3 x 1.0 m^3/hr x 8 hr ÷ 70 kg = 0.006 mg/kg.

The acute inhalation MOE is: MOE = 0.8 ÷ 0.006 = 130

5. Reentry - warehouse. Dichlorvos can be applied to food warehouses with wall-mounted automatic foggers. In estimating reentry exposure to warehouse facilities, EPA assumed 24 hours elapsed before reentry is allowed, as required on labels; and that workers spend 60 minutes per day in the treated area. Dichlorvos is applied at the rate of 2.0 grams active ingredient per 1,000 ft^3 over a period of 125 minutes per application. Dermal exposure was measured for the hands only and represents an average of the total exposure measured for three work stations. Because significant exposure occurs for only one day and occurs sporadically, this is considered an acute reentry scenario and MOEs are calculated using the $BMDL_{10}$ of 0.8 mg/kg for inhibition of rat cholinesterase.

   The dermal exposure is described in footnote (4).

   The methodology for inhalation exposure and risk are described in footnote (4). Assuming a worker reenters a treated warehouse 24 hours after application and works for one hour, the average dichlorvos concentration in the interval from 24 to 25 hours is 0.074 mg/m^3. The dose on a mg/kg basis is:

   0.074 mg/m^3 x 1.0 m^3/hr x 1 hr / 70 kg = 0.0010 mg/kg/day

   $$\text{MOE} = \frac{0.8 \text{ mg/kg/day}}{0.0010 \text{ mg/kg/day}} = 800$$

6. Reentry - railcars and trucks. Dichlorvos can be applied to railcars and trucks as a space spray, or as a surface spray. Some labels allow up to 2 g ai/1000 ft^3, others allow up to 2.5 g ai/1000 ft^3. The initial concentration of dichlorvos from 2.5 g ai/1000 ft^3 would be 88 mg/m^3. The concentration at later time intervals can be calculated from the equation, $C_t = C_0 \times e^{-kt}$, where k = 1, based on an assumed air exchange rate of 1 air change per hour. In estimating reentry exposure, EPA assumed 8 hours elapsed before reentry is allowed, and that workers could spend 1 hour per truck or railcar and could load 4 railcars or trucks per day. Workers loading rail cars or trucks would not be expected to have dermal exposure to dichlorvos. The air concentration was estimated using initial air concentrations calculated from the application rate, and assuming ventilation similar to a food processing establishment (k=1). This exposure scenario was considered to be short term due to rapid dissipation of dichlorvos. (Jaquith, D., 2005).

   Integrating the equation for a period of 8 to 9 hours,

   $C_t = -88 \text{ mg/m}^3 \times (e^{-9} - e^{-8}) = 0.0187 \text{ mg/m}^3$

   0.0187 mg/m^3 x 1.0 m^3/hr x 1 hr/truck x 4 trucks / 70 kg = 0.0011 mg/kg/day

   $$\text{MOE} = \frac{0.1 \text{ mg/kg/day}}{0.0011 \text{ mg/kg/day}} = 94$$

   There is considerable uncertainty about the air exchange rate. Under the conditions described, the air exchange rate could be as low as 1/3 per hour

10.0 Data Needs and Label Requirements

10.1 Toxicology

There are no outstanding toxicology data requirements.

10.2 Product Chemistry

The discrepancy in the percent of active ingredient in several of the technicals must be resolved.

10.3 Residue Chemistry

The residue chemistry database for dichlorvos is reasonably complete. All labels must conform to the use pattern reflected in the residue data submitted. The following data requirements remain outstanding.

GLN 860.1380: Storage Stability Data

The Reregistration requirements for storage stability data are not fulfilled. Information pertaining to the storage intervals and conditions of samples of the following commodities, from studies that were reviewed in the Residue Chemistry Chapter of the Guidance Document, must be submitted: packaged and bagged raw agricultural commodities and processed food; bulk stored raw agricultural commodities; milk; eggs; and meat, fat, and meat byproducts of dairy cows and poultry. Alternatively, the registrant may demonstrate that there are sufficient residue data which are supported by storage stability data to support all registered uses of dichlorvos.

The available storage stability data indicate that residues of dichlorvos are stable under frozen storage conditions for up to 90 days in/on plant commodities, up to 4.5 months in/on peanuts, and up to 8 weeks in animal commodities.

GLN 860.1480: Meat, Milk, Poultry, Eggs

The Reregistration requirements for data pertaining to this guideline topic are not completely fulfilled. A dermal magnitude of the residue study must be submitted for swine. No additional data are required for milk and edible tissues of ruminants, and for eggs and edible tissues of poultry. Swine use is on the labels for EPA Reg. Nos. 572-246 and 47000-130.

10.4 Occupational and Residential Exposure

All labels must conform to the parameters used in this risk assessment. Protective clothing requirements at least as stringent as that used in this risk assessment must be added to the label. Labels permitting fogging must be clarified to state that hand-held foggers are not permitted, and that the applicator must be outside the treated area during application.

The greenhouse exposure study requirement has been satisfied by a generic study on malathion, which allowed the Agency to determine a transfer coefficient for harvesting greenhouse grown cut flowers. MRID 46513901, (Dole, T and M. Lloyd, 2005)

Dichlorvos from trichlorfon.

Outstanding exposure data requirements exist for trichlorfon. A TTR study with analyses for trichlorfon and dichlorvos in the turf and in the toddler breathing zone above the turf (18") is requested to confirm the exposure estimates in this document. The study must be conducted at an appropriate pH (approx. 7). A field dissipation study may be substituted, provided it meets these requirements.

GDLN 875.2100 Foliar Residue Dissipation Study (replaces GDLN 132-1(a))
GDLN 875.2400 Dermal Exposure (replaces GDLN 133-3, Dermal Passive Dosimetry)
GDLN 875.2500 Inhalation Exposure (replaces GDLN 133-4, Inhalation Passive Dosimetry)

REFERENCES

Abdel-Saheb I. 1998. Drinking Water Assessment for Dichlorvos (Revised). May 21, 1998.

Abdel-Saheb I. 2001. Drinking Water Assessment for Dichlorvos (Revised), Nov 13, 2001.

Abdel-Saheb I. 2003. Drinking Water Assessment for Dichlorvos (Revised), March 16, 2003.

Alavanja MCR, Samanic C, Dosimeci M, Lubin J, Tarone R, Lynch CF, Knott C, Thomas K, Hoppin JA, Barker J, Coble J, Sandler DP, Blair A. (2003). Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study cohort. American Journal of Epidemiology, 157(9), 800-814.

Bangs, G. 2001. Summary of HED's Reviews of Outdoor Residential Exposure Task Force (ORETF) Chemical Handler Exposure Studies; MRID 44972201. ORETF Study Numbers OMA001, OMA002, OMA003, OMA004., DP Barcode D261948, memo dated April 30, 2001.

Berge, G. N.; Nafstad, I.; Fonnum, F. 1986. Prenatal effects of Trichlorfon on the guinea pig brain. Arch. Toxicol. 59:30-35.

Berge, G.N.; Fonnum, F.; Brodal, P. 1987 a. Neurotoxic effects of prenatal Trichlorfon administration in pigs. Acta Vet. Scand. 28:321-332.

Berge, G.N.; Fonnum, F.; Soli, N.; Sognen, E. 1987 b. Neurotoxicological examination of the piglet brain after prenatal and postnatal exposure to Trichlorfon. Acta Vet. Scand. 28:313-320.

Beringer, M. J. 1993. Occupational and Residential Risk Assessment for Dichlorvos. Memo to Dennis Utterback, Review Manager, Special Review Branch, Special Review and Reregistration Division. September 8, 1993.

Beringer, M. J. 1993. Updated Dichlorvos Occupational/Residential Risk Assessment. Memo to Dennis Utterback, Review Manager, Special Review Branch, Special Review and Reregistration Division. February 23, 1994.

Blondell, J. 1994. Memorandum: Review of Poison Control Center Data Call In. To Joshua First, December 5, 1994. US EPA.

Blondell, J. 1996. Review of Comments on Dichlorvos Incidences. Memo to D. Utterback. May 17, 1996.

Blondell, J and Spann, M. 1998. Review of Dichlorvos Incidence Reports. DP Barcode D242971, Chemical # 084001, Reregistration Case # 0310. March 31, 1998.

Boone, J. S., J. E. Chambers, and J. Tyler, 2001. Preliminary data from an ISEA presentation, *Exposure to Children and Adults to Transferable Residues of Chlorpyrifos from Dogs Treated with Flea Control Collars*

Collins, R. D. and DeVries, D. M. 1973. Air Concentrations and Food Residues from Use of Shell's No-Pest Insecticide Strip. Bull. Environ. Contam. Toxicol. 9(4):227-233, 1973.

Daiss, B., 2004. BMD analysis for Dichlorvos, memorandum dated December 21, 2004 to W. Dykstra)

Dannan, G. 1998. Toxicology Review for Reregistration Eligibility Document on Dichlorvos (DDVP). February 20, 1998.

Dannan, G. and S. Dapson, 1999. Dichlorvos (DDVP): According to the Registrant: Critical Studies on Dichlorvos which Must be Evaluated for the EPA HED RED. D255121. July 3, 1999.

Dawson, J. L. 1998. Dichlorvos Indoor Air Calculations using MCCEM. June 29, 1998.

Diwan, S. 1999. Dichlorvos (DDVP): Reassessment Of The Requirement For The Prenatal Developmental Toxicity Study In Guinea Pig - Report of the Hazard Identification Assessment Review Committee. June 8, 1999. HED Document No. 013427

Diwan, S. 2000. Evaluation of the Carcinogenic Potential of Dichlorvos (DDVP). (Sixth Review). HED Document No. 014029. March 7, 2000.

Dole, T and M. Lloyd, 2005. Review of *Determination of Dermal and Inhalation Exposure to Reentry Workers During Harvesting in Greenhouse Grown Cut Flowers*. MRID 465139-01, DP Barcode D319969. Memorandum to Jeff Evans, Chair, Science Advisory Committee on Exposure, dated August 11, 2005.

Dow, M. 1985. DDVP (Vapona) QUA, Memorandum to D. Pillitt (RD) dated October 2, 1985.

Dykstra, W. 2003. Acute Cholinesterase Studies in Rats with Technical Dichlorvos (DDVP). DP Barcode: D288142, D287150. TXR 0051385. May 19, 2003.

Dykstra, W. 2004. DDVP Human Inhalation Study (Arizona II), DP Barcode: 287238, MRID No.:45812001. Memorandum to E. Olson (SRRD) dated May 17, 2004.

Dykstra, W. 2004. DDVP Human Inhalation Study (Arizona II). DP Barcode: 287238. TXR 0052550. May 17, 2004.

Dykstra, W. 2005a. Review of Special Cholinesterase Studies. DP Barcode: D298913, PC Code: 084001. MRID:46239801 (repeat), 46153302 (main study), 46153301 (preliminary study). TXR 0052375. February 8, 2005.

Dykstra, W. 2005b. Review of Developmental Neurotoxicity Studies. DP Barcode: D305082. PC Code: 084001. MRID: 46153303 (time-course), 45805701, 45805702, 45805703 (acute-adult), 45842301 (acute-preweaning), 46153304 (repeated). TXR 0052712. February 8, 2005.

Dykstra, W. 2005c. Weight of Evidence Comparison of Human and Animal Toxicology Studies and Endpoints for DDVP. DP Barcode: 312212. TXR 0053055. June 23, 2005.

Dykstra, W. 2005d. Re-evaluation of DNT Studies for DDVP-Combined Studies Satisfy Guideline Requirement for Acceptable DNT. DP Barcode: D323156. TXR No. 0053832. Nov. 3, 2005.

Emlay, D.; Rudolph, R. (1977) Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars: Lab Project Number: TR-506. Unpublished study prepared by Zoecon Industries, Inc. 14 p. {OPPTS 875.1500} MRID 45792201.

ExpoSAC, 1998. Science Advisory Council for Exposure, Policy #: 003, Agricultural Default Transfer Coefficients, May 7, 1998.

ExpoSAC, 2001. Science Advisory Council for Exposure, Policy #: 11. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments. February 22, 2001.

ExpoSAC, 2001a. Draft policy on Pet Collar Exposure Assessment, December 13, 2001.

FQPA, 1996. The Food Quality Protection Act. (P.L. 104-170)

Ghali, G. 1993. Dichlorvos (DDVP): Reconsideration of Quantification of Human Risk. Memorandum to G. LaRocca and D. Utterback. July 7, 1993.

Ghali, G. 1997. Dichlorvos (DDVP): Hazard Identification Committee Report. December 19, 1997.
Gledhill, A., 1997. Dichlorvos: A Single Blind, Placebo Controlled, Randomised Study to Investigate the Effects of Multiple Oral Dosing on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers: Lab Project Number: CTL/P/5392: XH6063. Unpublished study prepared by Zeneca Central Toxicology Lab. 52 p. MRID 44248801.

Goh, K.S, S. Edmiston, K.T. Maddy, D.D. Meinders and S Margetich (1986) Dissipation of Dislodgeable Foliar Residue of Chlorpyrifos and Dichlorvos on Turf. Bull. Environ. Contam. Toxicol., 37:27-32.

Hirsch, L.; Lavor, E.M. 1969. Observations on Occupants of Arizona Homes Containing Various Geometric Designs of 20% Vapona Insecticide Resin Strips (Arizona II study). (Unpublished study received Nov 6, 1969 under 0H2477; prepared by Associates in Laboratory Medicine, P.C., submitted by Shell Chemical Co., Washington, D.C.; CDL:221669-AN). MRID 00060486.

Hjelde, T; Mehl, A; Schanke, T; Fonnum, F. 1998. Teratogenic effects of Trichlorfon (metrifonate) on the guinea pig brain. Determination of the effective dose and the sensitive period. Nerochem. Int. 2:469-477.

Hummel S. V. 1998a. Dichlorvos (0804001) Special Review: Response to PD 2/3 and Anticipated Residues for Dichlorvos resulting from the use of Dichlorvos, Naled, and Trichlorfon. April 9, 1998.

Hummel S. V. 1998b. Dichlorvos (084001). Anticipated Residues for Dichlorvos resulting from use of Dichlorvos and Naled. June 15, 1998.

Hummel, S. V. 1998c. Dichlorvos (084001). Product and Residue Chemistry Chapters for the Reregistration Eligibility Document. April 27, 1998.

Hummel S. V. 2000. Dichlorvos (084001). Refined Anticipated Residues and Acute Dietary Exposure and Risk for Residues of Dichlorvos resulting from use of Dichlorvos and Naled. April 7, 2000.

Hummel, S. V., D. Hrdy, M. Sahafayen. 2000. Dichlorvos (084001). Refined Anticipated Residues and Dietary Exposure and Risk for Residues of Dichlorvos resulting from use of Dichlorvos, Trichlorfon, and Naled. June 7, 2000.

Hummel, S. 2005. Dichlorvos (DDVP) HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code: 084001, Case #: 0310, DP Barcode: D302286. January 31, 2005.

Jaeger R. 1989. Transmittal of the Final FIFRA Science Advisory Panel Report on the September 28-29 Meeting. Memo to D. Campt. October 16, 1989.

Jaquith D. 1987a. Exposure Assessment for Dichlorvos. August 4, 1987.

Jaquith D. 1987b. Refinement of Exposure Assessment for Dichlorvos. August 7, 1987.

Jaquith D. 1987c. Further Refinement of Exposure Assessments for Dichlorvos. August 14, 1987.

Jaquith D. 1993a. Revisions to Exposure Assessment for Dichlorvos. April 15, 1993.

Jaquith D. 1993b. Assessment of Exposures of Residents to Dichlorvos Applied as a Total Release Fogger. MRID 41928801. May 10, 1993.

Jaquith D. 1993c. Review of Exposure Monitoring Study for Use of DDVP in Food Processing Establishments, DP Barcode D191571, December 6, 1993.

Jaquith D. 1996. Response to Public Comments on Dichlorvos PD 2/3. June 4, 1996.

Jaquith D. 1998a. Exposures from Dichlorvos (DDVP) Resin Strips. D246131. March 5, 1998.

Jaquith D. 1998b. Re-entry Exposures to Dichlorvos Resulting from Application to Residential Turf and Recreational Areas. D246126. March 16, 1998.

Jaquith D. 1998c. Exposures to Dichlorvos (DDVP) from Flea Collars. March 18, 1998.

Jaquith D. 1998d. Exposure Assessment for Dichlorvos (DDVP) Applied to Greenhouse and Mushroom Houses. April 22, 1998.

Jaquith D. 1998e. Exposure to Dichlorvos resulting from the Use of Bait Products. D246128. April 28, 1998.

Jaquith D. 1998f. Inhalation Exposures from Dichlorvos (DDVP) Resin Strips. June 12, 1998.

Jaquith D. 1998g. Revised Applicator Exposures to Dichlorvos resulting from Crack and Crevice Use and the Use of Aerosol Products. D261140. April 30, 1998.

Jaquith D. 1998h. Revisions of Exposures from Dichlorvos (DDVP) Resin Strips. D250069. September 30, 1998.

Jaquith D. 1998i. Exposures to Dichlorvos Resulting from the Use of Bait Products. D251336. January 27, 1999.

Jaquith D. 1998j. Response to Comments from EXPOSAC on Exposure Assessment for Dichlorvos (DDVP) from Flea Collars. D 246127. November 6, 1998.

Jaquith D. 1998k. Response to EXPOSAC Comments on Exposure Assessment for Total Release Foggers Containing Dichlorvos (DDVP). D251333. December 31, 1998.

Jaquith D. 1998l. Revised Applicator Exposures to Dichlorvos (DDVP) Resulting from Dairy Barn and Animal Spray Uses. D251330. January 27, 1999.

Jaquith D. 1998m. Response to Comments from the EXPOSAC and Others on Assessment of Re-entry Exposures to Dichlorvos Resulting from Application to Residential Turf and Recreation Areas. D251909. January 28, 1998.

Jaquith D. 1998n. Revised Exposure Assessment for Greenhouses and Mushroom Houses. D251337. January 27, 1999.

Jaquith, D. 1999a. Response to Amvac Comments on HED Interim Risk Assessment for DDVP. D255064. March 17, 1999.
\
Jaquith, D. 1999b. Examination of Recent Submissions from Amvac regarding Dichlorvos (DDVP) and Rationale for Not Including Them in the Exposure/Risk Assessment. May 27, 1999.

Jaquith, D., 1999c. Dislodgeable Foliar Residues and Exposure Assessment for Residential/Recreational Turf Applications of Dichlorvos (DDVP), PC Code 084001, Barcodes D248456, D248596, D255253, August 13, 1999.

Jaquith, D., 1999d. Calculation Error - Dichlorvos Resin Strips, D257002, August 16, 1999.

Jaquith, D, 2000. Dichlorvos (DDVP) Resin Strip Exposure Assessment for Individuals Exposed for a 2 Hour Period, PC Code 084001. July 21, 2000.

Jaquith, D., 2000a. Revision of Exposure Assessment for DDVP applied to Warehouses and Food Processing Plants. D226572. June 7, 2000.

Jaquith, D., 2001. Response to Comments on the Preliminary Risk Assessment (PRA) for Dichlorvos (PC Code 084001, DP Barcode D271993). May 31, 2001.

Jaquith, D., 2003. Addendum to Residential Turf Assessment for Dichlorvos (DDVP) PC Code 084001, DP Barcode D288914. March 28, 2003.

Jaquith, D., 2003a. Review of Protocol for Study Monitoring Indoor Air Concentrations of DDVP Using Pest Strips in Confined and Unoccupied Areas. DP Barcode D288575. March 14, 2003.

Jaquith, D., 2005. Exposure Assessment for Workers Applying DDVP to Rail Cars and Stationary Trucks and Subsequently Loading Cargo onto the Treated Vehicles (PC Code 084001, DPBarcode D289191), January 27, 2005.

Johnston, Jason , et al., A Re-analysis of Observations on Occupants of Arizona Homes Containing 20% Vapona Insecticide Resin Strips (Arizona II Home Study):, Exponent, Inc. December 4, 2002. Exponent, Inc. (Washington, D.C.).Laboratory Study No. Dichlorvos 02-01. MRID 45812001. Unpublished.

Jones, R. D., 2006. Qualitative Assessment of Human Exposure to Dichlorvos formed from Trichlorfon through Drinking Water and Inhalation Routes. EPA Memorandum to Dayton Eckerson and Sue Hummel, dated May 17, 2006.

Kent, R. 2001. Use of Human Toxicity Studies on Dichlorvos (DDVP) to Decrease the Interspecies Scaling Factor (PC Code 084001, DP Barcode D278926). TXR: 0050250. November 1, 2001.

Khasawinah, A. and Diwan, S. 1999. Trichlorfon and Dichlorvos (DDVP): Reassessment of the Requirements for the Prenatal Developmental Studies in Guinea Pig - Report of the Hazard Identification Assessment Review Committee. August 10, 1999. HED Document No. 013989. Klonne, D. (1999) Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns: Lab Project Number: OMAOO5: OMAOO1: OMAOO2. Unpublished study prepared by Ricerca, Inc., and Morse Laboratories. 2213 p. (MRID 44972201)

Knox, B.; Askaa, J.; Basse, A.; Bitsch, V.; Mandrup, M.; Ottosen, H.; Overby, E.; Pedersen, K.; Rasmussen, F. 1978. Congenital ataxia and tremor with cerebellar hypoplasia in piglets borne by sows treated with NeguvonR vet. (Metrifonate, Trichlorfon) during pregnancy. Nord. Vet. Med. 30:538-545.

Leighton, T. 2000. HED's Revision of the Trichlorfon Residential Exposure/Risk Assessment. PC Code 057901. DP Barcode D268125. August 9, 2000.

Lewis. P. 1998. Transmittal of the Final Report of the FIFRA Scientific Advisory Panel Meeting Held July 29-30, 1998. Memorandum to M. Mulkey, Director, Office of Pesticide Programs.

Lowit, A. 2006. Benchmark Dose Analysis of cholinesterase inhibition data in neonatal adult rats (MRID 46688914) following exposure to DDVP. June 9, 2006.

Maddy KT, Schneider F, Lowe J, Ochi E, Frederickson S, and Margotich S. 1981. Vapona (DDVP) Exposure Potential to Workers in Mushroom houses in Ventura County, California in 1981. HS-861. As cited in Jaquith 1998d.

Mastalerz, J.W. 1977. The Greenhouse Environment. John Wiley & Sons, New York, Table 2.1, page 14.

Mehl, N.; Schanke, T.; Johnsen, B.; Fonnum, F. 1994. The effect of Trichlorfon and other organophosphates on prenatal brain development in the guinea pig. Neurochem. Res. 19(5):569-574.

Morton, T. 1999. Trichlorfon (057901): Nature of Residue in Livestock(GLN 860.1300), Residue Analytical Method (GLN 860.1340), Storage Stability Data (GLN 860.1380), Magnitude of Residue in Livestock (GLN 860.1480), and Residue Depletion after Dermal Application (GLN 860.1300). DP Barcode # D244279, D254894. Case 0104; MRID Nos. 44500701, 44500702, 44500703, 44500704, 44781401, June 24, 1999.

Morton, T. 2000. Trichlorfon (057901): HED Revised Preliminary Risk Assessment for Trichlorfon. DP Barcode D268728. Case 0104. September 19, 2000.

Nigg, H. N., J. H. Stamper, W. D. Mahon. 1987. Pesticide Exposure to Florida Greenhouse Applicators. Grant No. CR-810743. Sponsored by EPA.

Parker RD, Nelson, HP, and Jones D. 1995. GENEEC: a Screening Model for Pesticide Environmental Exposure Assessment. The International Symposium on Water Quality Monitoring. American Society of Agricultural Engineers. P. 485.

Pope, A.; Heavner, J.; Guarnieri, J; Knobloch, C. 1986. Trichlorfon induced congenital cerebellar hypoplasia in neonatal pigs. JAVMA 189(7):781-783.

Rambo, G. 1987. Personal communication between George Rambo of the National Pest Control Association (NPCA) and David Jaquith of OPP.

REJV, 2002. Residential Exposure Joint Venture, electronic database, study period May 2001 - April 2002.

Reregistration Branch 4, 2002. Dichlorvos Resin Pest Strips - Additional Exposure and Risk Analyses. Addendum to Human Health Risk Assessment. DP Barcode D286338. October 23, 2002.

Rowland J. 1998. Dichlorvos (DDVP) - RE-EVALUATION - Report of the Hazard Identification Assessment Review Committee. June 3, 1998.

Rowland J. 1999. Dichlorvos (DDVP) - RE-EVALUATION - Report of the Hazard Identification Assessment Review Committee. June 2, 1999. HED Document No. 013434

Sahib I. 1998. Drinking Water Assessment for Dichlorvos. March 25, 1998.

Schaible, S. 1994. and Chronic Dietary Exposure Analysis for Dichlorvos. December 2, 1994.

Sette, W. F. 1998a. Dichlorvos (084001): Pathology Working Group Peer Review of 28 day Neurotoxicity Study. April 9, 1998.

Sette, W.F. 1998b. Dichlorvos (084001), Trichlorfon (057901). D237270: Summary Review of Published studies on Metrifonate, a drug metabolized to Dichlorvos, and their relevance to Dichlorvos risk assessment (MRID 44308001). April 10, 1998.

Sette, W. F. 1999a. DDVP (084001): Response to AMVAC letter of 1/19/99 related to EPA's basis for concern for potential developmental neurotoxic effects, and revised HED testing recommendations. D252753. May 3, 1999.

Stewart J. 1993. Review of Human Toxicology Data on Dichlorvos (DDVP). TXR 010157. Memorandum dated April 8, 1993.

Stewart J. 1998. Review of Toxicity Studies on Dichlorvos Using Human Volunteers. March 24, 1998. MRIDs 44317901, 4416201, 44248801, 44248802.

Stewart 1996a. Dichlorvos Special Studies. MRID 42880101, 42881101. May 30, 1996.

Stewart J. 1996b. Review of Supplementary Pathology Data: Staging of Severity of Mononuclear Cell Leukemia observed in Male fisher 344 Rats in the Two Year Carcinogenicity Study. MRID 43565601. June 20, 1996

Stewart J. 1996. Dichlorvos. Transmittal of the Quantitative Risk Assessment and Response to Registrant’s questions concerning Neurotoxicity Study and Cancer Peer Review. October 4, 1996.

Stewart J. and W. Burnam 1996. Fifth Carcinogenicity Peer Review of Dichlorvos. Tox Chem # 328, PC Code 084001. August 28, 1996.

Stewart J. 1997. Toxicology Branch Response to Public Comments on the PD 2/3 for Dichlorvos. April 16, 1997.

Stewart J. 1998. Review of Toxicity Studies on Dichlorvos Using Human Volunteers. March 24, 1998. MRIDs 44317901, 4416201, 44248801, 44248802.

Tarplee B. and Rowland J. 1998. Dichlorvos (DDVP) - Report of the FQPA Safety Factor Committee. June 2, 1998.

Tarplee, B. 2000. Dichlorvos (DDVP) - Reassessment Report of the FQPA Safety Factor Committee. February 23, 2000.

USEPA 1992. Pesticides in Groundwater Database - A Compilation of Monitoring Studies from 1971 to 1991. US Environmental Protection Agency, Office Of Pesticides, Prevention, and Toxic Substances. EPA Document Number 734-12-92-0001.

US EPA 1997. Reregistration Eligibility Decision (RED): Trichlorfon. US Environmental Protection Agency, Office Of Pesticides, Prevention, and Toxic Substances. EPA Document Number 738-R-96-017.

US EPA. 1997a. Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments. December 19, 1997. (See also ExpoSAC, 2001)

US EPA. 1998. FIFRA Scientific Advisory Panel. 7/30/98. A Set of Scientific Issues Being Considered by the Agency in Connection with DDVP (Dichlorvos) Risk Issues. pp 14-26 .

US EPA. 1998a. PHED Surrogate Exposure Guide. Estimate of Worker Exposure from the Pesticide Handlers Exposure Database, Version 1.1. August, 1998.

US EPA, 2000. "Benchmark Dose Technical Guidance Document" Draft report. Risk Assessment Forum, Office of Research and Development, U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-00/001

US EPA 2001. Preliminary OP Cumulative Risk Assessment. December 3, 2001. http://www.epa.gov/pesticides/cumulative/pra-op/

US EPA, 2002. Methods Used to Conduct a Preliminary Cumulative Risk Assessment for Organophosphate Pesticides. Report from the FIFRA Scientific Advisory Panel Meeting of February 5-7, 2002 (Report dated March 19, 2002). SAP Report 2002-01. http://www.epa.gov/scipoly/sap/index.htm#june.

US EPA 2002a. Revised Organophosphorus Pesticide Cumulative Risk Assessment. Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington, DC. June 10, 2002. http://www.epa.gov/pesticides/cumulative/rra-op/

Appendices

1.0 TOXICOLOGY DATA REQUIREMENTS

The toxicology data requirements (40 CFR 158.340) for food uses for dichlorvos are in Table 1. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

Test	Technical	
	Required	Satisfied
870.1100 Oral Toxicity	yes	yes
870.1200 Dermal Toxicity	yes	yes
870.1300 Inhalation Toxicity	yes	yes
870.2400 Primary Eye Irritation	yes	yes
870.2500 Primary Dermal Irritation	yes	yes
870.2600 Dermal Sensitization	yes	yes
870.3100 Oral Subchronic (rodent)	yes	yes
870.3150 Oral Subchronic (nonrodent)	yes	yes[a]
870.3200 21-Day Dermal	no	
870.3250 90-Day Dermal	no	
870.3465 90-Day Inhalation	yes	yes
870.3700a Developmental Toxicity (rodent)	yes	yes
870.3700b Developmental Toxicity (nonrodent)	yes	yes
870.3800 Reproduction	yes	yes
870.4100a Chronic Toxicity (rodent)	yes	yes[b]
870.4100b Chronic Toxicity (nonrodent)	yes	yes
870.4200a Oncogenicity (rat)	yes	yes[b]
870.4200b Oncogenicity (mouse)	yes	yes
870.4300 Chronic/Oncogenicity	yes	yes
870.5100 Mutagenicity—Gene Mutation - bacterial	yes	yes
870.5300 Mutagenicity—Gene Mutation - mammalian	yes	yes
870.5xxx Mutagenicity—Structural Chromosomal Aberrations	yes	yes
870.5xxx Mutagenicity—Other Genotoxic Effects	yes	yes
870.6100a Delayed Neurotox. (hen)	yes	yes
870.6100b 90-Day Neurotoxicity (hen)	no	
870.6200a Neurotox. Screening Battery (rat)	yes	yes
870.6200b 90 Day Neuro. Screening Battery (rat)	yes	yes
870.6300 Developmental Neurotoxicity	yes	yes
870.7485 General Metabolism	yes	yes
870.7600 Dermal Penetration	yes	yes
Special Studies for Ocular Effects		
Oral (rat)	no	
Subchronic Oral (rat)	no	
Six-month Oral (dog)	no	

a = subchronic (oral) dog study is satisfied by chronic dog study
b = chronic toxicity in rats and oncogenicity in rats are satisfied by chronic toxicity/carcinogenicity rat study

2.0 REFERENCES FOR TOXICOLOGY STUDIES

Alternative Selection for Acute RfD:

Study Selected: Acute Cholinesterase Study - Humans Non-guideline

MRID: 44248802

Title: Dichlorvos: A Study to Investigate the Effect of a Single Oral Dose on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers; Gledhill, AJ; March 25, 1997

Executive Summary: Dichlorvos was administered in a single oral dose of 70 mg (equivalent to 1 mg/kg bw) in corn oil by capsule to fasted young healthy male volunteers. Prior to dosing, baseline RBC cholinesterase activity was measured on study days -22, -20, -18, -15, -13, -11, -8, -6, -4 and immediately prior to dosing. The study subjects were medically supervised for clinical signs and body temperature changes for 24 hours and for RBC cholinesterase inhibition for up to fourteen days after administration of the DDVP capsules. Plasma cholinesterase was not measured in this study.

Under study conditions, no adverse clinical signs or changes in body temperature were reported. When the group mean RBC cholinesterase activities were analyzed, there were statistically significant reductions ($p \leq 0.01$) from the predose mean on days 5/6, day 7, and day 14. These statistically significant reductions represent percent decreases of 10, 12, and 11%, respectively. No reduction in RBC cholinesterase activity was apparent at other reporting periods. The individual predose values used to calculate the mean RBC cholinesterase activity varied by 17% for volunteer 1, 16% for volunteer 2, 6% for volunteer 3, 10% for volunteer 4, 7% for volunteer 5, and 9% for volunteer 6.

The NOAEL for RBC cholinesterase depression is 1.0 mg/kg bw and a LOAEL was not established in the study.

Although the study results indicate that a significant decrease in mean RBC cholinesterase was first observed at 5/6 days after treatment, with significance also seen at 7 and 14 days posttreatment, measurements at posttreatment days 1 and 3 were not significantly different from baseline. These results are inconsistent with known information on the chemical. Namely, given the rapid bioavailability and metabolism of dichlorvos, it is unlikely that a significant decrease in RBC cholinesterase would first be observed at day 5/6 posttreatment and not also at days 1 and 3 posttreatment. The statistical significance observed could be attributed to variation among individual participants.

Lack of information on time of peak effect.

In the acute human study, the first cholinesterase measurement was recorded 24 hours after dosing. In the study (MRID 46153303) on the measurement of RBC and brain ChE activity in pre-weaning and adult female rats treated with a single dose of 15 mg/kg dichlorvos, time-course data

demonstrate that the time of peak effect for both RBC and brain ChE measurements is 1-3 hours post-dosing. Therefore, the absence of biologically significant RBC ChE depression in the human study may be due to the absence of blood sampling at the time of peak effect (1-3 hours), since in the human study, the first measurement did not occur until 24 hours after dosing.

Based on the information on time to peak effect, we conclude that the lack of cholinesterase measurements prior to 24 hours post-treatment in the acute human study may have influenced the apparent NOAEL. We have therefore opted not to use the acute human study for regulatory purposes.

CITATION: G. Milburn (2003) Dichlorvos: developmental neurotoxicity study in rats. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. Laboratory report number CTL/RR0886/Regulatory/Report, November 10, 2003. MRID 46153302. Unpublished.

G. Milburn (2003) Dichlorvos: preliminary developmental neurotoxicity study in rats. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. Laboratory report number CTL/RR00885/Regulatory/Report, October 13, 2003. MRID 46153301. Unpublished.

SPONSOR: Amvac Chemical Corporation.

EXECUTIVE SUMMARY:

In a developmental neurotoxicity study (2003, MRID 46153302, study RR0886) Dichlorvos (99.0% a.i., batch #ST120700) was administered to 30 time-mated female Alpk:APfSD (Wistar-derived) rats per group by gavage in de-ionized water at dose levels of 0, 0.1, 1.0, or 7.5 mg/kg bw/day from gestation day (GD) 7 through postnatal day (PND) 7 and direct treatment of the F1 offspring was carried out during PND 8-22, inclusive. On PND 5, litters were culled to 8 pups (4/sex as closely as possible), and litters containing fewer than 7 pups and/or fewer than 3 pups of each sex were removed from the study. The dams were subjected to a functional observational battery (FOB) on GDs 10 and 17 and on PNDs 2 and 9. The F1 offspring were observed for attainment of preputial separation or vaginal patency. Animals were allocated from within litters for use in the following investigations: functional observational battery assessments (PNDs 5, 12, 22, 36, 46, and 61); locomotor activity assessment (PNDs 14, 18, 22, and 60); auditory startle habituation (PNDs 23 and 61), water maze testing (PND 24-27 or PND 59-62); and post mortem investigations including brain weight, neuropathology, and morphometry (PNDs 12 and 63). Dosing was based on a preliminary developmental neurotoxicity study in rats (MRID 46153301).

One high-dose female was sacrificed on LD 3 due to clinical signs (pallor, piloerection, and slightly hunched posture and thin appearance) and had a pale liver at necropsy. One mid-dose female died on GD 24 due to parturition difficulties. There were no treatment-related effects on maternal body weight, FOB parameters, or gestation length. The maternal NOAEL is 7.5 mg/kg/day, the highest dose tested. A maternal LOAEL was not established.

During LD 1-5, the control, low-, mid-, and high-dose groups, respectively, had pup mortality of 22.6, 17.4, 17.5, and 28.1%, and there were total litter losses of 20.0, 10.0, 17.9, and 18.5% of the litters in these same respective groups. There were 2 total litter resorptions in the high-dose group. The number of litters available which were used for F1 offspring was 23, 21, 21, and 14 and the viability indices were 77.4, 82.6, 82.5, and 69.0% for the control, low, mid, and high dose groups, respectively.

Due to the low number of pups available in the high dose group, it was necessary to combine this study (RR0886) with a repeat study (2004, MRID 46239801; study No. RR0988) consisting of controls and a dose level of 7.5 mg/kg in order to have sufficient pups for all assessments.

The DNT Committee determined that the two DNT studies combined (RR0886 and RR0988) had acceptable numbers of total pups examined in the controls and high dose groups (> 35 pups/sex examined in combined studies) and, therefore, the developmental results of the combined studies could be evaluated for the NOAEL/LOAEL. The classification of the studies taken together was changed from unacceptable/non-guideline to Acceptable/non-guideline. A comparison of the developmental findings showed that the auditory startle reflex habituation Vmax in PND 23 high dose males in study RR0886 had statistically significant increases (37-49%) in 4 out of 5 blocks and study RR0988 had increases (7-15%), although not statistically significant, in this same Vmax parameter in PND 23 high dose males in 5 out of 5 blocks in comparison to controls for each study.

Therefore, the developmental/offspring NOAEL was determined to be 1.0 mg/kg/day (based on study RR0886) and the developmental/offspring LOAEL was 7.5 mg/kg/day (based on both studies RR0886 and RR0988) with the effect being increases in auditory startle reflex habituation Vmax in PND 23 high dose males in both studies.

This study when combined with the accompanying study is classified Acceptable/non-guideline and may be used for regulatory purposes. It does satisfy the guideline requirement for a developmental neurotoxicity study in rats [OPPTS 870.6300, §83-6; OECD 426 (draft)], pending review of the positive control data.

CITATION: G.M. Milburn (2004) Dichlorvos: supplemental developmental neurotoxicity study in rats. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK SK10 4TJ. Laboratory report number CTL/RR0988/Regulatory/Report, January 28, 2004. MRID 46239801. Unpublished.

SPONSOR: Amvac Chemical Corporation.

EXECUTIVE SUMMARY: In a preliminary developmental neurotoxicity study (MRID 46153301) Dichlorvos (99.0% a.i., batch #ST120700) was administered by gavage in de-ionized water to 15 time-mated female Alpk:APfSD (Wistar-derived) rats per dose at dose levels of 0, 0.1, 1.0, or 7.5 mg/kg bw/day from gestation day (GD) 7 through postnatal day (PND) 22. In-life observations included maternal clinical signs, body weight, and food consumption (during gestation) and the number, survival, clinical signs, and body weight of the pups. Erythrocyte (RBC) and whole brain acetylcholinesterase (AChE) activities were measured as follows: in 5 dams/group

on GD 22; in 5 dams/group on PND 22; in selected fetuses from the dams killed on GD 22 (blood from sufficient fetuses to attain adequate pooled sample volume and whole brain from 4 fetuses/sex/litter); and in 5 pups/sex/group (1 per litter where possible) on each of PNDs 2, 8, 15, and 22. Plasma AChE activity was not measured.

There were no maternal deaths during the study. Three dams had abnormal clinical signs: one control dam with piloerection on day 26; one mid-dose dam with observations of paleness (days 24-26), hunched, subdued behavior (day 26), and a total litter loss by day 26 (LD 3); and one high-dose dam with irregular breathing on days 25-27. There were no treatment-related effects on maternal food consumption, maternal body weight, or gestation length. The study author mentioned body weight decreases in high-dose dams beginning on LD 11, but these were of insufficient magnitude to be considered biologically significant (just 3-4% less than controls). Under the conditions of this study, the LOAEL for maternal systemic toxicity (other than acetylcholinesterase inhibition) is not identified, and the NOAEL is greater than or equal to 7.5 mg/kg bw/day.

There were no treatment-related effects on the overall proportion of pups born alive, the mean percentage of live pups per litter, or live litter size on LD 1. Pup survival, body weight, and clinical signs were unaffected by treatment. Two dams had total litter losses: one mid-dose dam had a total litter loss by LD 3, and one low-dose dam had a total litter loss (of 1 pup) by LD 2. An increased proportion of male pups in the mid-dose group (64.8% vs. 46.2% for controls; $p<0.01$) was considered incidental to treatment because there was no similar finding at the highest dose level. Under the conditions of this study, the LOAEL for offspring toxicity (other than acetylcholinesterase inhibition) is not identified, and the NOAEL is greater than or equal to 7.5 mg/kg bw/day.

In maternal animals, RBC AChE activity was biologically significantly inhibited at the mid- and high-dose treatment levels on GD 22 by 25% and 48%, respectively ($p<0.01$) and on LD 22 by 24% and 50%, respectively ($p<0.05$ and $p<0.01$). RBC AChE activity was also inhibited in high-dose male and female (GD 22) fetuses by 28% ($p<0.5$) [$p<0.05$] and 21% (n.s.), respectively. There were no treatment-related effects on RBC AChE activity in male or female pups. The LOAEL for dichlorvos erythrocyte acetylcholinesterase inhibition in maternal rats is 1.0 mg/kg bw/day, with a NOAEL of 0.1 mg/kg bw/day. The LOAEL for erythrocyte acetylcholinesterase inhibition in offspring or fetuses is 7.5 mg/kg bw/day (based on male and female fetuses on GD 22), and the NOAEL is 1.0 mg/kg bw/day.

In maternal animals, whole brain AChE activity was biologically significantly inhibited in high-dose animals on GD 22 and LD 22 by 59% and 67%, respectively ($p<0.01$). Brain AChE activity was also inhibited in high-dose male and female (GD 22) fetuses by 16% ($p<0.5$) [$p<0.05$] and 21%, respectively ($p<0.01$). There were no treatment-related effects on brain AChE activity in male or female pups. The LOAEL for brain acetylcholinesterase inhibition in maternal animals is 7.5 mg/kg bw/day, with a NOAEL of 1.0 mg/kg bw/day. The LOAEL for brain acetylcholinesterase inhibition in offspring or fetuses is 7.5 mg/kg bw/day (based on male and female fetuses on GD 22), and the NOAEL is 1.0 mg/kg bw/day.

Based on the results of this study, dose levels of 0, 0.1, 1.0, and 7.5 mg/kg bw/day were chosen for the main study.

CITATION: **Milburn, G.M.. (2003) Dichlorvos: time course of cholinesterase inhibition in pre-weaning and adult rats. Central Toxicology Laboratory, Cheshire, UK SK10 4TJ. Doc. No. CTL/AR7310/Regulatory/Report. 26-SEPT-2003. MRID 46153303. Unpublished.**

Twomey, K. (2002) Dichlorvos (DDVP): Acute cholinesterase inhibition study in rats. Central Toxicology Laboratory, Cheshire, UK SK104T3. Laboratory report number CTL/AR7079/SUM/Regulatory/Report; Study No. AR7079, 30-MAY-2002. MRID 45805701. Unpublished.

Twomey, K. (2002) Dichlorvos (DDVP): Second acute cholinesterase inhibition study in rats. Central Toxicology Laboratory, Cheshire, UK SK104TJ. Laboratory report number CTL/AR7126/SUM/Regulatory/Report; Study No. AR7126, 19-JUNE-2002. MRID 45805702. Unpublished.

Twomey, K. (2002) Dichlorvos (DDVP): Third acute cholinesterase inhibition study in rats. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK SK104TJ. Laboratory report number CTL/AR7138/Regulatory/Report; Study No. AR7138, 26-JUNE-2002. MRID 45805703. Unpublished.

Moxon, M.E. (2002) Dichlorvos: Acute cholinesterase inhibition study in pre-weaning rats. Central Toxicology Laboratory, Cheshire, UK SK104T3. Laboratory report number CTL/AR7147/Regulatory/Report; Study No. AR7147, 22-NOV-2002. MRID 45842301. Unpublished.

Moxon, M.E. (2003) Dichlorvos: Repeat dose cholinesterase inhibition study in pre-weaning and young adult rats. Central Toxicology Laboratory, Cheshire, UK SK104TJ. Laboratory report number CTL/KR1490/Regulatory/Report; Study No. KR1490, 24-OCT-2002. MRID 46153304. Unpublished.

SPONSOR: **AMVAC, Los Angeles, CA**

EXECUTIVE SUMMARY: In a series of special comparative cholinesterase inhibition (ChEI) studies, Dichlorvos (DDVP; 99% a.i., lot #ST 120700) was administered by gavage to groups of either Sprague-Dawley or Wistar rats. For time-course evaluation (MRID 46153303) 5 females/group were given a single oral dose of 0 or 15 mg/kg on PND 15 or 42 and sacrificed 1, 3, 8, 24, or 72 hours later. In three acute studies (MRIDs 45805701, 45805702, 45805703) groups of 5 adult rats/sex were given a single oral dose of 0, 1, 5, 15, or 35 mg/kg and sacrificed one hour post-dosing or on post-dosing days 8 and 15. In a fourth acute study, groups of 5 pre-weaning rats/sex were given a single oral dose of 0, 1, 5, or 15 mg/kg on PND 8, 15, or 22 and terminated one hour post-dosing. Finally repeated administration was studied by giving seven daily doses of 0, 0.1, 7.5, or 15 mg/kg/day to groups of 5 rats/sex beginning on either PND 12 or 42; animals were

sacrificed one hour after the last dose. RBC and brain ChE activities were measured in all animals in each study. Plasma enzyme activity was not measured in any study.

Based on the analytical data for MRID 45805701, the low-dose animals were actually dosed with 2.1 mg/kg, rather than the desired dose of 1.0 mg/kg/day. For the remaining studies, the analytical data indicated that the mixing procedure was adequate and that the difference between nominal and actual dosage to the study animals was acceptable for all studies.

At a single dose of 35 mg/kg, one female died with cholinergic signs and four males were killed for humane reasons due to severe toxicity. The remaining animals of both sexes given 35 mg/kg displayed some or all of the following signs: decreased activity, lachrymation, miosis, irregular breathing, clonic convulsions, tremors/fasciculations, prostration, decreased righting and splay reflexes, and salivation. A single dose of 15 mg/kg resulted in miosis and fasciculations in one adult female, and tremors in one male and one female on PND 8 and one female on PND 22. No treatment related clinical signs were observed in animals of the 1 or 5 mg/kg dose groups following acute exposure.

Following repeated exposure of pre-weaning rats, tremors were observed in 5/5 males and 5/5 females at 15 mg/kg/day on 3-5 days of the dosing interval. In young adult rats at 15 mg/kg/day, tremors were observed in 3/5 males and 5/5 females on one to four days of the dosing interval. In addition, tremors were seen in one adult male after the last dose of 7.5 mg/kg/day. No clinical signs of toxicity were observed in the remaining groups.

Acute exposure to doses ≥5 mg/kg resulted in clear dose-related inhibition of enzyme activity in both compartments in all groups. At 1 mg/kg, RBC enzyme activity was significantly inhibited in PND 8 females, and PND 15 males and females, but not adults. Brain enzyme activity from animals treated with 1 mg/kg was not significantly inhibited in adult or pre-weaning males and females. Although there was inhibition of brain enzyme activity at the low dose in MRID 45805701, the actual analytical dose at this level was 2.1 mg/kg and not 1 mg/kg. Repeat of the 1 mg/kg dose level was identified as a NOAEL for brain enzyme inhibition as demonstrated in other acute studies.

Two studies included recovery groups held for up to 15 days post-exposure. RBC enzyme activity of males and females treated with 35 mg/kg remained slightly inhibited by 9-15% at 8 days after exposure. This is not considered biologically significant. No inhibition of RBC enzyme activity was seen at any other dose at 8 or 15 days post-dosing. Brain enzyme activity was not affected at any dose during the recovery interval. Brain and RBC enzyme activities were maximally inhibited one hour after dosing in both adult and pre-weaning female rats. Thereafter, ChE inhibition in both compartments decreased to approximately control levels by 8 hours post-dosing.

Dose-related inhibition of RBC and brain ChE activities was also apparent after repeated dosing in both adult and pre-weaning rats. Biologically significant inhibition of RBC enzyme activity (>50%) occurred at doses of 7.5 and 15 mg/kg/day in both sexes of adults and pre-weaning and at the low dose for adult animals (11-17%). Brain enzyme activity was statistically and biologically inhibited in both sexes at doses of 7.5 and 15 mg/kg/day for adults (>50%) and at all doses for pups (>20%).

For acute exposure:

the adult LOAEL for brain ChEI is 5 mg/kg for males and females
the adult NOAEL for brain ChEI is 1 mg/kg for males and females;

the offspring LOAEL for brain ChEI is 5 mg/kg (both sexes)
the offspring NOAEL for brain ChEI is 1 mg/kg (both sexes)

the adult LOAEL for red blood cell ChEI is 5 mg/kg (both sexes)
the adult NOAEL for red blood cell ChEI is 1 mg/kg (both sexes);

the offspring LOAEL for red blood cell ChEI is 1 mg/kg (both sexes)
the offspring NOAEL for red blood cell ChEI is not identified.

For acute exposure, the overall adult LOAEL for cholinesterase inhibition in rats is 5 mg/kg based on enzyme inhibition in brain and red blood cells; the adult NOAEL is 1 mg/kg.

For acute exposure, the overall offspring LOAEL for cholinesterase inhibition in rats is 1 mg/kg based on enzyme inhibition in red blood cells; the offspring NOAEL was not identified.

For repeated exposure:

the adult LOAEL for brain ChEI is 7.5 mg/kg/day (both sexes)
the adult NOAEL for brain ChEI is 0.1 mg/kg/day;

the offspring LOAEL for brain ChEI is 0.1 mg/kg/day (both sexes)
the offspring NOAEL for brain ChEI is not identified;

the adult LOAEL for red blood cell ChEI is 0.1 mg/kg/day (both sexes)
the adult NOAEL for red blood cell ChEI is not identified;

the offspring LOAEL for red blood cell ChEI is 7.5 mg/kg/day (both sexes)
the offspring NOAEL for red blood cell ChEI is 0.1 mg/kg/day;

For repeated exposure, the overall adult LOAEL for cholinesterase inhibition in rats is 0.1 mg/kg/day based on enzyme inhibition in red blood cells; the adult NOAEL is not identified.

For repeated exposure, the overall offspring LOAEL for cholinesterase inhibition in rats is 0.1 mg/kg/day based on enzyme inhibition in brain; the offspring NOAEL is not identified.

The cholinesterase activity measurements following an acute oral dose of dichlorvos demonstrate approximately equal susceptibility between juvenile and adult rats. In contrast, results from repeated exposures show that juvenile rats are more susceptible than adults for brain ChEI. In pups the brain ChE activity appeared to be more sensitive than RBC enzyme activity. This susceptibility for brain cholinesterase was observed in terms of the dose level at which an effect was observed

(i.e., the LOAEL for brain cholinesterase inhibition was lower for juveniles than for adults). However, the LOAEL for RBC enzyme inhibition was lower for adults than for juvenile rats. The fact that brain enzyme activity in young animals was the most sensitive to inhibition by the test article is of concern for potential developmental neurotoxicity.

Taken together these studies are classified Acceptable/Non-guideline for the determination of RBC and brain cholinesterase activities following treatment with dichlorvos in adult and juvenile rats. Main deficiencies include omission of plasma measurements and lack of assessment in dams and fetuses on GD 20.

870.6100 (81-7) Acute Delayed Neurotoxicity - Hen. MRID 41004702

CITATION: Beavers, J.; Driscoll, C.; Dukes, V.; et al. (1988) DDVP: An Acute Delayed Neurotoxicity Study in Chickens: Final Report: Project No. 246-103. Unpublished study prepared by Wildlife International Ltd. 86 p. (MRID 41004702

EXECUTIVE SUMMARY: In an acceptable acute delayed neurotoxicity study (MRID 41004702), groups of ten chickens were exposed either to vehicle (distilled water), DDVP at 16.5 mg/kg, or the positive control, Tri-*o*-tolyl Phosphate (TOCP), at 600 mg/kg in corn oil. All birds treated with DDVP were administered an intramuscular injection of atropine sulfate at 5 mg/kg concurrent with DDVP dosing (the oral LD_{50} value of DDVP in chickens not administered atropine is reported at 16.15 mg/kg); atropine also was administered at 2 mg/kg on an individual basis as needed to DDVP-treated birds.

After 21 days, DDVP-treatment and vehicle control birds were redosed (with atropine treatment as previously) and observed for an additional 21 days before sacrifice. TOCP-treated birds were sacrificed 21 days after the initial dose.

During the first forced locomotor activity evaluation on day 3, two hens (G30 and G37) of the DDVP-treated group displayed slight to moderate ataxia, and refused to walk or perform the second walk. By day 7 (the second evaluation) hen G37 was noted as being slightly ataxic when dropped, appeared normal during the hop, but refused to walk alone. This bird appeared normal when standing or walking in a group, but refused to move when alone; this hen continued to refuse to walk alone at each evaluation except for day 25. On days 36 and 39, the same hen also refused to hop. However, when observed in a group, this bird did not appear ataxic, and appeared to move in a normal manner.

On histopathological examination, bird G37 showed swelling of the axis cylinder and nerve fiber degeneration in the sciatic nerve. Nerves from 5/10 positive control (TOCP-treated) hens showed evidence of peripheral neuropathy, while those from 5/10 hens showed no significant neural degenerative lesions; however, 3/5 of these hens had exhibited slight to moderate ataxia during locomotor assessments. In summary, there were no brain or spinal cord degenerative changes in any of the control, TOC, or DDVP-treated groups. However, there were sciatic nerve degenerative changes in 0/10, 5/10, and 1/10 in the negative control, TOCP, and DDVP groups, respectively.

Although the authors considered the results equivocal, the findings have been interpreted by HED as indicating a positive result for DDVP for acute delayed neurotoxicity.

870.3100 (82-1) 13-Week Gavage Study in Sprague-Dawley Rats - MRID 41004701

CITATION: Kleeman, J. (1988) 13-Week Gavage Toxicity Study with DDVP in Rats: Final Report: Project ID: HLA 6274-102. Unpublished study pre- pared by Hazleton Laboratories America, Inc. 294 p. MRID 41004701.

EXECUTIVE SUMMARY: In an acceptable 13-week subchronic study (MRID 41004701), Crl:CD^{R}(SD)BR rats, 10/sex/group, were gavaged with 0, 0.1, 1.5 or 15 mg DDVP/kg/day, 5 days/week, "for at least 13 weeks." The following (Table 5) summarizes possible effects:

Table 5.

Effect	Controls		0.1 mg DDVP/kg/day		1.5 mg DDVP/kg/day		15 mg DDVP/kg/day	
	M	F	M	F	M	F	M	F
Reduced RBC count, hemoglobin & hematocrit Week 14	-	-	-	-	+	-	+	+
Higher Mean Corpuscular Volume	-	-	-	-	-	-	-	+
Higher Cholesterol	-	-	-	-	-	-	+	-
Reduced Plasma ChE								
Week 7	-	-	-	-	+	+	+	+
Week 14	-	-	-	-	+	+	+	+
Reduced RBC ChE								
Week 7	-	-	-	-	+	+	+	+
Week 14	-	-	-	+	+	+	+	+
Reduced Brain ChE (termination)	-	-	-	-	-	-	+	+

In addition, salivation and/or urine stains were noted in some high-dose males and females at approximately 30 to 60 minutes post-dosing. According to Table 12 (p. 52) of MRID 41004701, at terminal sacrifice 2/10 high-dose and 1/10 low-dose females (but no control females) had generalized retinal atrophy. On page 79 "unilateral retinal degeneration" occurred in 1/9 control females, 1/10 in the low-dose group, 0/10 in the mid-dose, and 2/10 in the high-dose. Males in the high-dose group had a noticeably (but not significantly) elevated mean liver weight at termination (14.14 g vs. a control value of 12.46 g). However, the mean liver-to-body weight ratio was significantly ($p \leq 0.05$) elevated (to a value of 0.0293 vs. a control value of 0.0267).

The following mean plasma and RBC cholinesterase measurements were obtained for weeks 7 and 14:

Table 6.

	Males (Week 7)		Females (Week 7)	
Dosage Level (mg/kg/day)	Plasma ChE mu/mL Mean (S.D.)	RBC ChE mu/mL Mean (S.D.)	Plasma ChE mu/mL Mean (S.D.)	RBC ChE mu/mL Mean (S.D.)
0	318 (67.3)	1195 (163.1)	813 (326.2)	1269 (246.9)
0.1	285 (32.0)	1166 (244.3)	933 (382.1)	1148 (125.9)
1.5	226*(48.5)	903*(138.0)	692 (89.7)	956*(145.8)
15	112*(24.2)	629*(109.3)	338*(79.0)	740*(95.4)

*Reported as statistically significant, with $p \leq 0.05$.
Data are from Tables 13 and 14, p. 53 and 54 of MRID 41004701.

Table 7.

	Males (Week 14)		Females (Week 14)	
Dosage Level (mg/kg/day)	Plasma ChE mu/mL Mean (S.D.)	RBC ChE mu/mL Mean (S.D.)	Plasma ChE mu/mL Mean (S.D.)	RBC ChE mu/mL Mean (S.D.)
0	314 (56.7)	1358 (145.5)	1091 (462.0)	1321 (82.3)
0.1	282 (59.9)	1247 (113.9)	1150 (485.2)	1212*(81.4)
1.5	259 (69.9)	1014* (62.6)	1020 (257.0)	1002*(81.5)
15	204*(45.1)	787*(103.6)	575*(142.2)	874*(86.8)

*Reported as statistically significant, with $p \leq 0.05$.
Data are from Tables 13 and 14, p. 53 and 54 of MRID 41004701.

According to MRID 41004701 (p. 29): "The apparent decrease of inhibitory effect at week 14 [as compared to week 7] may have been due to a longer post-treatment interval before blood collection and partial recovery of cholinesterase activity."

The following mean brain cholinesterase measurements were obtained at termination:

Table 8.

Dosage Level (mg/kg/day)	Males Brain ChE mu/mL Mean (S.D.)	Females Brain ChE mu/mL Mean (S.D.)
0	1105 (376.6)	1338 (490.0)
0.1	1213 (656.4)	1290 (376.2)
1.5	1060 (183.2)	1290 (336.5)
15	791*(290.0)	680*(216.6)

*Reported as statistically significant, with $p \leq 0.05$.

In the review [HED Doc. No. 007448] it is stated that: "The data presented demonstrate that administration of DDVP at doses of 0, 0.1, 1.5 and 15 mg/kg[/day] resulted in no adverse effect on body weight or food consumption. Although hematology parameters were reduced, it is doubtful whether the reductions were biologically significant, because the reductions were within ten percent of control values. Plasma and RBC cholinesterase activity [sic] were reduced in mid and high dose animals, and RBC cholinesterase activity was reduced in 0.1 mg/kg[/day] females at 14 weeks. However, the investigators did not consider the RBC cholinesterase reduction in low dose females to be biologically significant since it was less than ten percent below control. The reduction of brain cholinesterase activity in high dose male and female rats at study termination was biologically significant."

"No other changes were seen in the test animals which could be attributed to administration of the test compound. The increased liver/body [weight] ratio seen in high dose males was not accompanied by any body weight or enzyme changes."

The data presented support a LOAEL of 1.5 mg/kg[/day] based on cholinesterase inhibition (plasma and RBC in females and RBC in males). The NOAEL is 0.1 mg/kg[/day]. A NOAEL of 1.5 mg/kg/day may be defined based on decreased brain cholinesterase activity in both sexes.

870.6100 (82-5) Subchronic Neurotoxicity Study in Hens - MRID 43433501

CITATION: Redgrave, V. (1994) DDVP: 28-Day Neurotoxicity in the Domestic Hen: Lab Project Number: AVC 1/921405: RAD 2/942053. Unpublished study prepared by Huntingdon Research Centre, Ltd. 465 p. MRID 43433501.

EXECUTIVE SUMMARY: Groups of 21 adult domestic hens were given oral daily doses by gavage of 0, 0.3, 1.0, or 3.0 mg DDVP/kg in distilled water. Fourteen birds from each group were treated for 28 days; an interim sacrifice of 6 birds/group was performed on day 49 and the final sacrifice of 6 birds/ group was performed on day 77. Satellite groups of three birds from each

original group of 21 were sacrificed on day 4 and day 30 for brain cholinesterase and brain and spinal cord neurotoxic esterase activity. An additional group of four birds was administered 0.1 mg DDVP/kg for 28 days for cholinesterase determination only. A positive control group of 21 hens was administered 7.5 mg TOCP/kg, and sacrificed as described above.

Mortality occurred in 1 bird in the 1.0 mg/kg dose group and in 4 birds in the 3.0 mg/kg dose group. Subdued behavior, unsteadiness, and vomiting were observed in the 3.0 mg/kg group shortly after dosing from day 4 to day 29. Clinical signs were also observed in 2 birds after dosing with 1.0 mg/kg on days 2 and 14. No delayed motor ataxia was observes, and there was no clear evidence of organophosphate induced delayed neuropathy. Decreased body weight was observed during the first 14 days of dosing at 1.0 and 3.0 mg/kg, but compensatory increases occurred from day 14 onward. Brain cholinesterase activity was decreased at day 4 in the 1.0 mg/kg and 3.0 mg/kg dose groups (44% and 63% decrease, respectively, compared to controls); and, at day 30, brain cholinesterase was dose-dependently decreased by 26%, 34%, and 54% in the 0.3, 1.0, and 3.0 mg/kg dose groups, respectively. A slight increase in minimal axonal degeneration was observed at 1.0 and 3.0 mg/kg. The positive control responded appropriately.

A LOAEL of 0.3 mg/kg can be defined based on decreased brain cholinesterase activity. The NOAEL is 0.1 mg/kg/day. A NOAEL of 0.3 mg/kg is defined based on axonal degeneration of more than one level of the spinal cord at 1.0 mg/kg and above of DDVP.
This study meets the guideline requirements of 82-5 and is classified as Acceptable.

870.3200 (83-2a) Two Year Gavage Study in F344 Rats. NTP TR 342, MRID 40299401

CITATION: Chan, P. (1987) NTP Technical Report on the Toxicology and Carcinogenesis Studies of Dichlorvos (CAS No. 62-73-7) in F344/N Rats and B63F1 Mice: (Gavage Studies): NTP TR 342. Draft Technical Report of July, 1987 prepared for public review and comment. US Dept. of Health and Human Services, Public Health Service, Publication No. NIH 88-2598. 239 p. MRID 40299401.

EXECUTIVE SUMMARY: In an oncogenicity gavage study (MRID 40299401), 4 or 8 mg/kg/day dichlorvos (DDVP) (97.8-98.2% a.i., lot SDC-092179, batch 01) in corn oil (Mazola® "100% pure") was administered as 5 mL/kg to 60 F344 rats/sex/dose 5 days/week for 103 weeks followed by a one-week observation period. The controls received corn oil only. Five rats/sex/dose were used only for plasma and RBC cholinesterase (ChE) determination after 6, 12, 24, 36, 52, 78, and 104 weeks and 5 rats/sex/dose were used for brain and sciatic nerve histology at study termination. The doses employed were based on results of a 13-week subchronic study where 10 rats/sex/dose were given 0, 2, 4, 8, 16, 32, or 64 mg/kg/day DDVP. All rats given 32 or 64 mg/kg/day and some rats given 16 mg/kg/day had tremors, diarrhea, and convulsions and died during the study, whereas the surviving rats had no clinical signs or weight loss.

Mortality and weekly body weight gains were similar in treated and control animals. Clinical signs among treated males included brown fur around the nose, mouth, and anal areas, leaning head, and diarrhea, and among treated females included vaginal discharge, wet fur in peri-anal or pelvic area, and diarrhea. From 6-78 weeks, plasma ChE levels in the 4 and 8 mg/kg/day treated groups were lower than the respective control levels by 52-72% and 53-72% in males and by 75-85% and 82-

88% in females, respectively. At 104 weeks, plasma ChE among treated groups of both sexes were only 4-18% below controls, perhaps due to the intervening week without treatment. RBC ChE levels were more variable: values were decreased (13-65%) in both dose group females for weeks 6-78 and in the high-dose males (17-90%) for weeks 24-104, but in the low-dose males were decreased (34-49%) only for weeks 36-78. Treatment time did not appear to be directly related to ChE inhibition. No gross lesions were found in the control or treated animals. The incidences of hepatic cytoplasmic vacuolation, renal tubule mineralization, and adrenal cortical vacuolation were increased in high-dose males and of pancreatic (acinar) atrophy were increased in high-dose females ($p \leq 0.05$); it was unclear whether these effects were treatment-related. Results of the brain and sciatic nerve histology examinations were not given.

Under the conditions of this study, 4 mg/kg/day was identified as the LOAEL for both sexes of rats based on decreased RBC and plasma ChE levels. A NOAEL was not identified.

Treatment-related neoplastic lesions were seen in both sexes of rats. Males had an increased incidence ($p \leq 0.05$) of lung adenoma (8 mg/kg/day), mononuclear cell leukemia (both doses), and pancreatic acinar adenoma (both doses). Females had an increased incidence of mammary gland fibroadenoma ($p \leq 0.05$ for both doses); an additional high-dose female had mammary gland fibroma.

This study was classified as "supplementary for chronic study; minimum for oncogenicity" when the Data Evaluation Report was originally prepared (1987). Although this study did not follow the "Subdivision F" guidelines for chronic toxicity, the most sensitive end-point for toxicity, namely ChE inhibition, was measured and used as a basis for NOAEL. Therefore, this study should be valid for performing risk assessment.

870.3200 (83-2b) Two Year Gavage Study in B6C3F1 Mice. NTP TR 342. MRID 40299401

CITATION: **Chan, P. (1987) NTP Technical Report on the Toxicology and Carcinogenesis Studies of Dichlorvos (CAS No. 62-73-7) in F344/N Rats and B63F1 Mice: (Gavage Studies): NTP TR 342. Draft Technical Report of July, 1987 prepared for public review and comment. US Dept. of Health and Human Services, Public Health Service, Publication No. NIH 88-2598. 239 p. MRID 40299401**

EXECUTIVE SUMMARY: In an oncogenicity gavage study (MRID 40299401), dichlorvos (DDVP) (97.8-98.2% a.i., Lot SDC-092179, batch 01) in corn oil (Mazola® "100% pure") was administered to 60 B6C3F1 mice/sex/dose 5 days/week for 103 weeks followed by a one-week observation period. Males were given 10 or 20 mg/kg/day DDVP, females 20 or 40 mg/kg/day DDVP, and controls corn oil only; the dosing volume was 10 mL/kg. Five mice/sex dose were used only for plasma and RBC cholinesterase (ChE) determination after 6, 12, 24, 36, 52, 78, and 104 weeks and 5 mice/sex/dose were used for brain and sciatic nerve histology at study termination. The doses employed were based on results of a 13-week study where 10 mice/sex/dose were given 0, 5, 10, 20, 40, 80, or 160 mg/kg/day DDVP; all males and 9 females given 160 mg/kg/day died during the study. The survivors had no dose-related body weight changes, toxic signs, or significant pathology.

No treatment-related mortality or body weight changes were observed, however, all male mice used for ChE determination died when blood was withdrawn at 24 weeks. Reported clinical signs consisted of a slight increase of left pelvic masses in high dose males and of distended abdomens in treated females. Plasma ChE levels in males were 54-62% and 69-76% lower than controls at 10 and 20 mg/kg/day, respectively, from 6-24 weeks (death of mice precluded further analysis). Plasma ChE levels in females were 64-73% and 79-90% lower than controls at 20 and 40 mg/kg/day, respectively from weeks 6-78, but were similar to or higher than controls at week 104, perhaps due to the intervening week without treatment. RBC ChE levels were more variable: levels were decreased (26-46%) at week 24 in both sexes and by 11-33% at weeks 36, 52, and 104 in females, but were similar to or greater than controls at weeks 6 and 12 (both sexes, both doses) and 78 (females, both doses). Treatment time did not appear to be directly related to ChE inhibition. No treatment-related gross or microscopic lesions were found and no lesions were seen in the animals used to investigate brain and sciatic nerve histology.
Under the conditions of this study, a LOAEL of 10 mg/kg/day was identified based on the decreased RBC and plasma ChE levels in males. A NOAEL was not identified.

The incidence of forestomach squamous cell papilloma was increased in high dose males (5/50 vs. 1/50 for controls, $p = 0.06$) and females (18/50 vs. 5/50 for controls, $p \leq 0.05$); forestomach carcinoma also occurred in 2/50 high-dose females. Three high-dose males each had one unusual neoplasm: glandular stomach carcinoid/carcinoma, duodenal adenocarcinoma, or a duodenal adenomatous polyp.

This oncogenicity study was classified as “core-minimum” when the Data Evaluation Report was originally prepared (1987).

870.4200 (83-2) 80-Week Feeding/Carcinogenicity study in Rats - TXR007765, NCI, 1977

EXECUTIVE SUMMARY: In an 80-week feeding/carcinogenicity study (NCI, 1977), groups of fifty 36-43 day old Osborne-Mendel rats/sex were administered DDVP (94%) at dose levels (time-weighted average) of 150 or 326 ppm (7.5 and 16.3 mg/kg/day by standard convention methods). The dosage for the high-dose group was 1000 ppm (50 mg/kg/day) for the first 3 weeks and was then changed to 300 ppm (15 mg/kg/day) for the remaining 77 weeks due to toxicity. A matched control group of 10 rats/sex was included. The pooled control group consisted of 60 male and 60 female rats. All animals were observed twice daily for signs of toxicity, weighed at regular intervals, and palpated for masses at each weighing. Gross and microscopic examination of all major tissues, organs and gross lesions were made from sacrificed animals, and where feasible, from animals found dead. Rats were sacrificed at 110-111 weeks.

Severe signs of toxicity including tremors, rough hair coat, diarrhea and poor appearance were observed in the 1000 ppm DDVP group during the first 3 weeks. All groups showed slight or moderate degrees of toxicity during the first year. Treated animals showed an increased frequency of toxic signs during the second year consisting of rough hair coats, epistaxis, hematuria, alopecia, dark urine, bloating and abdominal distension. No compound-related mortality was reported. Survival was 64% and 76% in males in the low- and high-dose groups, respectively, for over 105 weeks. Survival was 80% and 84% in females in the low- and high-dose groups, respectively, for

over 105 weeks. During the first year and a half, body weights of male and female rats in the high-dose group were consistently lower than the low-dose and matched control groups. Thyroid follicular hyperplasia was increased in males in the low-dose group (7%) and high-dose group (10%) when compared to controls (0%). The incidence of alveolar macrophages was increased in treated males (14-28%) and treated females (42-44%) when compared to controls (0-10%). The incidence of interstitial fibrosis of the myocardium was increased in treated males (24-32%) and treated females (30-38%) when compared to controls (10%). Malignant fibrous histiocytoma was increased in male rats in the low-dose group (8%) and high-dose group (16%) when compared to pooled controls (3%, linear trend p=0.018). This neoplasm occurred in 10% of the matched controls. Under the conditions of the study, DDVP was not demonstrated to be carcinogenic in rats.

The study is Unacceptable-Guideline and does not satisfy the guideline requirement (series 83-2) for a carcinogenicity study in rats. Too few animals (10/sex) were used as matched controls and only 2 dose levels were employed.

870.4200 (83-2) 94-Week Feeding/Carcinogenicity Study in $B_6C_3F_1$ Mice - TXR 007765, NCI, 1977

EXECUTIVE SUMMARY: In a 94-week feeding/carcinogenicity study (NCI, 1977), groups of fifty $B_6C_3F_1$ mice/sex, 35-36 days of age, were administered DDVP (94%) at dose levels (time-weighted average) of 318 or 635 ppm (47.7 and 95.3 mg/kg/day by standard convention methods). The dosage levels for the low- and high-dose mice were 1000 and 2000 ppm (150 and 300 mg/kg/day) for the first 2 weeks, then reduced to 300 and 600 ppm (45 and 90 mg/kg/day) for the remaining 78 weeks. A matched control group of 10 mice/sex was included. The pooled control group consisted of 100 males and 80 females. All animals were examined twice daily for signs of toxicity, weighed at regular intervals, and palpated for masses at each weighing. Gross and microscopic examination of all major tissues, organs and gross lesions were made from sacrificed animals and, where feasible, from animals found dead. The mice were sacrificed at 92-94 weeks.

Initially, mice fed DDVP exhibited severe signs of toxicity: tremors, rough coat, diarrhea and poor general appearance. After doses were reduced, the behavior and appearance of treated mice were comparable to controls. Survival was 92% and 90% in males in the low- and high-dose groups, respectively. Survival was 74% and 84% in females in the low- and high-dose groups, respectively. The body weight of male and female mice in the high-dose group was generally lower after the initial growth phase than the low-dose and control groups. Two squamous-cell carcinomas of the esophageal epithelium occurred, 1 in a low-dose male and 1 in a high-dose female. Two low-dose males had focal hyperplasia of the esophageal epithelium. And one high-dose female had a papilloma of the esophageal epithelium. There was insufficient information to establish the association of esophageal tumors with DDVP treatment. Under the conditions of the study, DDVP was not demonstrated to be carcinogenic in mice.

The study is Unacceptable-Guideline and does not satisfy the guideline requirement (series 83-2) for a carcinogenicity study in mice. Too few animals (10/sex) were used as matched controls and only two dose levels were employed.

870.4100 (83-1b) 52-Week Chronic Oral Toxicity Study in Dogs. MRID 41593101

CITATION: Markiewicz, V. (1990) A 52-Week Chronic Toxicity Study on DDVP in Dogs: Lab Project Number: 2534/102. Unpublished study prepared by Hazleton Laboratories America, Inc. 431 p. MRID 41593101

EXECUTIVE SUMMARY: In a chronic oral toxicity study (MRID 41593101), dichlorvos (DDVP) (purity not given but was 97.3% in the preceding range finding study; Lot No. 802097) was administered to 4 beagle dogs/sex/dose by capsule for 52 weeks at doses of 0, 0.1, 1.0, or 3.0 mg/kg/day. Due to excessive plasma cholinesterase inhibition at week 2, the low dose was changed from 0.1 to 0.05 mg/kg/day in both sexes on treatment day 22 to achieve a NOAEL.

No dogs died during the study. Clinical signs included ataxia, salivation, and dyspnea in one high-dose male on one day during week 33 and emesis in three high-dose females and one male and/or female at most other doses. Cumulative body weight gains were lower than that of controls only in the high-dose males, from approximately weeks 1-8. No treatment-related effects were noted on the food consumption, ophthalmoscopic examination, hematology, urinalysis, gross or microscopic pathology, organ weights, or clinical chemistry except for cholinesterase (ChE) measurements. After 2 weeks of treatment, plasma ChE levels were 21-26% lower than pretreatment values for both sexes given 0.1 mg/kg/day DDVP, prompting the dose decrease to 0.05 mg/kg/day on day 22. At subsequent test weeks (6, 13, 26, 39, and 52), plasma ChE levels in the low-dose group were within 12% of pretreatment values. Plasma ChE levels of dogs given 1.0 and 3.0 mg/kg/day DDVP were decreased 39-59% and 61-74%, respectively, throughout the study in both sexes. RBC ChE levels were decreased in low-dose dogs at week 6 (24% in males and 50% in females), likely due to effects of the earlier higher dose of 0.1 mg/kg/day, but were within 13% of pretreatment values at all other time points. At 1.0 or 3.0 mg/kg/day DDVP, RBC ChE levels in both sexes were lowered 33-65% and 67-94%, respectively, throughout the study. The % inhibition of neither plasma nor RBC ChE appeared to change with time. Brain ChE measurements taken at termination were comparable to concurrent controls for the low dose groups but were decreased at both 1.0 mg/kg/day (22%, $p \leq 0.05$ in males; 7%, N.S. in females) and 3.0 mg/ kg/day (47% in males and 29% in females, $p \leq 0.05$ for both).

Under the conditions of this study, the NOAEL was identified as 0.05 mg/kg/day for both sexes. The L0EL was 1.0 mg/kg/day, based on the inhibition of plasma and RBC ChE levels in both sexes and the inhibition of brain ChE in males. It should be noted that the actual LOAEL could be as low as 0.1 mg/kg/day since plasma ChE was decreased by nearly 25% after the initial administration of this dose to the low-dose group during the first two weeks.

This study was classified as acceptable (guideline) for satisfying the guideline requirement for a chronic oral toxicity study (83-1b) in dogs.

870.3700 (83-3a) Developmental Oral Toxicity Study in SD Rats.

CITATION: Tyl, R.; Marr, M.; Myers, C. (1991) Developmental Toxicity Evaluation of DDVP Administered by Gavage to CD (Sprague-Dawley) Rats: Lab Project Number: 60C-4629-10/20. Unpublished study prepared by Research Triangle Inst. 305 p. MRID 41951501

EXECUTIVE SUMMARY: In a developmental toxicity study (MRID 41951501), 25 pregnant Sprague-Dawley rats per group were administered Dichlorvos (96.86% a.i.; Lot No. 802097) by gavage at doses of 0, 0.1, 3.0, or 21.0 mg/kg/day on gestation days (GD) 6-15, inclusive. On GD 20, all dams were sacrificed and all fetuses were examined for external anomalies. Approximately one-half of all fetuses were examined for visceral anomalies and the remainder stained and examined for skeletal anomalies.

All animals survived until scheduled sacrifice. There was no evidence of maternal toxicity at 0.1 or 3.0 mg/kg/day. At the high dose, clinical signs of toxicity were indicative of cholinesterase inhibition. All high-dose dams exhibited tremors at some time during the dosing period. Other anticholinesterase-related signs of toxicity included prone positioning, hindlimb splay, circling, vocalization, excitability, hypoactivity, and labored respiration among others.

Absolute maternal body weights of the high-dose dams were significantly (4-6%; $p \leq 0.05$) lower than the controls on GD 9, 12, and 15 and body weight gains during the dosing period were significantly ($p \leq 0.01$) decreased by 28%. Food consumption and food efficiency of high-dose dams were significantly ($p \leq 0.01$) less than the controls during the dosing interval and overall (GD 0-20).

Therefore, the maternal toxicity LOAEL is 21 mg/kg/day based on clinical signs of toxicity, reduced body weight gain, and food consumption and efficiency. The maternal toxicity NOAEL is 3 mg/kg/day.

No treatment-related effects were observed for gravid uterine weights, number of fetuses/litter, pre- and post-implantation loss, numbers of corpora lutea/dam, number of implantations/dam, resorptions/dam, fetal body weights, or fetal sex ratios. There were no developmental malformations/variations in any fetus that were attributed to treatment.

Therefore, the developmental toxicity NOAEL is ≥21 mg/kg/day and the developmental toxicity LOAEL was not identified.

This study is classified as Acceptable (guideline) and satisfies the guideline requirements for a developmental toxicity study (83-3a) in rats.

870.3700 (83-3b) Developmental Oral Toxicity Study in New Zealand Rabbits.

CITATION: Tyl, R.; Marr, M.; Myers, C. (1991) Development Toxicity Evaluation of DDVP Administered by Gavage to New Zealand White Rabbits: Lab Project Number: 60C-4629-30/40. Unpublished study prepared by Research Triangle Institute. 247 p. MRID No. 41802401

EXECUTIVE SUMMARY: In a developmental (teratology) toxicity study (MRID 41802401), 16 pregnant New Zealand rabbits per group were administered Dichlorvos (97% purity; Lot No. 802097) by gavage at doses 0, 0.1, 2.5, or 7.0 mg/kg/day on gestation days (GD) 7-19. (Dose selection was based on a range-finding study in which maternal toxicity, including increased

mortality (5/8 died), decreased weight gain, and clinical signs, were manifested at the highest tested dose of 10 mg/kg/day.) At study termination (GD 30), the number of does with live fetuses was 14, 12, 11, and 9 in each of the control, 0.1, 2.5, and 7.0 mg/kg/day group, respectively. On GD 30, all surviving dams were euthanized and all fetuses were weighed and examined for external, skeletal, and visceral anomalies.

Maternal toxicity (dose-dependent) was evident in the form of dose-dependent increased mortality (four and two died in the high and mid-dose groups, respectively), decreased mean body weight gain and typical anticholinesterase-related clinical observations. Mean body weight gain during the dosing period (GD 7-19) was 67% and 58% below control in the mid and high dose groups, respectively. Mean body weight gain during the entire gestation period (corrected for gravid uterine weight) was variable where, compared to the control group, it was higher in the low and mid dose groups (by 140% and 45%, respectively) and lower (54%, $p<0.05$) in the high dose group. There were no abortions but two does in the low-dose group had premature deliveries (GD 23 and 30).

Therefore, based on mortality, and other effects, the maternal toxicity LOAEL is 7.0 mg/kg/day; the maternal toxicity NOAEL is 2.5 mg/kg/day.
There were no statistically significant treatment-related differences in the number (per doe) of corpora lutea, implantations, live fetuses, resorptions, or dead fetuses. Though not indicated to be significantly different than the control group, the low-dose group had fewer implantations/doe (4.9 ± 0.8 vs. 7.0 ± 0.8) and fewer live fetuses/doe (4.8 ± 0.8 vs. 6.5 ± 0.8). There were no apparent developmental malformations or variations that could be attributed to treatment.

Therefore, the developmental toxicity NOAEL is >7 mg/kg/day and the developmental toxicity LOAEL was not identified.

This study was classified as Core Minimum where all criteria were satisfied except for the minimum number (12) of available does/group which, due to mortality in the mid and high dose groups, were 11 and 9, respectively. The reviewer of this study also indicated that individual data on corpora lutea were not submitted.

870.3800 (83-4) Two-Generation Reproduction Study in SD Rats. MRID No. 42483901

CITATION: Tyl, R.; Myers, C.; Marr, M. (1992) Two-Generation Reproductive Toxicity Study of DDVP Administered in Drinking Water to CD (Sprague-Dawley) Rats: Final Report: Lab Project Number 60C-4629-170. Unpublished study prepared by Research Triangle Institute. 1225 p. MRID No. 42483901

EXECUTIVE SUMMARY: In a 2-generation reproduction study (MRID 42483901) DDVP (96.86%) was administered to 30 CD (Sprague-Dawley) rats/sex/dose in their drinking water at concentrations of 0, 5, 20 and 80 ppm. Equivalent dosages were the following:

Table 10.

Water Conc.	F0 & F1 ♂ (µg/kg/day)	F0 & F1 ♀ prebreeding	F0 & F1 ♀ gestation	F0 & F1 ♀ lactation

(ppm)		(µg/kg/day)	(µg/kg/day)	(µg/kg/day)
5.0	476-500	650-660	564-590	930-1176
20.0	1923-1952	2432-2673	2124-2420	4280-4596
80.0	6897-7528	9370-9472	7035-8150	13238-17468

After at least 10 weeks of continuous exposure, rats were randomly mated within treatment groups to produce the F1 generation; after mating the F0 males were necropsied. F1 litters were culled to 8 pups (4 ♀, 4 ♂ when possible) on post natal day 8 and weaned on day 21. Ten weanlings/sex/dose were necropsied and 30 weanlings/sex/dose were selected as F1 parents with at least 11-week prebreeding exposure to DDVP in their water. These rats were about 14-17 weeks old when mated and their F2(a) litters were culled to 8 pups/litter on post natal day 8. At weaning, 10 F2(a) weanlings/sex/dose level were necropsied.

Due to poor reproductive performance (not treatment or dose-related), F1 females were evaluated for vaginal estrus cyclicity and then rebred with untreated males to produce F2(b) litters which were culled on PND 8 (8 pups/litter) and necropsied (10/sex/dose) after weaning.

Systemic toxicity: A NOAEL for cholinesterase inhibition in parental animals was not observed. Cholinesterase levels were dose-dependently decreased in plasma (by 3.6 to 57.4%), erythrocytes (by 7.0 to 60.5%), and brain (by 1.1 to 60.3%) from F0 and F1 animals and, overall, females were more sensitive than males. No ChE measurements were done on the F2(a) or F2(b) progeny. Water consumption was also reduced in the 80 ppm dosed animals.

Reproductive toxicity: No effects on reproductive parameters were observed in the F0 mating, although mean pup body weight in the 80 ppm group at weaning (day 21) was significantly lower than controls (57.02 vs. 62.29 g). In the first mating of the F1 animals, incidences of pregnancies were low (controls: 17/30; 5 ppm: 14/30; 20 ppm: 16/30; 80 ppm: 11/30). Mean pup body weight in the 80 ppm group at weaning was noticeably (not significantly) lower than controls (52.22 vs. 57.43 g). As stated in the report conclusions: "Parental reproductive parameters were slightly affected in F1 animals at 80 ppm, although these changes did not achieve statistical significance. Offspring survival was also slightly reduced at 80 ppm, associated with accompanying maternal toxicity seen at this dose level."

Results of the estrous cyclicity assessment showed that in the 80 ppm F1 group, there was a statistically significant decrease in the percent of females cycling (63.3%, control 86.2%) accompanied by increased abnormal cycling (68.4%, control 16%).

In the F2(b) mating, incidences of pregnancies were still relatively low (controls: 19/29; 5 ppm: 19/30; 20 ppm: 17/30; 80 ppm: 13/30); in terms of pregnancies/confirmed copulations incidences were: controls: 19/25 (76%); 5 ppm: 19/27 (70.4%); 20 ppm: 17/27 (63%); 80 ppm: 13/26 (50%).

The LOAEL for systemic toxicity [drinking water administration] is 5 ppm (488 μg/kg/day in males, 577 μg/kg/day in females), based on RBC and plasma cholinesterase inhibition. The NOAEL is <5 ppm (<488 μg/kg/day in males, <577 μg/kg/day in females).

The reproductive LOAEL [drinking water administration] is 80 ppm (7592 μg/kg/day) based on the lack of cycling and abnormal cycling due to persistent or prolonged estrus. In addition, parental reproductive parameters (decreased pregnancy and fertility, and decreased live litters and survival) were slightly affected in F1 animals at 80 ppm, although these changes did not achieve statistical significance. Offspring survival was also slightly reduced. The reproductive NOAEL is 20 ppm (4438 μg/kg/day).

81-8ss Acute Oral Neurotoxicity Study in Rats.

CITATION: Lamb, I. (1993) An Acute Neurotoxicity Study of Dichlorvos in Rats: Final Report (Text and Summary Data): Lab Project Number: WIL-188003. Unpublished study prepared by WIL Research Labs., Inc. 984 p. MRID 42655301

EXECUTIVE SUMMARY: In an acute oral neurotoxicity study (MRID 42655301), a single gavage dose of dichlorvos (97.8% a.i., lot #80209) was administered in deionized water to 12 Sprague-Dawley rats/sex/ group at 0, 0.5, 35, or 70 mg/kg. The animals were observed for up to 14 days. Functional Observational Battery (FOB) tests were done pretest and on study days 0 (15 minutes after compound administration), 7 and 14. Animals surviving to study termination were sacrificed and perfused *in situ* for neurohistopathological evaluation. All animals were necropsied.

Two high-dose males and five high-dose females died within four hours of compound administration. All other animals survived until study termination. No body weight effects were observed. The FOB and motor activity effects (described below) of dichlorvos were most prevalent 10-20 minutes post-dosing and had essentially resolved by days 7 and 14. Statistically significant ($p<0.05$) postural alterations, tremors, salivation, and changes in fur appearance and skin color were observed in mid- and high-dose males and females. High-dose males exhibited an increased incidence ($p<0.05$) of exophthalmus. Group mean time to first step was significantly ($p<0.01$) increased in high-dose males (31.7 sec) and females (18.3 sec). Treatment-related ($p<0.05$) decreased group mean rearing, impaired mobility, abnormal gait, and decreased arousal level were also observed in mid- and high-dose males and females. Dose-related ($p<0.05$) alterations of touch, tail pinch, pupil response and air righting reflex were observed in mid- and high-dose males and in high-dose females. Dose-related decreased hindlimb resistance (mid- and high-dose, $p<0.05$), grip strength (high-dose, $p<0.01$), and rotarod performance (mid- and high-dose, $p<0.01$) were observed in male and female rats. Decreased ($p<0.01$) mean body temperature was observed in mid- and high-dose males and females, and increased ($p<0.01$) group mean catalepsy values were observed in high-dose animals of both sexes. No brain weight, brain dimension, or neurohistopathological effects were observed.

Under the conditions of this study, the LOAEL for dichlorvos is 35 mg/kg and the NOAEL is 0.5 mg/kg based on changes in the FOB, decreased motor activity, and decreased body temperature. This study is classified as acceptable (guideline) for an acute neurotoxicity study in rats (81-8ss).

81-8ss Subchronic Oral Neurotoxicity Study in Rats.

CITATION: Lamb, I. (1993) A Subchronic (13 Week) Neurotoxicity Study of Dichlorvos in Rats: Final Report: Lab Project Number: WIL-188004. Unpublished study prepared by WIL Research Labs, Inc. 1199 p. MRID 42958101.

EXECUTIVE SUMMARY: In a subchronic oral neurotoxicity study (MRID 42958101), dichlorvos (97.87% a.i., lot No. 802097) was administered in deionized water to 15 Sprague-Dawley rats/sex/group at gavage doses of 0, 0.1, 7.5, or 15.0 mg/kg/day for 90 days. Within each dose group, 10 rats/sex were allocated for brain cholinesterase determination and 5 rats/sex were allocated for neuropathology evaluation. Additionally, blood samples were collected for cholinesterase measurements prestudy and on study weeks 3, 7, and 13. Five rats/sex/dose from the cholinesterase group and 5/sex/dose from the neuropathology group were evaluated with the Functional Observational Battery (FOB) and motor activity tests pretest and on study weeks 3, 7, and 12. Body weight and food consumption were measured weekly.

There was no treatment-related mortality. Mean body weight in high-dose females was consistently lower than the control (11-21%) throughout the study. No body weight effects were observed in any other animals, and there was no treatment-related effect on food consumption. Tremors, salivation, exophthalmos, lacrimation, and clear material on the forelimbs were observed in high-dose males and females approximately 15 minutes post-dosing. Rales, chromodacryorrhea, and red/yellow/orange material around the nose and mouth were also seen in high-dose rats. Tremors were observed in three mid-dose males and nine mid-dose females. Generally, the clinical signs occurred during the third week of treatment in the mid-dose animals, and as early as the first week of dosing and throughout the study in the high-dose rats. Cholinesterase activity was decreased in mid- and high-dose male and female rats as follows: plasma 30-58%; erythrocyte 8-35%; brainstem and brain cortex 10-16%. There were no treatment-related effects in the FOB or motor activity tests. No treatment-related neurohistopathological lesions and no apparent changes in brain weight or size were observed.

Based on decreased cholinesterase activity and clinical cholinergic signs, the LOAEL for dichlorvos is 7.50 mg/kg and the NOAEL is 0.1 mg/kg. This study is classified as acceptable (guideline) for a subchronic neurotoxicity study in rats (81-8ss).

g. Mutagenicity

Mutagenicity Studies with Positive Results

Several in vitro and in vivo mutagenicity studies were reviewed and presented to the Cancer Peer Review Committee (CPRC) by Kerry Deerfield in a Memorandum entitled, “Review of the in vivo mutagenicity studies concerning Dichlorvos” (dated August 10, 1988). Another review may be found in the more recent Memorandum entitled, “Fifth carcinogenicity peer review of Dichlorvos” by Jocelyn Stewart (dated August 28, 1996). Though lacking sufficient detail, these two reviews provide some information about the types and variety of mutagenicity/ genotoxicity studies that were considered by the Agency since DDVP has been registered.

DDVP has been shown to be a direct acting mutagen by common in vitro bacterial genetic toxicity assays. For instance, DDVP is mutagenic in the base-substitution Salmonella strain, TA100 as well as in the E. coli WP2 mutation assay (Moriya et al., 1983). In this study, 238 pesticides including DDVP were tested by the Ames plate incorporation method in five Salmonella strains (TA1535, TA100, TA1537, TA1538, and TA98) as well as in E. Coli (WP2 hcr) both in the presence or absence of an S-9 metabolizing system. DDVP (technical, unknown purity) was added (0.1 mL in DMSO) at 0, 100, 500, 1,000, 5,000 or 10,000 µg/plate and all plates were incubated for two days at 37°C prior to counting revertant colonies. In Salmonella TA100, DDVP gave rise to a dose-dependent response from 100 to 5000 µg/plate with a maximum increased mutation of nearly 4.5-fold over control in the absence of S-9 activation while complete toxicity was seen at the highest dose tested. Addition of S-9 metabolizing system reduced the mutation frequency to a maximum of nearly 2-fold (at 5000 µg/plate) over background. DDVP was also positive in E. coli WP2 hcr, though no actual data were provided. The other tested strains failed to respond to DDVP in the presence or absence of S-9 activation. Therefore, DDVP was shown to be a direct acting mutagen in TA100 (and in E. coli WP2 hcr) where, compared to 44 other direct acting mutagens in the same study, DDVP ranked 26 with a mutagenic potency of 0.027 revertants/nmole (most and least potent were Captan in TA100 and ETU in TA1535 scoring 93.7 and 0.00065 revertants/nmole, respectively) (Moriya et al., 1983).

A single dose of apparently 5000 µg DDVP (>97% a.i.) in cultures of E. coli (B/r WP2 and WP2 hcr) and in S. typhimurium (TA1535 and TA1538) was tested with or without S-9 metabolic activation. (According to HED doc. # 007765, p. 143, 0.1 mL of pesticide solution containing 22.6 µM DDVP was used. However, the author of this document interprets this to mean that 22.6 µmoles, equaling 5000 µg, of DDVP in 0.1 mL solution was used; otherwise, the amount of DDVP in 0.1 mL of the 22.6 µM solution would be only 0.5 µg.) Water served as negative (solvent) control. In the absence of S-9 activation, DDVP was positive in both the E. coli and TA1535 strains (10-30 fold increased revertants above background). S-9 metabolic activation abolished DDVP's mutagenicity in TA1535 but not in E. coli (Moriya et al., 1978).
This study was considered acceptable despite using one dose only and no reporting of concurrent control values (HED doc. # 007765).

Positive mutation findings were also reported in two E. coli WP2 strains (trp^- and the plasmid-containing CM881) in another study which only tested DDVP (a.i. not specified) at concentrations from 0.1 µg/mL (in the agar incorporation method) to 2000 µg/mL (in the treat and plate method) in the absence of S-9 metabolic activation. DDVP induced reversion by base substitution in both the agar (5 µg/mL agar) or the standard treat and plate method (2000 µg/mL) (Bridges, 1978).
This study was judged inconclusive as a comprehensive test of mutagenicity because it was not also performed with mammalian metabolic activation (HED doc. # 007765).

An earlier study screened 11 S. typhimurium histidine-requiring strains and seven E. coli tryptophan-requiring strains by spot testing DDVP (% a.i. not specified) and 139 other organophosphorus compounds by adding 5-10 µl of each chemical to each bacterial strain and counting revertants compared to controls after 48 and 72 hr incubation at 37°C. Results were represented qualitatively using +/- designation. DDVP was positive (+) in strains that were designed to detect base-pair substitution mutagens (such as TA1530, TA1535, WP2, uvrA, and

WP67) but was negative (-) in strains that detect frame-shift mutagens (e.g., TA1536, TA1537, and TA1538) (Hanna and Dyer, 1975). This study was judged acceptable without metabolic activation but, overall, was considered inconclusive (HED doc. # 007765).

In addition, DDVP is a direct acting mutagen in some in vitro mammalian test systems. For instance, in the forward mutation assay at the TK locus (L5178Y/$TK^{+/-}$) of cell cultured mouse lymphoma cells, DDVP (technical, 97.5% a.i., Lot No. 11381-23-5) was tested in up to 20 doses ranging from 0.0089 to 1.0 µl/mL, both in the presence or absence of metabolic activation. Concurrent negative controls (DMSO) and positive controls were run using ethylmethanesulfonate (EMS) for nonactivated and 7,12-dimethylbenz[a]anthracene (DMBA) for activated cultures. The test article was completely cytotoxic (0% growth) at doses ≥ 1 µl/mL and, therefore doses ≤ 0.33 µl/mL were used to ascertain cloning and mutagenesis. In the absence of metabolic activation, there was a dose-related (0.024- 0.33 µl/mL) increase in mutant frequencies of 2.3-13.3 times that of DMSO control. Addition of metabolic activation seemed to diminish the mutation frequency where at the two highest tested doses of 0.24 and 0.18 µl/mL the mutant frequency was 3.7 and 2.7 times DMSO, respectively. Similar results were seen when the test was repeated in a second series of experiments with and without metabolic activation. Positive control chemicals elicited appropriate responses where, relative to solvent control, mutant frequency was induced by 6.8 to 16.3x with EMS in nonactivated cultures and by 2.2 to 6.3x with DMBA in S-9 activated cultures (Microbiological Associates, Inc., Study No.T-5211.702003, dated 10/14/86, Acc. No. 265524). This study was considered acceptable (TXR # 005663).

Positive results were also described in another TK mouse lymphoma forward mutation assay where DDVP (% a.i. not specified) was tested at seven concentrations ranging from 6.25-250 nl/mL in the absence of metabolic activation only. No cells survived at the two highest doses of 200 and 250 nl/mL but at the dose 100 nL/mL the mutant frequency was 7.6x the solvent control (EtOH) while the positive control (methylmethanesulfonate) responded appropriately yielding 5.4x the mutation frequency of EtOH. A repeat test gave similar qualitative results. (Study performed by Litton Bionetics under contract to NTP/NIEHS, report dated 8/27/85, Acc. No. 259463).
Despite the apparent direct acting mutagenicity results by DDVP, this study was considered inconclusive as a "comprehensive mutagenicity test in this system" because no S-9 metabolic activation was done (TXR # 004376).

DDVP seems to also have clastogenic activity by inducing chromosomal aberrations (AB), sister chromatid exchanges (SCE), and polyploidy in cultured Chinese hamster ovary (CHO) cells (Tezuka et al., 1980). To $3x10^5$ pre-cultured CHO cells, DDVP (a.i. > 98%) in DMSO (final concentration of solvent in culture was kept to 1%) was added at a final DDVP concentration of 0, $1x10^{-4}$, $2x10^{-4}$, $5x10^{-4}$, and $1x10^{-3}$ M. After adding 5-bromomodeoxyuridine to a final concentration of 2 µM, each culture was incubated for 26.5 hr in the dark. All doses were run in duplicate using established procedures, where 50 and 100 metaphases were generally used for scoring and detecting SCEs and ABs, respectively, at each concentration. There was a statistically significant (<0.001) dose-dependent increase in the mean number of SCE/cell with a maximum increase over control of nearly 5-fold at the $5x10^{-4}$M concentration (no data was available at the highest dose tested and no explanation given). Chromosomal aberrations also were induced ($p<0.001$) at the $5x10^{-4}$M DDVP concentration where, of 100 scored cells, AB were found in 34 cells compared to 9/200 for control and 4/100 for each of the two lowest DDVP doses (no data and no explanation were available for

the highest dose tested). There were no cells with 10 or more AB per cell. Increased polyploidy was also observed at the three lowest DDVP doses (no data was available for the highest dose) where the per cent of examined cells with polyploidy ranged from 9.3 to 15.7 %, compared to 2.5% in control cells. According to the "Discussion" in this article, previous studies with DDVP in cultured human lymphocytes or fibroblasts did not show inductions of SCE or AB, and this apparent divergence with the results of this study was attributed to possible differences in sensitivity among the different test systems (Tezuka et al., 1980).

According to a Memorandum (dated August 10, 1988) entitled, "Review of in vivo mutagenicity studies concerning Dichlorvos" that was presented to the Cancer Peer Review Committee (CPRC) by Kerry Deerfield, DDVP is also clastogenic (causing AB and SCE) in CHO cells with or without metabolic activation (NTP draft report, 1987, TR 342, NIH pub. No. 88-2598). [The review by K. Dearfield mistakenly cites that the test system in the above study by Tezuka et al., 1980 used V79 cells (hamster fibroblasts) rather than CHO cells.] This NTP study is not available to this reviewer to clarify and provide more details.

As shown below, however, an in vivo study by Microbiological Associates, Inc. (Study dated 9/26/85) failed to show that DDVP has clastogenic activity in mice.

Mutagenicity Studies with Negative Results

In a micronucleus test, DDVP (98.5% a.i., in corn oil) was administered (i.p.) at 0 (vehicle), 4, 13, or 40 mg/kg/day to adult CD-1 mice (5/sex/dose/scheduled sacrifice) on two consecutive days and bone marrow polychromatic erythrocytes (PCE) were examined for micronuclei at 30, 48, and 72 hr after the last dose. A group (5/sex) of positive control mice were administered (i.p.) a single dose (0.15 mg/kg) of the mutagen triethylene melamine (TEM) in water at 30 hr prior to killing. From a preliminary DDVP dose-range finding study (8 doses from 1 to 100 mg/kg) the LD_{50} for both sexes is 56 mg/kg. In the main assay, two males and three females in the high dose group and one male in the mid dose group died prior to scheduled killing. (Dead animals in the high dose group were replaced.) Also lethargy and tremors were seen in the high dose group. Therefore, a clinical MTD seems to have been achieved.

In none of the 18 DDVP test groups were micronuclei significantly increased (range 0-1.2 per 1000 scored PCE) compared to negative control (0-1). There was a significant response in the TEM positive control group with a mean of 15.6 (males) and 13.2 (females) micronuclei/1000 PCE. (Microbiological Associates, Inc., Study dated 8/15/85)
This study was classified as acceptable/current guideline (HED doc. # 004376).

In another in vivo mutagenicity study, DDVP (98.5% a.i., in corn oil) was tested for sister chromatid exchange (SCE) induction in B6C3F1 mice (5/sex/group) which were implanted (s.c.) with 50 mg bromodeoxyuridine pellet four hours prior to receiving a single injection (i.p.) of 0 (corn oil), 3, 10, or 30 mg DDVP/kg. Dose-selection for this study was based on a preliminary study in which mice received one of eight doses ranging from 1-100 mg DDVP/kg where the combined (male/female) LD_{50} was calculated as 47 mg/kg. A positive control group (5/sex) received an i.p. injection of cyclophosphamide (CP) at 10 mg/kg in water. After 24 hours, bone marrow from both femurs was removed and processed to determine SCE by standardized methods

where fifty second-division metaphase cells per animal were scored for SCE. No animals died in the main SCE assay and no clinical signs of toxicity were observed except for lethargy in the high dose group. The mean SCE/cell/animal were similar among all animals in the negative control and the DDVP-treated groups (males: 4.9-5.9/females: 5.6-6.3); also the mitotic indices (% of metaphase cells in first, second, and third division) in all DDVP treated groups were comparable to the negative control group indicating that there was no cell cycle delay even at the highest DDVP dose. As expected, CP was positive with a mean SCE/cell/ animal of 29.9 in males and 18.1 in females. (Microbiological Associates, Inc., Study dated 9/26/85)

This study was classified as acceptable and HED concluded that "although no evidence for target cell toxicity (mitotic delay) was reported even at a dose causing clinical toxicity, the study was otherwise conducted adequately, and thus the negative results for SCE are supportable." (HED doc. # 004376)

This reviewer partly disagrees since the highest tested dose of 30 mg/kg was below the MTD as judged by an LD_{50} of 47 mg/kg (preliminary study) and a lack of clinical signs of toxicity with the exception of lethargy.

Another in vivo study (MRID no. 42619901) assessed the potential for genotoxic effects in the germ cells and in bone marrow in male ICR mice (10/group) by administering daily oral (gavage) doses of 0, 12.5, 25, or 50 mg/kg/day of DDVP (a.i. 98.1%, dissolved in water to give a constant dosing volume of 20 mL/kg) for five consecutive days. Cyclophosphamide (CP) was also administered (10 mice/group) at a single oral dose of 40 or 150 mg/kg (in water, dosing volume 20 mL/kg). All animals also received a single i.p. injection (1.6 mg/kg) of the spindle inhibitor colchicine two hours before killing. Bone marrow cells and spermatogonia were prepared according to established procedures; from each animal, fifty metaphase cells were examined, structural aberrations were recorded, and the mitotic index (MI) was determined. There were no indication of a clastogenic effect in either germinal (spermatogonia) or somatic cells (bone marrow) harvested 24 hours following the final administration of the test material. The positive control group responded appropriately. The reviewer of this study concluded that the maximally tolerated dose was achieved based on a preliminary test where there was 80 % mortality after a single dose of 70 mg DDVP/kg (100% mortality after a single dose of ≥ 90 mg/kg); furthermore, the five repeated doses of DDVP "allowed a slightly reduced dosing load while challenging the animals without excessive mortality" as was seen at ≥70mg/kg.

This study (MRID No. 42619901) was judged acceptable and, therefore, it satisfied the requirement for in vivo cytogenetic mutagenicity data (HED doc. # 010446).

h. <u>Metabolism</u>

CITATION: Cheng, T. (1989) Metabolism of (Carbon 14)-DDVP in Rats: Project ID HLA 6274-105. Unpublished study prepared by Hazleton Laboratories America, Inc. 322 p. MRID 41228701.

Cheng, T. (1991) Supplement to: Metabolism of carbon 14|-DDVP in Rats (Preliminary and Definitive Phases) (...): Lab Project Number: HLA

6274-105-1. Unpublished study prepared by Hazleton Laboratories America, Inc. 89 p. MRID 41839901.

EXECUTIVE SUMMARY: Groups of Sprague-Dawley rats (5/sex/group) were administered a single dose of 20 μC_i [^{14}C]DDVP (radiolabelled at the vinyl position and purified to 100%) either intravenously (1 mg/kg), orally (1 or 20 mg/kg; low and high doses, respectively), or orally (1 mg/kg) after 15 daily oral doses of unlabeled DDVP (1 mg/kg) and a control group (2/sex) were orally dosed with water (vehicle). Of the total orally administered dose (low or high), nearly 88-94% was absorbed through the gastrointestinal tract and, within 24 hr, nearly 43-57% of the original dose (low or high) was eliminated in expired air and excreta. After seven days, the total excreted/air expired recovery was approximately 60-77%; and, of the original dose, 11-17% was recovered in urine/cage washes, 4-7% in feces, and 41-58% as expired $^{14}CO_2$. The relative amounts of radioactivity retained in carcass, liver, and other tissues combined were 13-26%, 3-5%, and 1-2%, respectively. During the seven days post-dosing period (low or high single dose), males expired slightly less $^{14}CO_2$ than females (41-45% vs. 52-54%, respectively). The excretion patterns were similar after i.v. or oral administration and little, if any, other differences relating to sex or dose were found in the excretion or distribution of [^{14}C]DDVP. Of the five radiolabelled compounds that were detected in urine, two were identified by mass spectrometry as hippuric acid (HA) and urea. Relative to total urinary radioactivity, the concentration of HA ranged from 6.8-10.5 % (low dose group) to 4.2-5.6 % (high dose group), while the amount of urea was 19.6-33.1% (low dose group) and 41.1-51.1% (high dose group). Urea and HA also seemed to be present in feces, albeit at lower concentrations than were found in urine. Three other urinary compounds were not identified but were assumed to be dehalogenated metabolites. Other metabolites, representing nearly 8 to 19% of total urinary radioactivity, were considered to be glucuronide conjugates (not identified).

The overall metabolic profile suggests the involvement of the one-carbon pool biosynthetic pathway as evidenced by the presence of a relatively large amount of radioactivity in the form of expired $^{14}CO_2$ and the presence of dehalogenated metabolites as well as urea and hippuric acid. These studies (MRID # 41228701 and 41839901) were considered acceptable and should satisfy the guideline requirement for a metabolism study (HED doc. # 008132 and 009444).

It should be noted that the above metabolism summary was based on the specified subject MRID and HED documents and, as a result, subtle differences or disagreements (for instance, relative amounts of metabolites) are inevitable between this summary and other metabolism summaries (e.g., the document dated August 28, 1996 and entitled, “fifth carcinogenicity peer review of dichlorvos” prepared by Joycelyn Stewart).

It should also be pointed out that, according to the IRIS summary on dichlorvos dated 09/01/96, there are several additional published studies on the availability, distribution, and metabolism following administration of DDVP by different routes to different species.

I. <u>Human Studies</u>

CITATION: Gledhill, A. (1997) Dichlorvos: A Study to Investigate the Effect of a Single Oral Dose on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers:

Lab Project Number: CTL/P/5393: XH6064. Unpublished study prepared by Zeneca Central Toxicology Lab. 44 p. MRID 44248802.

Gledhill, A. (1997) Dichlorvos: A Single Blind, Placebo Controlled, Randomised Study to Investigate the Effects of Multiple Oral Dosing on Erythrocyte Cholinesterase Inhibition in Healthy Male Volunteers: Lab Project Number: CTL/P/5392: XH6063. Unpublished study prepared by Zeneca Central Toxicology Lab. 52 p. MRID 44248801.

Gledhill, A. (1997) Dichlorvos: A Study to Investigate Erythrocyte Cholinestrase Inhibition Following Oral Administration to Healthy Male Volunteers: Lab Project Number: XH5170: Y09341: C05743. Unpublished study prepared by Zeneca Central Toxicology Lab. 104 p. MRID 44416201.

EXECUTIVE SUMMARY: Dichlorvos (lot no. 608002S074, a.i. 98%, dissolved in corn oil and packed in capsule) was administered in a single oral dose of 70 mg (equivalent to 1 mg/kg) to six fasted young healthy male volunteers. RBC cholinesterase (ChE) activity was measured prior to dosing on days -22, -20, -18, -15, -13, -11, -8, -6, -4, and 0 (immediately prior to dosing), and after DDVP administration on days 1, 3, 5/6, 7, and 14. All subjects were medically supervised for clinical signs and body temperature changes for twenty four hours after dosing. Under the study conditions, no adverse clinical signs and no body temperature variations were reported. Mean RBC ChE activity was statistically significantly inhibited by 12% or less on days 5/6, day 7, and day 14. The reduction in RBC ChE was not considered to be biologically meaningful.
This study is considered non-guideline (MRID # 44248802).

In a single blind oral study, each of six fasted male volunteers was administered a daily dose of 7 mg DDVP (equivalent to about 0.1 mg/kg/day) in corn oil via a capsule over 21 days. Three control subjects received corn oil as a placebo. The activity of RBC ChE was measured for each participant prior to dosing, to establish baseline levels, and also after dosing on days 2, 4, 7, 9, 11, 14, 16, 18, 25, and 28. There were no reported toxicity attributable to DDVP administration. Compared to pre-dosing mean value, the mean RBC ChE activity was statistically significantly reduced by 8, 10, 14, 14, and 16 percent on days 7, 11, 14, 16, and 18, respectively. Under the study conditions, the LOAEL for RBC ChE inhibition was established at 0.1 mg/kg/day (MRID No. 44248801). As discussed below, this study was used for intermediate-term dermal exposure risk assessment.

In another human study (MRID 44416201), DDVP (lot no. 402010A, a.i., 98%, dissolved in corn oil and packed in a capsule) was administered to each of six fasted healthy male Caucasian males over two experimental phases where each phase was followed by repeated measurements of RBC ChE. In the first phase, volunteers ingested a capsule of 35 mg DDVP on day 1, and on day 8 or 9 they received a corn oil capsule and finally they received another 35 mg DDVP capsule, eight or nine days after the corn oil. Measurements of RBC ChE were performed pretest (days -7, -5, and -3) and after administration of each DDVP capsule (24, 72, 120, and 168 hr post each dose) or corn oil (at 24, 72, and 120 hr). Adverse physical signs and symptoms including body temperature were recorded for each volunteer. After 24 hr and 120 hr of the first DDVP dosing, group mean RBC ChE activities were significantly depressed to 88% (not 93% as reported by original reviewer in

DER #22) and 90 %, respectively, of predosing levels. (There seems to be an error in computing the day 1 group mean ChE level after the first DDVP dosing which should be 15098 I.U., or 88%, instead of 15908 I.U., or 93%, as shown in Table 2 of DER #22.) However, following the second dose of DDVP, there were no statistically significant changes in group mean RBC ChE activity at any time (94 - 98% of predose activity). Also, no changes in ChE values were seen after dosing with corn oil (96 - 105% of predosing). Individual post-dose ChE activity ranged from 80% to 103% (not 85 to 100% as per DER #22) of predose values at all reporting periods. There were no changes in body temperature and no symptoms were attributed to DDVP.

In the second phase of this study, the same volunteers were administered repeated daily doses of 21 mg DDVP for 12 or 14 days and RBC ChE activity was monitored every two or three days up to day 29, and also on days 33, 40 and 55 (Table 3, DER #22) or on days 33, 40, 47, and 54, instead of days 33, 40 and 55 (as specified under Section 2 entitled "Study Design" in DER #22). Plasma was also prepared from all blood samples and immediately frozen and stored at -20°C; however, plasma ChE was not measured. Compared to the group mean pretest value, group mean RBC ChE activity was significantly decreased (<0.01) from day 5 through day 33, reaching a minimum of 69% on day 22 after which it seemed to gradually recover until the last measurement on day 54 (or 55) when it was 91% of pretest activity. Four of the six subjects reported various symptoms; one felt tired (days 5-9) with headache and nausea (day 6), another felt anxious one hour after the first dose, a volunteer had an abdominal colic (day 12), and one subject developed an upper respiratory tract infection (days 7 thru 12). Despite the fact that these symptoms (with the possible exception of upper respiratory tract infection) are typical indicators of cholinesterase poisoning, the investigators ruled out DDVP as a possible cause.

According to DER #22, the HED study reviewer concluded that, based on no decrease in RBC ChE in phase 1, NOAEL is 35 mg/person (or 0.5 mg/kg for an average 70 kg person). This reviewer, however, does not think that NOAEL was achieved since, compared to pretest value, the group mean RBC ChE was statistically significantly depressed to 88% (day 1) and 90% (day 5) and also because, at day 1, one individual (# IV) had this enzyme activity drop to nearly 80% of pretest level (Table 1 in DER #22); furthermore, the reported physical symptoms in four subjects (three if the upper respiratory tract infection is deemed unrelated) appear to be characteristic of ChE poisoning. In phase 2, based on the steady decline in RBC ChE activity, the original HED reviewer concluded that "NOAEL has not been established for this portion of the study."
This study is considered non-guideline (MRID No. 44416201).

Other human studies (journal articles) were also reviewed and were considered supplementary due to employing too few subjects and/or lacking individual data (Stewart, 1993; HED document No. 010157 and Dannon, 1998)

3.0 Residue Chemistry Science Assessments for Reregistration of Dichlorvos.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A = Not Applicable	Yes [2]	
860.1300: Plant Metabolism	N/A	No	00013545, 00074844,
860.1300: Animal Metabolism	N/A	No	00013546, 00066696, 00117261, 00117262, 00126462, 00126463, 42721601 [3], 42951701 [4]
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00042702, 00042704, 00042706, 00047472, 00049086, 00049971, 00049975, 00051556, 00074706, 00074777, 00107572, 00115993, 00117747, 00118115, 00139845
- Animal commodities	N/A	No	00042702, 00042704, 00049086, 00049087, 00049975, 00060469, 00060470, 00060472, 00074706, 00115939, 00115993, 00117257, 00117747, 00118113, 00118592, 00118639, 00140392
860.1360: Multiresidue Methods	N/A	No	42611001 [5]
860.1380: Storage Stability Data	N/A	Yes [6]	00074776, 00076809, 00140392, 43377701 [7]
860.1500: Crop Field Trials			
Root and Tuber Vegetables Group			
- Radishes	0.5 [180.235(a)]	No [8]	00118572, 00119536

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
Leafy Vegetables (except *Brassica* Vegetables) Group			
- Lettuce	1 [8] [180.235(a)]	No [8]	00033139, 00082271, 00118572, 00119536
Fruiting Vegetables (except Cucurbits) Group			
- Tomatoes	0.05 [9] [180.235(a)]	No [8]	00033144, 00107572, 00115993, 00117686, 00118169, 00118572
Cucurbit Vegetables Group			
- Cucumbers	0.5 [9] [180.235(a)]	No [8]	00082271, 00107572, 00118572
Miscellaneous Commodities			
- Mushrooms	0.5 [9] [180.235(a)	No	00074658, 00117686, 00117690
- Tobacco	None established	No [10]	
860.1520: Processed Food/Feed			
- Corn, field	0.5 (processed food) [10] [185.1900]	No	42993501 [13]
- Cottonseed	0.5 (processed food) [11] [185.1900]	No	42993501 [13]
- Rice	0.5 (processed food) [11] [185.1900]	No	42993501 [13]
- Peanuts	0.5 (processed food) [11] [185.1900]	No	42952601 [7]
- Soybeans	0.5 (processed food) [11] [185.1900]	No	42993501 [13]

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Wheat	0.5 (processed food) [11] [185.1900]	No	42993501 [13]
860.1480: Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.02 (milk and the fat, meat, and meat byproducts of cattle, goats, horses, and sheep) [180.235(a)] 0.1 (edible tissue of swine) [180.235(b)]	Yes [12]	00115945, 00116436, 43037401 [13]
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.05 [180.235(a)]	No	00118639, 00119537, 00139843, 00139844, 43047901 [13]
860.1400: Water, Fish, and Irrigated Crops	None established	No	
860.1460: Food Handling			
- Food Service Establishments	None established	No	
- Grain Processing and Manufacturing Establishments	0.5 (RAC) [14] [180.235(a)]		42768702 [13], 42775901 [13], 42878801 [13], 42910801 [13], 42910901 [13]
- Bulk Stored Raw and Processed Commodities [15]	0.5 (RAC) [14] [180.235(a)]	No	00117747, 42916601 [7]
- Bulk stored peanuts [15]	0.5 [180.235(a)]	No	43003101 [7]
- Packaged and Bagged Raw and Processed Commodities	0.5 (RAC, ≤6% fat) [11] 2 (RAC, >6% fat) [11] [180.235(a)] 0.5 (processed food) [11]	No	00056593, 00056595, 00056596, 42853701 [7]

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
	[185.1900]		
- Crack and Crevice Treatments	None established	No [16]	
860.1000: Reduction of Residue			
- Dried Beans	N/A	No	42910701 [13]
- Cocoa Beans	N/A	No	42910701 [13]
- Coffee Beans	N/A	No	42910701 [13]
- Tomato	N/A	No	42910701 [13]
- Meat, Eggs, Pasteurized Milk	N/A	No	42910701 [13]
- Degradation - Packaged and Bagged Raw and Processed Commodities	N/A	No [17]	42858201 [13]
- Degradation - Bulk Stored Raw and Processed Commodities	N/A	No [17]	42903801 [7]
860.1850: Confined Rotational Crops	N/A	No [8]	
860.1900: Field Rotational Crops	None	No [8]	

1 References without endnotes were reviewed in the Residue Chemistry Chapter of the Dichlorvos Reregistration Standard dated 2/26/86. All other references were reviewed as noted.

2. Label amendments are required to incorporate the parameters of use patterns reflected in the submitted data and to reflect the use patterns that the registrant wishes to support which are supported by residue data. Product labels with uses in mushroom houses must be amended to reflect a 1-day PHI. All uses in greenhouses (food use only) and tobacco warehouses must be deleted from product labels. Product labels which allow uses in food-handling establishments must be amended to specify that applications may only be made in: in warehouses, silos, bulk bins, and food/feed processing, food/feed manufacturing, handling and storage plants containing non-perishable, packaged or bagged raw or processed food/feed commodities or bulk raw or processed food commodities; or in non-food areas of food-handling establishments [including garbage rooms, lavatories, floor drains (sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)]. Use in food handling establishments - food service areas must be canceled. There are no tolerances or data supporting this use.

3 CB No. 11768, DP Barcode D190450, 7/21/93, D. McNeilly.

4. CB No. 12766, DP Barcode D196572, 12/17/93, D. McNeilly.

5. CB No. 11244, DP Barcode D187061, 9/29/93, D. McNeilly.

6. Information pertaining to the storage intervals and conditions of samples of the following commodities, from studies that were reviewed in the Residue Chemistry Chapter of the Registration Standard (1987), must be submitted: packaged and bagged raw agricultural commodities and processed food; bulk stored raw agricultural commodities; milk; eggs; and meat, fat, and meat byproducts of dairy cows and poultry. Alternatively, the registrant may demonstrate that there are sufficient residue data supported by storage stability data to support all registered uses of dichlorvos.

7. CB Nos. 12658, 13230, 13296, and 13297; DP Barcodes D195720 , D199212, D199977, and D199979; 6/2/94; S. Hummel.

8. The registrant is not supporting any agricultural uses of dichlorvos. Another registrant has indicated a willingness to support dichlorvos use on tomatoes. If this use is to be supported, residue data are required. We note that the tomato use is no longer on any dichlorvos labels.

9. Residues are expressed as naled.

10. The registrant is not supporting use of dichlorvos in tobacco warehouses.

11. Resulting from application to packaged or bagged nonperishable commodities.

12. A dermal magnitude of the residue study must be submitted for swine. Swine dermal use remains on dichlorvos labels.

13. CB Nos. 13006, 13294, 13295, 13296, and 13427; DP Barcodes D197522 , D199975, D199976, D199979, and D200905; 7/18/94; S. Hummel. Non-detectable residues were reported from direct dermal uses and from secondary residues in livestock feeds.

14. Resulting from application to bulk stored nonperishable commodities, regardless of fat content.

15. See also "860.1520: Processed Food/Feed."

16. Data had been required reflecting crack and crevice treatment of food handling establishments; however, because this use is more restrictive than the registered use on bulk stored and packaged and bagged commodities, these data are no longer required.

17. Although no additional data are required concerning this guideline topic for the purposes of reregistration, the Agency's risk assessment could be better refined if the registrant provides information concerning the typical length of time commodities remain in storage following treatment. This information would include typical total storage times, frequency of applications, and rates of application (g/1000 cu. ft.).

4.0 Tolerance Reassessment

Table C. Tolerance Reassessment Summary for Dichlorvos.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
	Tolerances Listed Under 40 CFR §180.235(a)(1)*		
Cattle, fat	0.02(N)	0.05	Harmonize with CODEX.
Cattle, meat	0.02(N)	0.05	Harmonize with CODEX.
Cattle, mbyp	0.02(N)	0.05	Harmonize with CODEX.
Cucumbers	0.5 [1]	Revoke	The registrant is not supporting use of dichlorvos on this commodity. Tolerance has been revoked.
Eggs	0.05(N)	0.05	
Goats, fat	0.02(N)	0.05	Harmonize with CODEX.
Goats, meat	0.02(N)	0.05	Harmonize with CODEX.
Goats, mbyp	0.02(N)	0.05	Harmonize with CODEX.
Horses, fat	0.02(N)	0.05	Harmonize with CODEX.
Horses, meat	0.02(N)	0.05	Harmonize with CODEX.
Horses, mbyp	0.02(N)	0.05	Harmonize with CODEX.
Lettuce	1 [1]	Revoke	The registrant is not supporting use of dichlorvos on this commodity. Tolerance has been revoked.
Milk	0.02(N)	0.05	Harmonize with CODEX.
Mushrooms	0.5 [1]	0.5	The tolerance should be revised to be expressed in terms of dichlorvos.
Poultry, fat	0.05(N)	0.05	
Poultry, meat	0.05(N)	0.05	
Poultry, mbyp	0.05(N)	0.05	
Radishes	0.5	Revoke	The registrant is not supporting use of dichlorvos on this commodity.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Raw agricultural commodities, nonperishable, bulk stored regardless of fat content (post-H)	0.5	4.0	*[Raw agricultural commodities, nonperishable, bulk stored]*
Raw agricultural commodities, nonperishable, packaged or bagged, containing 6 percent fat or less (post-H)	0.5		
Raw agricultural commodities, nonperishable, packaged or bagged, containing more than 6 percent fat (post-H)	2.0	4.0	*[Raw agricultural commodities, nonperishable, packaged and bagged]*
Sheep, fat	0.02(N)	0.05	Harmonize with CODEX.
Sheep, meat	0.02(N)	0.05	Harmonize with CODEX.
Sheep, mbyp	0.02(N)	0.05	Harmonize with CODEX.
Tomatoes (pre- and post-H)	0.05 [1]	Revoke	The registrant is not supporting use of dichlorvos on this commodity.
Tolerances Listed Under 40 CFR §180.235(a)(2)			
Edible swine tissue [2]	0.1	Revoke	Residue data have been required and not submitted.
Tolerances Listed Under 40 CFR §180.235(a)(3)			
Packaged or bagged nonperishable processed food	0.5	4.0	The tolerance should be moved to §180.235(a)(1). *[Processed food, nonperishable, packaged or bagged]*
Tolerances to be Proposed Under 40 CFR §180.235(a)			
Soybean, hulls	--	15.0	
Aspirated grain fractions	--	20.0	

*** Concurrently with the revocation of the tolerance for edible swine tissue in §180.235(a)(2) and the moving of the tolerance for packaged or bagged nonperishable processed food in §180.235(a)(3), §180.235(a)(1) should be redesignated §180.235(a).**

[1] Residues expressed as naled. Another registrant has expressed interest in supporting the tolerance on tomato. However, data have been required and not submitted.

[2] Resulting both from its use as an anthelmintic in swine feed and as an insecticide applied directly to swine; prescribed by 21 CFR 558.205 as a feed additive in swine, with a tolerance of 0.1 ppm for residues of dichlorvos in edible swine tissue listed in 21 CFR 556.180.

APPENDIX K: Revised EFED risk assessment for the Dichlorvos Reregistration Eligibility Document

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC Code: 084001
DP Barcodes: D318301

MEMORANDUM

June 20, 2005

Subject: Revised EFED risk assessment for the Dichlorvos Reregistration Eligibility Document

To: Bob McNally, Branch Chief,/Eric Olson, Chemical Review Manager
Special Review Branch
Special Review and Reregistration Division (7508C)

From: Diana Eignor
Ibrahim Abdel-Saheb
Environmental Risk Branch II
Environmental Fate and Effects Division (7507C)

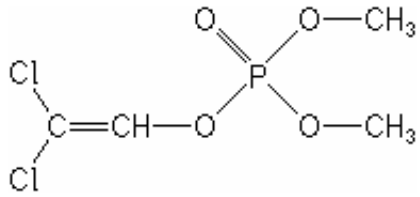
Through: Tom Bailey, Chief, ERB II
Environmental Fate and Effects Division (7507C)

EFED has completed a revised screening level ecological risk assessment for the reregistration of dichlorvos. Attached is the dichlorvos ecological risk assessment.

Risk conclusions can be found in the Executive Summary on page 4.

DICHLORVOS (DDVP)

Revised Ecological Risk Assessment



Diana Eignor
Ibrahim Abdel-Saheb

Approved By:

Thomas A. Bailey, Chief
Environmental Risk Branch 2
Environmental Fate and Effects Division

June 20, 2005

TABLE OF CONTENTS

APPENDICES

I. EXECUTIVE SUMMARY

Dichlorvos (2,2-Dichlorovinyl dimethyl phosphate), also known as DDVP , is an organophosphate insecticide first registered for use in 1948. Dichlorvos is used in various scenarios for pest control but there are no agricultural crop uses for this chemical. Target pests are flies, gnats, mosquitoes, chiggers, ticks, cockroaches, armyworms, chinch bugs, clover mites, crickets, cutworms, grasshoppers, and sod webworms. Dichlorvos is registered for domestic indoor, terrestrial non-food, greenhouse (non-food) and domestic outdoor use. This document includes an assessment of risks to terrestrial animals resulting from the use of dichlorvos on the federal-label listed uses for dry granular bait use in animal premise areas and liquid spray use for turf and flying insects. Risks to aquatic organisms are assessed based on modeled EECs for the turf scenario.

Terrestrial Exposure

- Immediately following granular bait application, granules and/or residues are expected to be around animal premises. Birds and small mammals may be exposed from application to this site.

- Terrestrial animals may be exposed to dichlorvos resulting from application of liquid products used as a coarse spray to turf or to outdoor areas for flying insect control *(e.g.,* sites such as recreational parks and trails).

Aquatic Exposure

- Aquatic animals may be exposed to dichlorvos resulting from drift from ground spray application to the turf and outdoor flying insect sites.

- It is unlikely that aquatic organisms will be directly exposed to dry granular bait**.**

Risk to Terrestrial Organisms

- The chronic risk endangered species LOCs are exceeded for turf applications (both 1 and 4 applications) for birds that consume short grass, tall grass, and broadleaf plants/small insects.

- For the flying insect scenario, chronic RQs exceed endangered species for birds consuming short grass, tall grass, and broadleaf plants/small insects.

- The acute risk, acute restricted use, and acute endangered species LOCs for a small bird (20 g weight) are exceeded for the bait formulation scenario .

- The chronic LOC is exceeded for 15 g, 35 g, and 1000 g mammals that consume short grass, tall grass, and broadleaf plants/small insects in the turf scenario.

- For turf application, there are acute endangered species LOC exceedences for the 15 g and 35 g mammals that consumes short grass.

- Chronic risk to birds and mammals from the bait formulation can not be assessed at this

time.

Risks to Aquatic Organisms

- The acute risk, acute restricted use, and acute endangered species LOCs for freshwater invertebrates are exceeded for turf scenarios in FL and PA for both one and four applications of dichlorvos.

- In addition, the chronic level of concern is exceeded for freshwater invertebrates [egg production and growth (length and weight) endpoint] for all of the turf scenarios (one and four applications).

II. PROBLEM FORMULATION

A. Introduction

Dichlorvos (2,2-Dichlorovinyl dimethyl phosphate), also known as DDVP , is an organophosphate insecticide first registered for use in 1948. Dichlorvos is used in various scenarios for pest control but there are no agricultural crop uses for this chemical.

The objectives of the current ecological risk assessment were to identify current registered dichlorvos uses, identify potential exposure pathways and ecological receptors, estimate exposure concentrations, identify ecological endpoints, and characterize risks for ecological receptors. This screening-level risk assessment follows the Agency's Ecological Risk Assessment Guidelines (USEPA, 2000). This document includes an assessment of risks to terrestrial animals resulting from the use of dichlorvos on the federal-label listed uses for dry granular bait use in animal premise areas and liquid spray use for turf and flying insects. Risks to aquatic organisms are assessed based on modeled EECs for the turf scenario.

B. Stressor Source and Distribution

1. Chemical and Physical Properties

Common Name:	Dichlorvos (DDVP)
Chemical Name:	2,2-Dichlorovinyl dimethyl phosphate
Trade Names:	Dichlorvos, DDVP, and Vapona
CAS No.	62-73-7
Molecular Formula:	$C_4 H_7 Cl_2 O_4 P$
Molecular Weight:	220.98 g/mol
Physical state:	colorless to amber liquid with a mild chemical odor
Boiling Point:	140° C at 0.01 mm Hg
Vapor Pressure:	1.2×10^{-2} mm Hg at 20°C
Solubility:	15,000 mg/L (25 °C)
Henry's Law Const.:	5.01E-8 atm m^3/mole (measured)
Formulations:	Granules for Bait (*e.g.* Active ingredient 7.44%, Inert ingredients 92.56%); Liquid (*e.g.* Active ingredient 40.2%, Inert ingredients 59.8%)

2. Mode of Action

Dichlorvos is an organophosphate insecticide which is a potent cholinesterase (ChE) inhibitor. Acetylcholinesterase is an enzyme necessary for the degradation of the neurotransmitter acetylcholine (ACh) and subsequent cessation of synaptic transmission. Inhibition of these enzymes results in the accumulation of ACh at cholinergic nerve endings and continual nerve stimulation, which can result in death. For non-target organisms, it causes reversible inhibition of erythrocyte acetylcholinesterase (RBC ChE) as well as plasma butyryl ChE by binding to the active site of the enzyme.

3. Regulatory History

- Dichlorvos was first registered in 1948.
- DDVP is now in the Special Review process.
- EPA published a Notice of Preliminary Determination (Position Document 2/3) in the Federal Register on September 28, 1995.

- Dichlorvos is currently banned or restricted in 6 countries. The bans in Angola, Fiji, and Denmark; the cancellation in Sweden; and restrictions in Kuwait all occurred in 1999 (Source: PIC Circular X, Appendix V: Synopsis of Notifications of Control Actions, United Nations Environment Programme, December, 1999, http://www.fao.org/AG/AGP/AGPP/Pesticid/PIC/circular.htm). .
  - Angola's control action applies to the banning of the product Vapona 24 EC.
  - Dichlorvos is banned for all uses in Fiji with no remaining uses allowed because of the potential health hazard.
  - In Denmark, all authorizations for products containing dichlorvos as an active substance have been withdrawn from the market 31 December 1997 and a further use has been banned from 01 August 1998. No uses are allowed. Dichlorvos is assessed to be carcinogenic in category 3 (cars., 3 cat., 3) and the formulated products are highly acute toxic (T+ and T classified respectively) in Denmark. The products are therefore assessed to be harmful to health.
  - In Sweden , registration was cancelled (voluntarily withdrawn). This substance was restricted due to its mutagenic properties in Sweden.
  - In Kuwait, dichlorvos use is severely restricted.. Import of this chemical was stopped from June 1994. Action was taken for health reasons.
- All uses of dichlorvos in the UK were suspended 4/19/2002. See http://www.doh.gov.uk/com/dichlorvos.htm. Extant approval is for storage by any persons and for use by persons other than the approval holder or their agents of existing stocks (approvals expire 18 April 2004). (Source: Banned and Non-Authorized Pesticides in the UK, Pesticides Safety Directorate, June 21, 2002, http://www.pesticides.gov.uk/Blue_Book/Contents.htm.)

4. Use Characterization

Dichlorvos is an organophosphate insecticide registered for indoor, terrestrial non-food, greenhouse (non-food) and domestic indoor and outdoor use. There are no agricultural crop uses for this chemical. Although the LUIS report classifies catch basin as an aquatic non-food site for dichlorvos, it is more appropriately considered a terrestrial non-food outdoor use based on target pest (flying or resting adult mosquitoes), formulation type (resin strip), placement of strip (10 inches above water level) and mode of action (fumigant).

Target pests are flies, gnats, mosquitoes, chiggers, ticks, cockroaches and other nuisance insect pests. For the turf and ornamental uses target pests also include armyworms, chinch bugs, clover mites, crickets, cutworms, grasshoppers, and sod webworms. Formulation types include baits, liquids and impregnated materials.

The majority of dichlorvos uses are indoors; including mushroom houses, greenhouses, commercial, residential and industrial buildings, farm buildings, food handling establishments, trash receptacles, and wine cellars. Ecological risk assessments are not performed for indoor uses.

In the 1987 Dichlorvos Registration Standard, EFED addressed the two major outdoor sites, figs and mosquito adulticide/larvicide. A third major outdoor site, turf, was not considered because all registered products containing dichlorvos for that site were multiple active ingredient (MAI) products, and policy at that time was not to consider MAI products. The current assessment addresses outdoor flying insects (including mosquitoes), turf, and bait formulations used around animal premises. The mosquito larvicide and fig uses have been canceled.

For the outdoor sites listed below, EFED finds minimal potential for exposure to terrestrial and aquatic animals based on the fate properties of dichlorvos and treatment sites being small and localized. Maximum application rates and reapplication intervals for outdoor sites are listed below. No risk assessments were performed for these sites:

- Around agricultural premises/structures (liquids): (spot or band treatment only): liquid spray -0.0115 lb/1000 sq. ft ^{2} ; 0.5 lb ai/A; 7 day reapplication interval for commercial sites and 30 day reapplication interval for residential sites.

- Catch basin - Insect traps, impregnated resin strips (including the insecticidal strip suspended 10 inches above water in catch basin areas to control flying insects): 1 x 80g strip/1000ft ^{3} ; (80g strip contains 18.6% dichlorvos = 14.88g dichlorvos/strip =0.0327 lb/strip; usual control last 10 to 15 weeks.

- Manure treatment/garbage/refuse areas (liquids and baits): Dry bait: 0.046 lb/1000 ft ^{2} ; Liquid spray : 0.046 lb/1000 ft ^{2} ; 2 lb ai/A; 1 day reapplication interval.

- Direct treatment to Animals: Liquid spray: 0.0013 lb ai/animal (livestock): 0.02 g/animal (poultry); 1 day reapplication interval. (Maximum use rate for birds is from Amvac 1/12/98 letter clarifying uses); also registered labels state to spray at rate of 1 quart/1000 sq. ft. (2 lb and 4 lb/gal EC formulations; birds may be present).

The maximum application rates and reapplication intervals for outdoor sites considered in this risk assessment are listed below:

- Liquid sprays for turf and flying insects (including mosquitoes): 0.0046 lb/1000 ft ^{2} (0.2 lb ai/A); 1 day reapplication interval for commercial sites and 7 day reapplication interval for residential sites; ground application only; coarse sprays only . According to BEAD, a worse case scenario for turf is 4 applications with 30 day application interval and 75 applications per year for flying insect control.

- Dry bait formulations around animal premise areas: 0.0025 lb/1000 ft ^{2} (equivalent to 0.1 lb ai/a) Some of the labels bear directions to reapply every 3 to 5 days until control is achieved. Therefore, a worse case scenario would be 120 applications per year based on label specifications.

For the outdoor flying insect (including mosquitoes) site, some of the labels have specificity of where to apply, *e.g.,* recreational areas, trails, outdoor living areas, eating areas of drive-in restaurants, refuse areas, garbage collection/disposal areas, outdoor latrines, refuse areas around service stations, loading docks, animal feedlots, stockyards, corrals, holding pens, lawns, turf and ornamental plants. On the other hand, many of the labels have vague directions for use, *e.g.,* apply outdoors where pests are a problem. Dichlorvos does not appear to be used in this country for adult mosquito control. It is not listed in State Management recommendations for mosquito control, and the American Mosquito Control Association (AMCA) has indicated “as far as they could tell”, it wasn’t being used in this country. It appears a worst case scenario for insect control is around 75 applications to a given site over a year period (personal communication with Douglas Sutherland, 4/15/98). For turf use, dichlorvos would normally be

applied only once or twice per season. It is possible that up to four applications may be made, but this would be unusual (Douglas Sutherland, BEAD entomologist, personal communication, 4/13/98). However, since the label does not limit the number of applications, the high end estimate of 4 applications per season is modeled in addition to 1 application per season.

5. Measurement Endpoints

Each assessment endpoint requires one or more "measures of ecological effect," which are defined as changes in the attributes of an assessment endpoint itself or changes in a surrogate entity or attribute in response to pesticide exposure. Ecological measurement endpoints for the screening level risk assessment are based on a suite of registrant-submitted toxicity studies, as well as open literature review (U.S. EPA. 2004a). The ECOTOX (ECOTOXicity) database is used to identify additional data from the open literature. The ECOTOX database is a user-friendly, publicly-available, quality-assured, comprehensive tool for locating toxicity data from the open literature and is maintained by the EPA Mid-Atlantic Ecology Division. However, for this risk assessment for dichlorvos, a detailed open literature search was not conducted.

Toxicity studies are usually performed on a limited number of organisms in the following broad groupings:

- Birds (mallard duck and bobwhite quail) used as surrogate species for terrestrial-phase amphibians and reptiles
- Mammals (laboratory rat)
- Freshwater fish (bluegill sunfish and rainbow trout) used as a surrogate for aquatic phase amphibians
- Freshwater invertebrates (water flea - *Daphnia magna*)
- Estuarine/marine fish (sheepshead minnow)
- Estuarine/marine invertebrates (Eastern oyster and mysid shrimp)
- Terrestrial plants (corn, onion, ryegrass, wheat, buckwheat, cucumber, soybean, sunflower, tomato, and turnip)
- Algae and aquatic plants (algae, diatoms, and duckweed)

6. Endangered Species

Potential risks posed by dichlorvos use on listed or endangered species must be evaluated. The potential for individual effects at exposure levels equivalent to the level of concern (LOC) is made based on the median lethal dose estimate and dose-response relationship established for the effects study corresponding to each taxonomic group for which the LOCs are exceeded.

C. Conceptual Model

A conceptual model (CM), which summarizes graphically the results of the problem formulation for evaluating risks to ecological receptors following application of dichlorvos as a dry granular bait around animal premise areas is provided in Figure 1. The CM for the application of dichlorvos as a liquid spray for turf and flying insects is presented in Figure 2. The CMs are working hypotheses about how dichlorvos is likely to reach (*i.e.*, exposure pathways) and affect ecological entities (*i.e.*, attribute changes) of concern on and adjacent to a treated area. In order for a pesticide stressor to pose an ecological risk, it must reach an ecological receptor in biologically significant concentrations. The CMs outline specifically which measures of exposure, ecological receptors, and measures of effects or measurement endpoints will be used to estimate risks from proposed reregistration uses of dichlorvos.

Based on the registered uses, dichlorvos is used on areas located in a wide diversity of ecoregions and habitats spanning the continental United States, Hawaii, Alaska, and Puerto Rico. The wide diversity of land forms and vegetation types across dichlorvos use areas also provides for a large diversity of mammals, birds, reptiles, amphibians, terrestrial invertebrates, and freshwater and estuarine/marine fish and invertebrates that could potentially be exposed.

1. Terrestrial Environment

a. Exposure

Immediately following granular bait application, granules and/or residues are expected to be around animal premises. Birds and small mammals may be exposed from application to this site. Wildlife exposure could result from mistakenly ingesting granules as seeds or ingesting them as part of incidental soil ingestion while foraging for food. Wildlife exposure could also result from a number of other exposure pathways and wildlife actions or behaviors including inhalation of dust particulates; dermal uptake via direct contact of skin with the granules and residues in soil and turf; contact with residues in puddles present in the area at the time of application or formed after a rain event; or ingestion of water from residues in puddles. Currently, terrestrial wildlife exposure for granular bait formulations are estimated via the amount of toxicant per unit area in a screening-level risk assessment. This index was developed considering these other routes of exposure; however, they are not separately accounted for in the index calculation.

Terrestrial animals may be exposed to dichlorvos resulting from application of liquid products used as a coarse spray to turf or to outdoor areas for flying insect control, including mosquitoes *(e.g.,* sites such as recreational parks and trails). Use is by ground application *(e.g.,* back-pack sprayers or truck-mounted sprayers) using coarse sprays directed to the vegetation. One day reapplication intervals are permitted for both sites, except for homeowner where it is seven days. Continuous year-round exposure is possible in some areas of the country, *e.g.,* Florida, for both sites.

Currently registered labels for turf and flying insects allow for fogging and misting, and there are no label prohibitions against aerial application. Labels do not specify maximum numbers of applications or reapplication intervals. Drift can be minimized by prohibiting aerial application, and restricting application to coarse sprays. However, for the turf site, BEAD sources indicate a typical application is only twice per year (with a thirty day reapplication interval), with four applications representing worst-case. For the flying insect (including adult mosquitoes) use, it does not appear that dichlorvos is being used in this country. BEAD sources indicate a worst case scenario for a pesticide used for adult mosquito control would be around 75 applications to a given site over a year period. There are no label restrictions for the use of granular bait. Based on the label directions to reapply every 3 to 5 days until control is achieved, a worse case scenario would be 120 applications per year.

b. Receptors of Concern

Ecological receptors of concern identified for consideration in the terrestrial environment include primary producers, represented by both upland and wetland/riparian vegetation, and primary and secondary consumers, both vertebrates and invertebrates, representing common ecological functional feeding groups (*i.e.*, herbivores and insectivores). Herbivores as used here include animals that feed on foliage (stems and leaves), seeds, and/or fruit; the term granivore is sometimes used to identify animals that feed primarily on seeds. Omnivores (*i.e.*, consumers that feed on a mixed diet of animals and plants) are also potentially exposed but are not specifically included in the receptor list for a screening level risk assessment because exposure concentrations and risk levels will fall between the exclusive feeding groups.

Based on the sources/transport pathways, exposure media, and potential receptors of concern, specific questions or risk hypotheses formulated to characterize direct effects of dichlorvos following application on areas to selected assessment endpoints is provided below.

c. Terrestrial Environment Risk Hypotheses for Dichlorvos Uses

Birds and mammals are subject to reduced survival or reduced reproduction when exposed to dichlorvos as a result of labeled use.

Upland and riparian/wetland plants are subject to adverse effects (reduced survival) when exposed to dichlorvos as a result of labeled use.

2. Aquatic Environment

c. Exposure

Aquatic animals may be exposed to dichlorvos resulting from drift from ground spray application to the turf and outdoor flying insect sites. Following a rain event, dichlorvos may reach aquatic environments from areas of spray application in sheet and channel flow runoff since dichlorvos is soluble in water. Direct exposure to aquatic animals from misapplication of the pesticide is also possible. Aquatic organisms could also be exposed to dichlorvos from groundwater that is subsequently discharged into a surface water body. Continuous year-round exposure to aquatic animals is possible in some areas of the country, *e.g.,* Florida, for both the turf and flying insect scenarios. It is unlikely that aquatic organisms will be directly exposed to dry granular bait, therefore that pathway is not evaluated.

Currently registered labels for turf and flying insects allow for fogging and misting, and there are no label prohibitions against aerial application. Labels do not specify maximum numbers of applications or reapplication intervals. Drift can be minimized by prohibiting aerial application, and restricting application to coarse sprays. However, for the turf site, BEAD sources indicate a typical application is only twice per year (with a thirty day reapplication interval), with four applications representing worst-case. For the flying insect (including adult mosquitoes) use, it does not appear that dichlorvos is being used in this country. BEAD sources indicate a worst case scenario for a pesticide used for adult mosquito control would be around 75 applications to a given site over a year period.

b. Receptors of Concern

For the aquatic ecosystem, ecological receptors include all aquatic life (fish, amphibians, invertebrates, plants) and those terrestrial animals (e.g., birds and mammals) that consume aquatic organisms. Based on the above sources/transport pathways, exposure media, and potential receptors of concern, specific questions or risk hypotheses formulated to characterize direct effects of dichlorvos application to selected assessment endpoints is provided below.

c. Aquatic Environment Risk Hypotheses for Dichlorvos Uses

Aquatic invertebrates and fish are subject to adverse effects such as reduced survival and reduced reproduction when exposed to dichlorvos as a result of labeled use.

Aquatic plants are subject to adverse effects (reduced survival) when exposed to dichlorvos as a result of labeled use.

Figure 1. Ecological conceptual model for the application of dichlorvos as dry granular bait. Solid arrows indicate pathways addressed in assessment.

Figure 2. Ecological conceptual model for the application of dichlorvos as liquid spray. Solid arrows indicate pathways addressed in assessment.

D. Key Uncertainties and Information Gaps

The following uncertainties and information gaps were identified as part of the problem formulation:

1. Ecotoxicity Information Gaps

There are no terrestrial plant data for dichlorvos which leads to uncertainty in the evaluation of plant risk and indirect effects to other organisms. **Appendix A** at the end of this document provides the summary status of all the ecotoxicological data requirements

2. Environmental Fate Information Gaps

There are no data gaps in the environmental fate information. **Appendix B** at the end of this document provides the summary status of all the environmental fate data requirements

E. Analysis Plan

1. Specific Considerations

This document includes an assessment of risks to terrestrial animals resulting from the use of dichlorvos as a bait formulation and spray application for the turf and flying insect scenarios. Risks to aquatic organisms are assessed based on modeled EECs for liquid spray application for the turf scenario. For the flying insect scenario, current models are inappropriate to use so a quantitative assessment for flying insects can not be performed. It is likely the EECs in the surface water for the flying insect scenario would be less than the turf scenario since the treatment area would be smaller.

Ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors (US EPA, 1992a). This risk assessment examines the ecological risk of dichlorvos use, and attempts to determine at what level dichlorvos can be used to minimize deleterious effects on the environment. These negative effects include structural and/or functional characteristics or components of ecosystems. In order to estimate the ecological risk associated with dichlorvos use, use information, chemical and physical properties, and fate/transport data were evaluated.

2. Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Two criteria are used to select the appropriate ecological assessment endpoints: (1) identification of the valued attributes of the environment that are considered to be at risk, and (2) the operational definition of assessment endpoints in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, the selection of assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern.

a. Toxicity *Endpoints*

Aquatic and terrestrial non-target toxicity endpoints (animals and plants) are provided by the acute and, where appropriate, chronic toxicity data. These toxicity endpoints are compared with the environmental concentrations of dichlorvos, based on fate properties, exposure method, etc. For this assessment, the most sensitive toxicity endpoints for each surrogate taxa (ie. freshwater fish and invertebrates, estuarine/marine fish and invertebrates, aquatic plants, terrestrial plants, birds, and mammals) will be used in Risk Quotient (RQ) calculation with various exposure values.

An acute and chronic endpoint is selected from the available test data as the data sets allow. Endpoints used in this assessment are listed in **Table 1**.

Table 1. Summary of Assessment and Measurement Endpoints used in calculations

Assessment Endpoint	Measurement Endpoint
1. Survival, reproduction, and growth of **birds**	Acute oral Mallard duck LD_{50} = 7.78 mg/kg Subacute dietary Pheasant LC_{50} = 568 mg/kg Chronic Mallard Duck NOEC = 5 ppm
2. Survival, reproduction, and growth of **mammals**	Oral Rat LD_{50} = 56 mg/kg (female) Chronic Rat NOEC = 20 ppm
3. Survival and reproduction of **freshwater fish** and **invertebrates**	Acute Lake Trout LC_{50} = 183 ppb Acute Daphnia EC_{50} = 0.07 ppb Chronic Rainbow trout NOAEC = 5.2 ppb Chronic Daphnia NOEAC = 0.0058 ppb
4. Survival and reproduction of **estuarine/marine fish** and **invertebrates**	Acute Sheepshead minnow LC_{50} = 7350 ppb Chronic Sheepshead minnow NOAEC = 960 ppb Acute Mysid LC_{50} = 19.1 ppb Chronic Mysid NOAEC = 1.48 ppb
5. Perpetuation of non-target **terrestrial plants** (crops and non-crop species)	NA
6. Survival of beneficial insect populations	Honey bee (acute contact basis) LD_{50} = 0.495 µg/bee
7. Maintenance and growth of **aquatic plants** from standing crop or biomass	Acute algae 48 hr EC_{50} = 14000 ppb

LD_{50} = Lethal dose to 50% of test population
NOAEC = No observed adverse effect concentration
LOAEC = Lowest observed adverse effect concentration
LC_{50} = Lethal concentration to 50% of the test population
EC_{50}/EC_{25} = Effect concentration to 50%/25% of the test population

4. Planned Analyses

a. Fate and Exposure

Terrestrial Environment

Ingestion of granular bait used in animal premise areas represents a significant exposure pathway in terrestrial animals. In addition, terrestrial organisms may be exposed in treated areas (turf and flying insect areas) via spray applications. Therefore, the terrestrial screening-level risk assessment examined exposure to granular bait using the maximum labeled use rate. Turf use was assessed using four applications as the worse case scenario. For the flying insect scenario, weekly applications over a year period was chosen as a worst-case scenario. A terrestrial foliar dissipation half life of 0.0875 days was used in the terrestrial modeling for liquid spray. This half life was based on data from acceptable studies submitted to the Health and Effects Division (HED), titled "Dislodgeable foliar residues and exposure assessment for residential/recreational turf applications of dichlorvos (DDVP), Barcodes D248456, D248596, D255253). Only parent dichlorvos was modeled for terrestrial exposure scenarios.

Aquatic Environment

OPP generally uses computer simulation models to estimate exposure of aquatic organisms, such as plants, fish, aquatic-phase amphibians, and invertebrates, to a pesticide. These models calculate estimated environmental concentrations (EECs) in surface water using laboratory data that describe the rate at which the pesticide breaks down and how it moves into the environment. Monitoring data, if available, may also be used to determine EECs or to support the model's calculations. The PRZM-EXAMS model is initially used to calculate high-end estimates of surface water concentrations of pesticide in a generic pond. This model was used to generate EECs of dichlorvos in surface water for the turf scenarios. The User's Manual and PRZM-EXAMS Model Description can be consulted for additional information at: www.epa.gov/oppefed1/models/water/index.htm. No EECs are generated in instances where no toxicity was observed at concentrations above the active ingredient's water solubility at or above the recommended limit concentration for a particular type of study.

The Florida and Pennsylvania turf scenarios were used in the standard Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM-EXAMS) modeling. Both one application and 4 applications were modeled. The rationale for choosing four applications for turf was based on information received from BEAD indicating a worst-case scenario would probably be about four applications. The PRZM model input called "decay rate on foliage" was based on data from acceptable studies submitted to the Health and Effects Division (HED), titled "Dislodgeable foliar residues and exposure assessment for residential/recreational turf applications of dichlorvos (DDVP), Barcodes D248456, D248596, D255253).

For the flying insect (including adult mosquitoes) use, the GENEEC model is inappropriate to use. It is likely EECs found in surface water from treatment for flying insects (including adult mosquitoes) would likely be lower than EECs from treatment to turf, since the treatment area would likely be less. Since the applications for flying insect control are ground applications *(e.g.,* back-pack sprayers or truck-mounted sprayers) using coarse sprays directed to the vegetation (no fogging or misting), EFED cannot perform a quantitative assessment.

It is unlikely that aquatic organisms would be directly exposed to the dry granular bait use in animal premise areas, therefore that pathway is not evaluated.

c. Risk Quotient and Levels of Concern

Risk characterization integrates exposure and ecotoxicity data to evaluate the likelihood of adverse effects. For ecological effects, the Agency accomplishes this integration using the quotient risk method. Risk quotients (RQs) are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

RQ = EXPOSURE / TOXICITY

RQs are then compared to the Office of Pesticide Program's levels of concern (LOCs) to assess potential risk to non-target organisms and the need to consider regulatory action. Calculation of an RQ that exceeds the LOC indicates that a particular pesticide use poses a presumed risk to non-target organisms. LOCs currently address the following categories of presumed risk:

- **acute** - potential for acute risk is high and regulatory action beyond restricted use classification may be warranted
- **acute restricted** - the potential for acute risk is high, but may be mitigated through restricted use classification
- **acute endangered species** - threatened and endangered species may be adversely affected
- **chronic risk** - the potential for chronic risk is high and regulatory action may be warranted.

The ecotoxicity values used in the acute and chronic risk quotients are endpoints derived from required laboratory toxicity studies. Ecotoxicity endpoints derived from short-term laboratory studies that assess acute effects are:

- LC_{50} - fish and birds
- LD_{50} - birds and mammals
- EC_{50} - aquatic plants and aquatic invertebrates
- EC_{25} - terrestrial plants

The NOAEC (No Observable Adverse Effect Concentration) is the endpoint used to assess chronic effects. **Table 2** gives formulas for calculating RQs and LOCs for various risk presumptions.

Table 2. Formulas for RQ calculations and LOC used for risk assessment of dichlorvos

Risk Presumption	RQ	LOC
Birds and Wild Mammals		
Acute Risk	EEC[1]/LC_{50} or LD_{50}/ft^{2*} or LD_{50}/day^{2}	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day (or LD50<50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day	0.1
Chronic Risk	EEC/NOAEC[5]	1.0
Aquatic Animals		
Acute Risk	EEC[3]/LC_{50} or EC_{50}	0.5

Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOAEC	1.0
Terrestrial and Plants Inhabiting Semi-Aquatic Areas		
Acute Risk	EEC^4/EC_{25}	1.0
Acute Endangered Use	EEC/EC_{05} or NOAEC	1.0
Aquatic Plants		
Acute Risk	EEC^3/EC_{50}	1.0
Acute Endangered Species	EEC/EC_{05} or NOAEC	1.0

* mg/ft²
[1]Abbreviation for Estimate Environmental Concentration (ppm) on avian/mammalian food items
[2] mg of toxicant consumed/day
[3] EEC = ppm or ppb in water
[4] EEC = lbs ai/A
[5] No chronic risk was calculated for terrestrial animals based on the LD_{50}/ft^2 index

III. ANALYSIS

A. Exposure Characterization

1. Environmental Fate and Transport Characterization

Acceptable studies for dichlorvos are available for all guidelines. The status of the data requirements is described in **Appendix B.** Selected physical and chemical properties are summarized in **Table 3**.

Table 3. Selected physical and chemical properties of dichlorvos

Property	Value
Molecular Formula	$C_4 H_7 Cl_2 O_4 P$
Molecular Weight	220.98 g/mol
Physical State	colorless to amber liquid
Odor	mild chemical odor
Boiling point	140° C at 0.01 mm Hg
Vapor pressure	1.2×10^{-2} mm Hg at 20°C
Henry's Law coefficient	5.01E-8 Atm. m 3 /mol (measured)
Solubility	in water at 25° C= 15000 mg/L
CAS Number	62-73-7

a. Persistence

Metabolic transformation is the major mode of dissipation of dichlorvos under field conditions. Acceptable laboratory and field studies also indicate rapid dissipation through volatilization (vapor pressure = 1.2 x 10^{-2} mmHg). Volatility is not going to be a major route of dissipation under field conditions when the soil is moist and the pesticide is wetted in. It appears dichlorvos degrades through aerobic soil metabolism and abiotic hydrolysis as well, but is secondary to volatilization. Hydrolysis is pH dependant where the half-lives were 11.6 days at pH 5, 5.5 days at pH 7 and 21.1 hours at pH 9.
Acceptable lab and field studies indicate that the major modes of dissipation of dichlorvos are volatilization (vapor pressure 1.2 x 10^{-2} torr) and microbial degradation in an aerobic soil. Dichlorvos is unstable to hydrolysis at 25°C at pH 9. Under field conditions when the soil is moist and the pesticide is wetted, volatilization is not going to be a major route of dissipation. These mechanisms of dissipation indicate dichlorvos has low persistence in the environment.

Hydrolysis is pH dependent where the half-life is 11.65 days at pH 5, 5.19 days (124.62 hours) at pH 7, and 0.88 days (21.12 hours) at pH 9 respectively at 25° C. Major degradates were 2,2-dichloroacetic acid (DCA), 2,2-dichloroacetaldehyde (DAA), des-methyl dichlorvos, and glyoxylic acid. The guideline requirement for hydrolysis (163-2) is fulfilled (MRID 41723101).

Aqueous photolysis found that dichlorvos dissipated with half-lives 10.2 days in the irradiated samples and 8.9 days in the dark control samples. Major degradates of dichlorvos in the Day 15 irradiated samples were 2,2-dichloroacetaldehyde (32.7%) and des-methyl dichlorvos (17.8%) of the applied radiocarbon. Under dark condition, major degradates were 2,2-dichloroacetaldehyde (42.0%) and desmethyl dichlorvos (16.3%). The guideline requirement for photodegradation in water (163-2) is fulfilled (MRID 43326601).

Soil photolysis study showed that dichlorvos photodegraded with a half-life of 15.5 hours on a sandy loam soil surface (pH 7). Dichlorvos had a half life of 16.5 hours when incubated in darkness under similar conditions. After 72 hours of irradiation, 97% of the applied dichlorvos had dissipated from the soil by a combination of degradation and volatilization. Degradates identified in the irradiated soil were 2,2-dichloroacetic acid (26.6%) and 2,2-dichloroethanol (4.4%). The only degradation product formed under dark condition was 2,2-dichloroacetic acid of which 34% volatilized and 54.2% remained in soil. The guideline requirement for photodegradation on soil (161-3) is fulfilled (MRID 43642501).

Dichlorvos metabolized with a half-life of 10.18 hours in a sandy loam soil (pH 6.2) incubated in the dark under aerobic conditions. The major non-volatile metabolites formed during this aerobic metabolism were 2,2-dichloroacetaldehyde and dichloroethanol (each accounted for less than 12% of the initially applied radioactivity). 2,2-dichloroacetic acid accounted for up to 62.8% of the initially applied radioactivity at 48 hours post-treatment. The only volatile metabolite was 14 CO_2 which accounted for 60.8% of the initially applied radiocarbon at 360 hours post-treatment. The guideline requirement for aerobic soil metabolism (162-1) is fulfilled (MRID 41723102).

Dichlorvos metabolized with half-life of 6.3 days in sandy loam soil (pH 6.8) that was incubated in the dark under anaerobic conditions (flooding plus nitrogen atmosphere) at 25° C for up to 60 days . The major nonvolatile degradates in the water phase and soil extracts were 2,2-dichloroaceticacid (which accounted for up to 50.9% of the applied radioactivity at day 60), 2,2-dichloroacetaldehyde (which accounted for up to 12.6% of the applied radioactivity at day 5),

and 2,2-dichloroethanol (which accounted for up to 24.7% at day 60.0). The guideline requirement for anerobic soil metabolism (162-2) is fulfilled (MRID 43835701).

Terrestrial field dissipation studies (164-1) showed that dichlorvos dissipated too rapidly within the time taken to perform the sampling process. Dichlorvos degraded rapidly to 2,2-dichloroacetic acid (DCA), which was detected only in the 0-4 inch soil. There was no dichlorvos or 2,2-dichloroethanol (DCE) detected at any soil depth. DCA residues were detected in the soil below 0-4 inches at levels similar to that of the control samples. A good mass balance of DDVP was reported in this study through air filters and cellulose cards trapping. The guideline requirement for terrestrial field dissipation (164-1) is fulfilled (MRIDs 44297701 and 44386701).

b. Mobility

Leaching/adsorption/desorption study indicated that due to the rapid degradation of dichlorvos an equilibration time for dichlorvos between the soil and solution phases could not be established. The high water solubility (10 x 10^3 ppm) and low organic carbon coefficient (Koc = 36.9 cm^3 /g) for dichlorvos indicate its high potential for leaching. The Koc calculation was based on Kd values reported in an acceptable soil TLC (MRID # 41354105). DDVP is not, however, persistent enough in sand to trigger any studies to assess its potential for leaching to ground water. Therefore, no groundwater concern is anticipated for dichlorvos. Under field conditions, dichlorvos dissipated rapidly through volatilization and thus, residues of dichlorvos are not likely to contaminate groundwater by leaching. The guideline requirement for leaching and adsorption/desorption (163-1) is fulfilled (MRID 41723103, 40034904, 41354105).

2. Aquatic Resource Exposure Assessment

Aquatic Organism Exposure Modeling

Dichlorvos residues can be present in water as a result of use of three pesticides: dichlorvos, naled, and trichlorfon. Dichlorvos is a degradate of naled and trichlorfon. This assessment discusses the potential for dichlorvos to contaminate water from the use of dichlorvos as the sole active ingredient. Although these estimates are only for dichlorvos, there are several dichlorvos degradates that have been identified including desmethyl dichlorvos (methyl O-(2,2-dichlorovinyl) phosphate), dichlorethanol, and dichloroacetic acid; this latter degradate is very mobile. Turf and general outdoor (flying insect) were the sites of interest. Concentrations were calculated based on a maximum application rate of 0.2 lb a.i/A for both sites.

Turf Scenario

Tier II Estimated Environmental Concentrations (EECs) for dichlorvos for the turf scenarios were estimated using EFED's aquatic models PRZM-EXAMS (EXposure Analysis Modeling System). PRZM is used to simulate pesticide transport as a result of runoff and erosion from an 10-ha agricultural field, and EXAMS considers environmental fate and transport of pesticides in surface water and predicts EECs in a standard pond (10,000-m^2 pond, 2-m deep), with the assumption that the small field is cropped at 100%. Calculations are carried out with the linkage program shell - PE4VO1.pl - which incorporates the standard scenarios developed by EFED. Additional information on these models can be found at: http://www.epa.gov/oppefed1/models/water/index.htm.and in **Appendix C**. Representative inputs for the model are shown in **Table 4**, and results are tabulated in **Table 5.** For a more detailed explanation and outputs from this model, see **Appendix C.**

Table 4. PRZM/EXAMS Input parameters

Input Parameter	Value
PC Code	84001
Molecular weught (g/mole)	220.9
Water Solubility	10000 ppm
Hydrolysis half-life (pH 7)	5.2 days
Aerobic Soil Half-life	0.42 days
Photolysis half-life	10.2 days
Aerobic Aquatic Metabolism Half-Life	No data
Kd	0.3
Soil Organic Carbon Partitioning (Koc) (1/kg)	37
Organic Carbon Percentage	0.812
Use	Turf
Application Rate (lb ai/A)	0.2
Application Date	May 15
Application Method	Ground Spray
Number of Applications/Year	turf at one application turf at four applications (at 30-day retreatment interval)

* Parameters were selected in accordance with the Proposed Interim Guidance for Input Values document, dated April 6, 2000.

Table 5. Estimated Environmental Concentrations (EECs) For Aquatic Exposure Based on PRZM/EXAMS

Site	Application Method	Application Rate (lbs ai/A)	No. Apps./ Interval Between Apps.	Initial (PEAK) EEC (ppb)	21-day average EEC (ppb)	60-day average EEC (ppb)
Turf (FL)	ground	0.2	1 app.	0.112	0.037	0.014
Turf (FL)	ground	0.2	4 apps at 30	0.169	0.061	0.036

			day interval			
Turf (PA)	ground	0.2	1 app.	0.112	0.037	0.014
Turf (PA)	ground	0.2	4 apps at 30 day interval	0.147	0.054	0.034

Less than 20% (4% - 17%) of Estimated Environmental Concentrations (EEC) reached aquatic media were as contribution of spray drift; the remaining (>80%) is due to runoff (**Table 5**).

Flying Insect Scenario

For the flying insect (including adult mosquitoes) use, EFED currently has no models that would be appropriate for modeling EECs. PRZM/EXAMS and the GENEEC model are inappropriate to use. It is likely EECs found in surface water from treatment for flying insects (including adult mosquitoes) would likely be lower than EECs from treatment to turf, since the treatment area would likely be less. Since the applications for flying insect control are ground applications (*e.g.,* back-pack sprayers or truck-mounted sprayers) using coarse sprays directed to the vegetation (no fogging or misting), EFED cannot perform a quantitative assessment.

Granular Bait Scenario

For the granular bait scenario in animal premise areas, it is unlikely that aquatic organisms will be directly exposed, therefore that pathway is not evaluated and a quantitative assessment is not performed.

3. Terrestrial Organism Exposure Modeling

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals, emphasizing a dietary exposure route for uptake of the pesticide. For obtaining EECs for acute exposure from multiple applications and chronic exposure from both single and multiple applications of liquid dichlorvos and granular bait products, the T-REX v 1.1 (U.S. EPA. 2004b) program was used.

For the liquid spray application to turf, the maximum application rate modeled was 0.2 lb ai/A. One application and four applications (with 30 day application interval) were modeled for turf. The rationale for choosing four applications for turf was based on information received from BEAD indicating a worst-case scenario of four applications.

For liquid spray application for flying insects (including adult mosquitoes), the maximum application rate modeled was 0.2 lb ai/A. for 75 applications per year. The rationale for choosing weekly applications for mosquito control was based on information received from BEAD indicating a worst case scenario for adult mosquito control would probably be around 75 applications to a given site over a year period.

For the granular bait scenario, the maximum application rate modeled was 0.1 lb ai/A. A single application and a worse case scenario of 120 applications per year were modeled. The rationale for choosing 120 applications per year is based on label specifications bearing directions to reapply every 3 to 5 days until insect control is achieved.

A foliar dissipation half-life of 0.0875 days was used for liquid spray application scenarios based on Dichlorvos Total Residue in Turf data on studies conducted in Florida and Canada (MRID No. 44610501, and 44794901 respectively).

Terrestrial EECs were calculated using T-REX v 1.1 (U.S. EPA. 2004b) and are shown in Tables 6, 7, and 8.

Table 6. Estimated Environmental Concentrations for Modeled Scenarios for Turf (1 application and 4 applications)

	Upper Bound Kenega Value for Turf (1 application) (ppm)	Upper Bound Kenega Value for Turf (4 applications with 30 day application interval) (ppm)
Food Item		
Short Grass	19.30	19.30
Tall Grass	8.84	8.84
Broadleaf plants/sm Insects	10.85	10.85
Fruits/pods/seeds/lg insects	1.21	1.21

Predicted maximum residues are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Table 7. Estimated Environmental Concentrations for Modeled Scenarios for Flying Insects (75 applications with 5 day application interval)

	Upper Bound Kenega Value for Flying Insects (75 applications with 5 day application interval) (ppm)
Food Item	
Short Grass	19.30
Tall Grass	8.84
Broadleaf plants/sm Insects	10.85
Fruits/pods/seeds/lg insects	1.21

Predicted maximum residues are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Table 8. Estimated Environmental Concentrations for Modeled Scenarios for Bait (1 application)

Crop	Application method	Application rate (lbs ai/A)[3]	% Unincorporated	EEC (mg ai/ft^2)
Bait (single application)	Broadcast	0.1	100	0.08

B. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an organism or plant. This characterization is based on registrant-submitted studies that describe acute and chronic toxicity information for various aquatic and terrestrial animals and plants. In addition, other sources of information, including the Ecological Incident Information System (EIIS), are conducted to further refine the characterization of potential ecological effects.

Toxicity testing reported in this section does not represent all species of birds, mammals, or aquatic organisms. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. Mammalian acute studies are usually limited to Norway or New Zealand rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians.

1. Evaluation of Aquatic Ecotoxicity Studies

a. Toxicity to Freshwater Animals

Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required for all pesticides to establish their toxicity to fish. TEP testing was required on the 1987 Standard to support the mosquito adulticide/larvacide use pattern. The preferred species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these studies are tabulated below in **Table 9**.

Table 9. Acute Toxicity Endpoints for Freshwater Fish

Species	% ai	96-hour LC50 (ppb)	Toxicity Category	MRID Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	100	500 (24 hours only)	Highly toxic	40098001 (Mayer & Ellersieck 1986)	Supplemental
Rainbow trout *(Oncorhynchus mykiss)*	42(EC)	320 (=750 for formulated product)	Highly toxic for formulated product	43284702 (Jones 1994)	Supplemental
Lake trout *(Salvelinus namaycus*h)	100 100	187 183	Highly toxic Highly toxic	40098001 (Mayer & Ellersieck 1986)	Supplemental
Bluegill sunfish *(Lepomis macrochirus*)	98	869	Highly toxic	40094602 (Johnson 1980)	Core
Bluegill sunfish *(Lepomis*	42(EC)	1860 (=4300 for formulated	Moderately toxic for the	43284701 (Jones 1994)	Supplemental

macrochirus)		product)	formulated product		

There are no core studies available for the rainbow trout. Mayer and Ellersieck (40098001) cite a 24-hour LC50 of 500 ppb for rainbow trout. The two 96-hour lake trout LC50s of 187 ppb and 183 ppb showed 24-hour LC50s of 486 ppb and 667 ppb, respectively. The studies are classified "supplemental" because they were not performed using standard test species. Mayer and Ellersieck state (p. 9) the correlation coefficient (r) between rainbow and lake trout for acute static LC50s is 0.99. Since the results are comparable within the limits of the toxic category *(i.e.*, highly toxic), the lake trout studies will be substituted for the rainbow trout study. Since the LC50s are less than 1 ppm, dichlorvos is categorized as highly toxic to freshwater fish on an acute basis.

Two studies were performed with an emulsifiable concentrate formulation (42.3% ai). Since the TEP and TGAI demonstrated similar toxicities (on an active ingredient basis), it does not appear inerts in the EC formulation are toxic.

Freshwater Fish, Chronic

A freshwater fish early life stage toxicity test was required in the 1987 Dichlorvos Registration Standard to support the mosquito larvicide use. Results of this test are provided in **Table 10.**

Table 10. Chronic Toxicity Endpoints for Freshwater Fish

Species/Study Duration	% ai	NOEC/LOAEL (ppb)	MATC [1] (ppb)	Endpoints Affected	MRID Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)* Early Life-Stage (Flow-through)	98.0	5.2/10.1	7.2	Larval survival	43788001 Davis 1995)	Core

1 defined as the geometric mean of the NOEC and LOAEL.

Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity study using the TGAI is required to establish the toxicity of dichlorvos to aquatic invertebrates. TEP testing was required on the 1987 Standard to support the mosquito adulticide/larvicide use pattern. The preferred species is *Daphnia magn*a. Results are presented in **Table 11**.

Table 11. Acute Toxicity Endpoints for Freshwater Invertebrates

Species	% ai	48-hour EC50 (ppb)	Toxicity Category	MRID Author/Year	Study Classification
Waterflea *(Daphnia pulex*)	100	0.07	Very highly toxic	40098001 (Mayer & Ellersieck 1986)	Core
Waterflea *(Simocephalus*	100	0.28	Very highly toxic	40098001 (Mayer &	Supplemental

serrulatus)				Ellersieck 1986)	
Waterflea (*Simocephalus serrulatus*)	100	0.26	Very highly toxic	40098001 (Mayer & Ellersieck 1986)	Supplemental

Since the EC50 values are less than 100 ppb, dichlorvos is categorized as very highly toxic to aquatic invertebrates on an acute basis. A study with the TEP was not submitted.

Freshwater Invertebrates, Chronic

A freshwater aquatic invertebrate life-cycle study was required in the 1987 Dichlorvos Registration Standard to support the mosquito larvacide use.

Table 12. Chronic Toxicity Endpoints for Freshwater Invertebrates

Species	% ai	21-day NOEC/LOAEL (ppb)	MATC [1] (ppb)	Endpoints Affected	MRID Author/Year	Study Classification
Waterflea (*Daphnia magna*)	98.0	0.0058/0.0122	0.0084	Egg production and growth (length and weight)	43890301 (Ward and Davis 1995)	Core

1 defined as the geometric mean of the NOEC and LOAEL.

b. Toxicity to Estuarine and Marine Animals

Estuarine and Marine Fish, Acute

Acute toxicity studies with estuarine/marine fish using both TGAI and TEP were required in the 1987 Registration Standard to support the mosquito larvicide use.

Table 13. Acute Toxicity Endpoints for Estuarine and Marine Fish

Species	% ai	96-hour LC50 (ppb)	Toxicity Category	MRID Author/Year	Study Classification
Sheepshead minnow (*Cyprinodon variegatus*)	98	7350	Moderately toxic	43571403 (Jones and Davis 1994)	Core
Sheepshead minnow (*Cyprinodon variegatus*)	42.39	6146 (=14500 for formulated product)	Moderately toxic for formulated product	43571406 (Jones and Davis 1994)	Core

Since the LC50 falls in the range 1000 to 10000 ppb ai, dichlorvos is categorized as moderately toxic to estuarine/marine fish on an acute basis. One study was performed with an emulsifiable concentrate formulation (42.3% ai). Since the TEP and TGAI demonstrated similar toxicities (on an active ingredient basis), the inerts in the EC formulation are probably not toxic.

Estuarine and Marine Fish, Chronic

An estuarine fish early life stage toxicity test was required in the 1987 Dichlorvos Registration Standard to support the mosquito larvacide use.

Table 14. Chronic Toxicity Endpoints for Estuarine and Marine Fish

Species/Study Duration	% ai	NOEC/LOAEL (ppb)	MATC [1] (ppb)	Endpoints Affected	MRID Author/Year	Study Classification
Sheepshead Minnow *(Cyprinodon variegatus)*	98	960/1840	1330	Survival and length	43790401 (Ward and Davis 1995)	Core

1 defined as the geometric mean of the NOEC and LOAEL.

Estuarine and Marine Invertebrates, Acute

Acute toxicity studies with estuarine/marine invertebrates (mysid and eastern oyster) using both TGAI and TEP were required in the 1987 Registration Standard to support the mosquito larvacide use.

Table 15. Acute Toxicity Endpoints for Estuarine and Marine Invertebrates

Species/Static or Flow-through	% ai.	96-hour LC50 /EC50 (ppb)	Toxicity Category	MRID Author/Year	Study Classification
Eastern oyster (shell deposition) *(Crassostrea virginica)*	98	89100	Slightly toxic	43571404 (Jones & Davis 1994)	Core
Eastern oyster (shell deposition) *(Crassostrea virginica)*	42 (EC)	920 (2180 for formulated product)	Moderately toxic for formulated product	43571407 (Jones & Davis 1994)	Supplemental
Mysid *(Americamysis bahia)*	98	19.1	Very highly toxic	43571405 (Jones & Davis 1994)	Core
Mysid *(Americamysis bahia)*	42 (EC)	18.7 (44.0 for formulated product)	Very highly toxic for formulated product	43571408 (Jones & Davis 1994)	Core

Since the LC50 for the most sensitive species (mysid) is less than 1000 ppb, dichlorvos is categorized as very highly toxic to estuarine/marine animals on an acute basis. Two studies were performed with an emulsifiable concentrate formulation (42.3% ai). Based on similarity between toxicity of the TGAI and TEP for the mysid, it does not appear that the inerts in the formulation are toxic. However, in the case of the oyster, a large discrepancy exists, with toxicity of the EC formulation (on an active ingredient basis) almost 10-fold greater than that of the TGAI. No explanation for this was provided by the performing laboratory or registrant. Since both the TGAI and TEP studies were scientifically sound, they do not have to be repeated.

Estuarine and Marine Invertebrate, Chronic

An estuarine aquatic invertebrate life-cycle study was required in the 1987 Dichlorvos Registration Standard to support the mosquito larvicide use.

Table 16. Chronic Toxicity Endpoints for Estuarine and Marine Invertebrates

Species/(Static Renewal or Flow-through)	% ai	21-day NOEC/LOAEL (ppb)	MATC [1] (ppb)	Endpoints Affected	MRID Author/Year	Study Classification
Mysid (*Americamysis bahia*)	98	1.48/3.25	2.19	Weight and length	43854301 (Ward and Davis 1996)	Core

1 defined as the geometric mean of the NOEC and LOAEL.

c. Toxicity to Aquatic Plants

Currently, terrestrial and aquatic plant studies are not required for pesticides other than herbicides, except on a case-by-case basis *(e.g.*,, labeling bears phytotoxicity warnings, incident data or literature that demonstrate phytotoxicity). Plant testing is not required for dichlorvos. Supplemental data are available (F.L. Mayer, 1986; 40228401) showing 48 hour EC50 values of >100000 ppb for green algae, 14000 ppb for algae (the species were not given) and 17000-28000 ppb for marine diatom.

Table 17. Toxicity Endpoints for Aquatic Plants

Species	Endpoint	MRID/Reference
Green algae	48 hr EC_{50} >100000 ppb	MRID No. 40228401 (U.S. EPA, F.L. Mayer 1986)
Algae (unknown species)	48 hr EC_{50} = 14000 ppb	MRID No. 40228401 (U.S. EPA, F.L. Mayer 1986)
Marine diatom	48 hr EC_{50} = 17000 - 28000 ppb	MRID No. 40228401 (U.S. EPA, F.L. Mayer 1986)

2. Evaluation of Terrestrial Ecotoxicity Studies

a. Toxicity to Terrestrial Animals

Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of dichlorvos to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of acute oral testing are tabulated in **Table 18.**

Table 18. Toxicity Endpoints for Avian Acute Oral

Species	% a.i.	LD50 (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification
Pheasant	93	11.3	Highly toxic	00160000	Core

(Phasianus colchicus)				(Hudson *et al*.1984)	
Northern bobwhite quail *(Colinus virginianus)*	96.5	8.8	Very highly toxic	40818301 (Grimes and Aber 1988)	Core
Mallard duck *(Anas platyrhynchos)*	93	7.78	Very highly toxic	00160000 (Hudson *et al*.1984)	Core

Since the LD50 of the most sensitive species (mallard) is less than 10 mg/kg, dichlorvos is categorized as being very highly toxic to avian species on an acute oral basis.

Two subacute dietary studies using the TGAI are required to establish the toxicity of dichlorvos to birds. The preferred test species are mallard duck and bobwhite quail. Results of subacute testing are in **Table 19.**

Table 19. Avian Subacute Dietary Toxicity Endpoints

Species	% a.i.	5-Day LC50 (ppm)1	Toxicity Category	MRID No. Author/Year	Study Classification
Pheasant *(Phasianus colchicus)*	94.8	568	Moderately toxic	00022923 (Hill *et al* 1975)	Core
Mallard duck *(Anas platyrhynchos)*	94.8	1317 (5-day old test species)	Slightly toxic	00022923 (Hill *et al* 1975)	Core
Mallard duck *(Anas platyrhynchos)*	94.8	>5000 (16-day old test species)	Practically non-toxic	00022923 (Hill *et al* 1975)	Core

Since the LC50 of the most sensitive species (pheasant) falls in the range of 501 to 1000 ppm, dichlorvos is categorized as being moderately toxic to avian species on a subacute dietary basis.

Birds, Chronic

Avian reproduction studies were required in EPA's 1987 Dichlorvos Standard to support the registered terrestrial and aquatic non-food use patterns. Results of the submitted tests are tabulated below.

Table 20. Chronic Endpoints for Avian Reproduction

Species	% a.i.	NOEC/LOAEL (ppm)	LOAEL Endpoints	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	98	30/100	eggs laid, viable embryos and live three week embryos, normal hatchlings, fourteen day old	43981701 (Cameron 1996)	Core

			survivors		
Mallard duck *(Anas platyrhynchos)*	98	5/15	eggshell thickness, eggs laid, viable embryos, live three week embryos	44233401 (Redgrave and Mansell 1997)	Core

Based on (1) no adverse effects noted at the 1 and 5 ppm treatment levels, and (2) statistically significant reductions in eggshell thickness, numbers of eggs laid, numbers of eggs set, numbers of viable embryos, and numbers of live three week embryos at the 15 ppm treatment level, the NOEC for mallards exposed to dichlorvos in the diet for 20 weeks is 5 ppm and the LOAEL is 15 ppm. Based on (1) no adverse effects noted at the 12 and 30 ppm treatment levels, and statistically significant reductions in fourteen day old survivor weight, terminal male and female body weight, numbers of eggs laid, numbers of viable embryos, numbers of live three week embryos, and numbers of normal hatchlings at the 100 ppm treatment level, the NOEC for bobwhite exposed to dichlorvos in the diet for 20 weeks is 30 ppm and the LOAEL is 100 ppm.

There is some scientific literature on related organophosphates showing adverse reproductive effects to birds from short-term exposures. These effects include reduced egg production within days after initiation of dietary exposure, and effects on eggshell quality, incubation and brood rearing behavior (Bennett and Ganio 1991).

Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Dichlorvos human toxicity endpoints for dietary exposure and occupational/residential exposure are reported in HED's document entitled: Dichlorvos: Hazards Identification Committee Report (G. Ghali to S. Lewis dated 12/19/97). The mammalian toxicity endpoint value used for ecological risk assessment purpose is reported below.

Table 21. Mammalian Toxicity Endpoints

Species/ Study Duration	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID
laboratory rat *(Rattus norvegicus)*	Dichlorvos technical % unspecified	acute oral	LD50=80 mg/kg (M) LD50=56 mg/kg (F)		0005467
laboratory rat *(Rattus norvegicus)*	Dichlorvos technical % unspecified	acute inhalation	LC50 > 0.218 mg/L		00137239
laboratory rat *(Rattus norvegicus)*	Dichlorvos technical % unspecified	acute dermal	LD50 = 107 mg/kg (M) LD50 = 75 mg/kg (F)		0005467

laboratory rat *(Rattus norvegicus)*	98.3%	2 generation reproduction	NOEC = 20 ppm	fertility, pup weight	Acc # 010174, MRID 42483901

Dichlorvos is categorized moderately toxic to small mammals on an acute oral basis and highly toxic on an acute dermal basis. In of a 2-generation reproduction study using Sprague-Dawley rats (where dichlorvos was administered in the drinking water), the reproductive toxicity NOEL was found to be 20 ppm based on reduced dams bearing litters, fertility index, pregnancy index, and pup weight on day-4.

Insects

Results of a honey bee acute contact study using the TGAI are tabulated below.

Table 22. Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (µg/bee)	Toxicity Category	MRID Author/Year	Study Classification
Honey bee *(Apis mellifera)*	technical % unspecified	0.495	highly toxic	00036935 (Atkins *et al* 1975)	Core

An analysis of the results indicate that dichlorvos is categorized as being highly toxic to bees on an acute contact basis.
A study on the toxicity of residues on foliage to honey bees (guideline 141-2) using the typical end-use product was required for dichlorvos in the 1987 Standard to support the terrestrial non-food and domestic outdoor sites. The study submitted showed residues of dichlorvos 4E applied at 0.5 lb ai/A were practically nontoxic to honey bees at three hours posttreatment.

b. Toxicity to Terrestrial Plants

Currently, terrestrial and aquatic plant studies are not required for pesticides other than herbicides, except on a case-by-case basis (*e.g.*,, labeling bears phytotoxicity warnings, incident data or literature that demonstrate phytotoxicity). Plant testing is not required for dichlorvos.

Table 23 summarizes the most sensitive ecological toxicity endpoints for aquatic and terrestrial organisms. Discussions of the effects of dichlorvos on aquatic and terrestrial taxonomic groups are presented below.

Table 23. Toxicity Endpoints Used in the Risk Assessment

Toxicity Test/ Species	Toxicity Endpoint	MRID Number and References
Avian acute oral/ Mallard duck	LD_{50} = 7.78 mg/kg	MRID # 00160000 (Hudson *et al*.1984)
Avian subacute dietary/Pheasant	LC_{50} = 568 mg/kg	MRID # 00022923 (Hill *et al* 1975)
Avian reproduction /Mallard duck	NOEC = 5 ppm	MRID # 44233401 (Redgrave and Mansell 1997)
Mammalian acute oral/ rat	LD_{50} = 56 mg/kg (female)	MRID # 0005467

Toxicity Test/ Species	Toxicity Endpoint	MRID Number and References
Mammalian chronic (reproduction)/rat	NOEC = 20 ppm	MRID # 42483901
Honey bee acute (acute contact basis)	LD_{50} = 0.495 µg/bee	MRID # 00036935 (Atkins *et al* 1975)
Terrestrial Plants	N/A	
Fish (freshwater) acute/ Lake trout	LC_{50} = 183 ppb	MRID # 40098001 (Mayer & Ellersieck 1986)
Fish (freshwater) chronic/Rainbow trout	NOAEC = 5.2 ppb	MRID # 43788001 (Davis 1995)
Fish (estuarine) acute/ Sheepshead minnow	LC_{50} = 7350 ppb	MRID # 43571403 (Jones and Davis 1994)
Fish (estuarine) chronic/Sheepshead minnow	NOAEC = 960 ppb	MRID # 43790401 (Ward and Davis 1995)
Invertebrate (freshwater) acute/*Daphnia pulex*	EC_{50} = 0.07 ppb	MRID # 40098001 (Mayer & Ellersieck 1986)
Invertebrate (freshwater) chronic/ *Daphnia magna*	NOAEC = 0.0058 ppb	MRID # 43890301 (Ward and Davis 1995)
Invertebrate (estuarine) acute/Mysid shrimp	LC_{50} = 19.1 ppb	MRID # 43571405 (Jones & Davis 1994)
Invertebrate (estuarine) chronic/ Mysid shrimp	NOAEC = 1.48 ppb	MRID # 43854301 (Ward and Davis 1996)
Aquatic plants/ Algae	EC_{50} = 14000 ppb	MRID # 40228401 (F.L. Mayer, 1986)

3. Terrestrial Field Testing

No terrestrial field testing studies are available for dichlorvos.

4. Use of the Probit Slope Response Relationship

The Agency uses the probit dose response relationship as a tool for providing additional information on the endangered and threatened animal species acute levels of concern (LOC). The acute listed species LOCs of 0.1 and 0.05 are used for terrestrial and aquatic animals, respectively. As part of the risk characterization, an interpretation of acute LOCs for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (i.e., mortality or immobilization) should exposure at the estimated environmental concentration actually occur for a species with sensitivity to dichlorvos on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measurement endpoints for each taxonomic group. The individual effects probability associated with the LOCs is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope. The upper and lower bounds of the effects probability are based on available information on the 95% confidence interval of the slope. A statement regarding the confidence in the applicability of the assumed probit dose response

relationship for predicting individual event probabilities is also included. Studies with good probit fit characteristics (i.e., statistically appropriate for the data set) are associated with a high degree of confidence. Conversely, a low degree of confidence is associated with data from studies that do not statistically support a probit dose response relationship. In addition, confidence in the data set may be reduced by high variance in the slope (i.e., large 95% confidence intervals), despite good probit fit characteristics.

Individual effect probabilities are calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by Ed Odenkirchen of the U.S. EPA, OPP, Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the LOC (0.1 for terrestrial animals and 0.05 for aquatic animals) is entered as the desired threshold.

5. Incident Data Review

There have been 6 incidents related to dichlorvos reported in the Environmental Incident Information System (EIIS) database (reported to the Agency from 1991 to 2002). Of these 6 incidents, 3 were of undetermined use, and 3 were registered uses.

Avian Incidences

Five of the incidences were terrestrial, with 4 related to bird kills. One incident involved an avian outdoor exposure from a site (apples) for which dichlorvos was never registered. Two bluebird chicks died in their nest box in the town of Redhook New York. The nest was within 300 yards of an apple orchard. The cause of death was dichlorvos poisoning (Reported by:Wildlife Pathology Unit, NY State Dept. Of Environmental Conservation Annual Report 1/1/94 -5/3/95. Ward Stone, Wildlife Pathologist. 1994 incident). Another incident involved a registered use of dichlorvos crystals in treated feed than resulted in 8 mallard ducks dying in an agricultural area. The last two incidents involved the use of dichlorvos in the home residence resulting in canary deaths (6 total deaths).

Mammalian Incidences

There is one mammalian incidence reported involving indoor exposure to animals. Amvac Chemical Corp. (Letter to Agency Dated 7/3/95) reported potential adverse effects exposure relating to a pest strip in which several exotic and wild native and non-native animals that included skunks and several fennis foxes (native of Egypt) were in a room roughly 4000 cubic feet. The room had a pest strip placed in it 3-4 days previous to control insects. The pest strip was labeled as covering 1000 cubic feet. Four fennis fox pups died. A veterinarian treated three other pups with atropine; two recovered. The foxes were the only animals that recovered. Two of the animals recovered after treating with atropine, indicating it is possible that the cause of poisoning was exposure to dichlorvos fumes.

Aquatic Incidence

One aquatic incident of undetermined use in Tennessee involving fish kills was reported affecting 379 organisms (species undetermined). No residue analysis was conducted.

Currently, no systematic or reliable mechanism exists for the accurate monitoring and reporting of wildlife kill incidents to the Agency. Moreover, before a pesticide incident can be reported or investigated, the dead animals must first be found. In the absence of monitoring following pesticide applications, kills are not likely to be noticed in agro-environments which are generally

away from human activity. Even if onlookers are present, dead wildlife species, particularly small song birds and mammals, are easily overlooked, even by experienced and highly motivated observers. Even in sparse vegetative cover, wildlife carcass detection is difficult and as vegetative cover increases the difficulty in detection is exacerbated. Under some circumstances intoxicated animals may seek heavy cover before dying which decreases the probability of detection further. Poisoned birds may fly from the sites, succumbing outside of the area or scavengers may remove carcasses before they can be observed, significantly reducing the chance of detection.

Balcomb (1986) reported that songbird carcasses removal rate ranged from 62 to 92 percent in the first 24 hours following placement, with a mean loss at 24 hours of 75% (S.D. = 12.4). Overall, by the end of the 5-day monitoring period, 72 of the 78 carcasses had been removed by scavengers. In addition, the number of birds per acre alone, not considering these other factors, makes detection of kills difficult. Best (1990) reported from 0.57 live birds per acre in the center to 2.8 live birds per acres in the perimeter of corn fields in Iowa and Illinois. Even if all the birds in a field were killed and remained on the field, the probability of observing carcasses, particularly when not systematically searching, at these densities, is not high. Research has shown that even when intense systematic searches are conducted by highly trained individuals for placed carcasses in agro-environments, recovery rates rarely exceed 50 percent (Madrigal *et al.*1996).

Even if dead animals are observed, they might not be reported to the Agency. Persons unfamiliar with the toxicity of pesticides to non-target species may fail to associate the finding with the pesticide application, especially if the two events are separated by several days and only a few birds are observed dead. Even if the association is made, the observer must be aware or have the motivation to find out where to report the incident. Therefore, the reporting of a few dead birds associated with the use of a chemical is believed to provide evidence that substantial effects may be occurring.

6. RISK CHARACTERIZATION

Risk characterization is the integration of exposure and effects characterization to determine the ecological risk from the use of dichlorvos and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide-use scenarios. The risk characterization provides an estimation and a description of the risk; articulates risk assessment assumptions, limitations, and uncertainties; synthesizes an overall conclusion; and provides the risk managers with information to make regulatory decisions.

A. Risk Estimation - Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of dichlorvos risk, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and assess the need to consider regulatory action. These criteria are used to indicate when a pesticide's directed label use has the potential to cause adverse effects on non-target organisms. **Table 2** of this document summarizes the LOCs used in this risk assessment.

1. Non-target Aquatic Animals

a. Freshwater Fish

An analysis of the results show that for single and multiple applications of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, no freshwater fish acute or chronic LOCs are exceeded. Freshwater fish risk quotients are listed in **Table 24.**

Table 24. Acute and chronic risk quotients for freshwater fish for turf scenarios (Risk Quotients for Freshwater Fish Based On a Lake Trout LC50 of 183 ppb and a Rainbow Trout NOAEL of 5.2 ppb). EEC values are calculated based on the maximum labeled application rate.

Site (No. Apps./Interval Between Apps.)	LC50 (ppb)	NOAEL (ppb)	EEC Initial/Peak (ppb)	EEC 60-day Ave. (ppb)	Acute RQ (Initial EEC/LC50)	Chronic RQ (60-day Ave. EEC/NOAEL)
FL Turf (1 app.)	183	5.2	0.112	0.014	0	0
FL Turf (4 app./30 day interval)	183	5.2	0.169	0.036	0	0
PA Turf (1 app.)	183	5.2	0.112	0.014	0	0
PA Turf (4 app./30 day interval)	183	5.2	0.147	0.034	0	0

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

b. Freshwater Invertebrates

An analysis of the results show that for single and multiple applications of dichlorvos to turf (both FL and PA scenarios) at the maximum application of 0.2 lb ai/A, the freshwater invertebrate acute endangered species, restricted use and acute risk LOC is exceeded. The chronic LOCs is exceeded for freshwater invertebrates (**Table 25**).

Table 25. Acute and Chronic Risk Quotients for Freshwater Invertebrates for turf scenarios Risk quotients for freshwater invertebrates based on based on a waterflea EC50 of 0.07 ppb and NOAEL of 0.0058 ppb.

Site (No. Apps./Interval Between	EC50 (ppb)	NOAEL (ppb)	EEC Initial/Peak (ppb)	EEC 21-day Ave. (ppb)	Acute RQ (Initial EEC/EC50)	Chronic RQ (21-day Ave. EEC/NOAEL

Apps.)						
FL Turf (1 app.)	0.07	0.0058	0.112	0.037	1.6***	6.38****
FL Turf (4 app./30 day interval)	0.07	0.0058	0.169	0.061	2.41***	10.52****
PA Turf (1 app.)	0.07	0.0058	0.112	0.037	1.6***	6.38****
PA Turf (4 app./30 day interval)	0.07	0.0058	0.147	0.054	2.1***	9.31****

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

c. *Estuarine/Marine Fish*

An analysis of the estuarine/marine fish species results show that for single and multiple applications of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, no acute or chronic LOCs are exceeded. Estuarine/marine risk quotients are listed in **Table 26.**

Table 26. Acute and chronic risk quotients for estuarine/ marine fish for turf scenarios
Risk quotients for estuarine/marine fish based on a sheepshead minnow LC50 of 7350 ppb and NOAEL of 960 ppb.

Site (No. Apps./Interval Between Apps.)	LC50 (ppb)	NOAEL (ppb)	EEC Initial/Peak (ppb)	EEC 60-day Ave. (ppb)	Acute RQ (Initial EEC/LC50)	Chronic RQ (60-day Ave. EEC/NOAEL)
FL Turf (1 app.)	7350	960	0.112	0.014	0	0
FL Turf (4 app./30 day interval)	7350	960	0.169	0.036	0	0
PA Turf (1 app.)	7350	960	0.112	0.014	0	0
PA Turf (4 app./30 day interval)	7350	960	0.147	0.034	0	0

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

d. Estuarine/Marine Invertebrates

An analysis of the results show that for single and multiple applications of dichlorvos to turf at the maximum application of 0.2 lb ai/A, no acute or chronic LOCs are exceeded.

Table 27. Acute and chronic risk quotients for estuarine/ marine invertebrates for turf scenarios

Risk quotients for estuarine/marine invertebrates based on a Mysid LC50 of 19.1 ppb and NOAEL of 1.48 ppb.

Site (No. Apps./Interval Between Apps.)	LC50 (ppb)	NOAEL (ppb)	EEC Initial/Peak (ppb)	EEC 21-day Ave. (ppb)	Acute RQ (Initial EEC/LC50)	Chronic RQ (21-day Ave. EEC/NOAEL)
FL Turf (1 app.)	19.1	1.48	0.112	0.037	0.0059	0.025
FL Turf (4 app./30 day interval)	19.1	1.48	0.169	0.061	0.0088	0.041
PA Turf (1 app.)	19.1	1.48	0.112	0.037	0.0059	0.025
PA Turf (4 app./30 day interval)	19.1	1.48	0.147	0.054	0.0077	0.036

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

1. Non-target Terrestrial Animals

a. **Liquid Formulations**

For liquid formulations, risk assessments were performed for two major categories of dichlorvos outdoor uses, turf and outdoor flying insects (including mosquitoes).

i. Birds

Turf Scenarios

An analysis of the results for a single broadcast application of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, no avian acute LOC is exceeded (**Table 28**). The avian chronic level of concern is exceeded for birds that consume short grass, tall grass, and broadleaf plants/small insects.

Table 28. Avian Acute and Chronic Risk Quotients for Single Application of Dichlorvos to Turf (Dietary based RQs based on Pheasant LC50 of 568 ppm and Mallard NOAEC of 5 ppm).

Site/App. Method	App. Rate (lbs ai/A)	Food Items	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
Turf/Spray/1 app	0.2	Short grass	0.03	3.86****
		Tall grass	0.02	1.77****
		Broadleaf plants/Small Insects	0.02	2.17****
		Fruits/Pods/Large Insects	0.00	0.24

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

An analysis of the results for four applications of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, no avian acute LOC is exceeded (**Table 29**). The avian chronic level of concern is exceeded for birds that consume short grass, tall grass, and broadleaf plants/small insects.

Table 29. Avian Acute and Chronic Risk Quotients for Four Applications of Dichlorvos to Turf (Dietary based RQs based on Pheasant LC50 of 568 ppm and Mallard NOAEC of 5 ppm).

Site/App. Method	App. Rate (lbs ai/A)	Food Items	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
Turf/Spray/4 app with 30 day application interval	0.2	Short grass	0.03	3.86****
		Tall grass	0.02	1.77****
		Broadleaf plants/Small Insects	0.02	2.17****
		Fruits/Pods/Large Insects	0.00	0.24

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

Flying Insect Scenario

An analysis of the results for 75 applications of dichlorvos for flying insect control at the maximum application rate of 0.2 lb ai/A, no avian acute LOC is exceeded (**Table 30**). The avian chronic level of concern is exceeded for birds that consume short grass, tall grass, and broadleaf plants/small insects.

Table 30. Avian Acute and Chronic Risk Quotients for 75 Applications of Dichlorvos for Flying Insect Control (Dietary based RQs based on Pheasant LC50 of 568 ppm and Mallard NOAEC of 5 ppm).

Site/App. Method	App. Rate (lbs ai/A)	Food Items	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
Flying Insects/Spray /75 app with 5 day application interval	0.2	Short grass	0.03	3.86****
		Tall grass	0.02	1.77****
		Broadleaf plants/Small Insects	0.02	2.17****
		Fruits/Pods/Large Insects	0.00	0.24

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

ii. Mammals

Turf Scenarios

An analysis of the results for a single broadcast application of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, the mammalian endangered species LOC is exceeded for the 15 g and 35 g mammals that consumes short grass(**Table 31**). The mammalian chronic level of concern is exceeded for 15 g, 35 g, and 1000 g mammals that consume short grass, tall grass, and broadleaf plants/small insects.

Table 31. Mammalian Acute and Chronic Risk Quotients for Single Application of Dichlorvos to Turf (Dose-based RQs based on Rat LD50 of 56 mg/kg and Rat NOAEC of 5 ppm).

	15 g mammal		35 g mammal		1000 g mammal	
	Acute RQ	Chronic RQ	Acute RQ	Chronic RQ	Acute RQ	Chronic RQ
Short grass	0.15*	8.34****	0.13*	7.16****	0.07	3.76****
Tall grass	0.07	3.82****	0.06	3.28****	0.03	1.72****
Broadleaf plants/Small Insects	0.08	4.69****	0.07	4.03****	0.04	2.12****
Fruits/Pods/Large Insects	0.01	0.52	0.01	0.45	0.00	0.24

Seeds (granivore)	0.00	0.12	0.00	0.10	0.00	0.05

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

An analysis of the results for four broadcast application of dichlorvos to turf at the maximum application rate of 0.2 lb ai/A, the mammalian endangered species LOC is exceeded for the 15 g and 35 g mammals that consume short grass(**Table 32**). The mammalian chronic level of concern is exceeded for 15 g, 35 g, and 1000 g mammals that consume short grass, tall grass, and broadleaf plants/small insects.

Table 32. Mammalian Acute and Chronic Risk Quotients for Four Applications of Dichlorvos to Turf (Dose-based RQs based on Rat LD50 of 56 mg/kg and Rat NOAEC of 5 ppm).

	15 g mammal		35 g mammal		1000 g mammal	
	Acute RQ	**Chronic RQ**	**Acute RQ**	**Chronic RQ**	**Acute RQ**	**Chronic RQ**
Short grass	0.15*	8.34****	0.13*	7.16****	0.07	3.76***
Tall grass	0.07	3.82****	0.06	3.28****	0.03	1.72***
Broadleaf plants/Small Insects	0.08	4.69****	0.07	4.03****	0.04	2.12***
Fruits/Pods/Large Insects	0.01	0.52	0.01	0.45	0.00	0.24
Seeds (granivore)	0.00	0.12	0.00	0.10	0.00	0.05

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

Flying Insect Scenario

An analysis of the results for 75 applications of dichlorvos for flying insect control at the maximum application rate of 0.2 lb ai/A, the mammalian endangered species LOC is exceeded for 15 g and 35 mammals consuming short grass (**Table 33**). The mammalian chronic level of concern is exceeded for mammals (15 g, 35 g, 1000 g) that consume short grass, tall grass, and broadleaf plants/small insects.

Table 33. Mammalian Acute and Chronic Risk Quotients for 75 Applications of Dichlorvos for Flying Insect Control (Dose-based RQs based on Rat LD50 of 56 mg/kg and Rat NOAEC of 5 ppm).

	15 g mammal		35 g mammal		1000 g mammal	
	Acute RQ	**Chronic RQ**	**Acute RQ**	**Chronic RQ**	**Acute RQ**	**Chronic RQ**

Short grass	0.15*	8.34****	0.13*	7.16****	0.07	3.76****
Tall grass	0.07	3.82****	0.06	3.28****	0.03	1.72****
Broadleaf plants/Small Insects	0.08	4.69****	0.07	4.03****	0.04	2.12****
Fruits/Pods/Large Insects	0.01	0.52	0.01	0.45	0.00	0.24
Seeds (granivore)	0.00	0.12	0.00	0.10	0.00	0.05

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

3 Non-target Terrestrial Invertebrates

Honeybee acute contact toxicity values indicate that dichlorvos is highly toxic to this insect species. Toxicity tests using residues on foliage indicate dichlorvos is practically non-toxic to honey bees.

The overall acute risk to honeybees and other non-target and beneficial insects is expected to be very high for applications of liquid products at 0.2 lb ai/a. Since dichlorvos is very highly toxic to bees (LD50)= 0.495 µg/bee, it is expected that bees, as well as other non-target and beneficial insects, could be harmed if exposed to dichlorvos during treatment.

4. Non-target Terrestrial and Aquatic Plants

As described in the analysis section, there were no registrant-submitted terrestrial plant studies so risk to terrestrial plants can not be assessed.

There are supplemental aquatic plant studies that can be used descriptively to discuss potential risk to aquatic plants. The 48 hour EC50 values of >100000 ppb for green algae, 14000 ppb for algae (the species were not given) and 17000-28000 ppb for marine diatom are reported by Mayer et al. 1986. The modeled peak EEC value for turf is 2.33 ppb. Comparisons of the toxicities and the aquatic EEC values indicate minimal aquatic plant risk.

5. Non-target Terrestrial Animals - Bait Formulations

An acute risk assessment for bait formulations was performed for dichlorvos outdoor use around animal premises. Birds and mammals may be exposed to the bait by ingesting granules. The number of lethal doses (LD50's) that are available within one square foot immediately after application can be used as a risk quotient (LD50's/ft 2) for the exposure to bait pesticides. Chronic risk assessments are not performed for bait products.

The acute risk quotients for birds and mammals are tabulated in **Table 34**. The results indicate that for applications of bait products applied at the maximum rate of 0.0025 lb/1000 ft ^{2}, the acute avian RQs exceed endangered species, restricted use and acute risk LOCs for 20 g birds. The endangered species LOC is exceeded for 100 g birds.

Granular bait can be applied up to 120 applications (worse case scenario) with 3 day application interval. However, for the bait application, dichlorvos can only be applied to animal premise areas (soil, near buildings) and not applied directly to grass and turf. When evaluating the aerobic soil half life of 0.42 days, it becomes clear that in a 3 day application interval, the original 0.1 lbs/A of dichlorvos would have gone through approximately 7 half life cycles, leaving only approximately 0.0008 lbs/A of the original parent product. Therefore, we assume that the risk quotients calculated for 1 application at 0.1 lbs/A approximate the risk quotients for 120 applications with 3 day application interval.

Table 34. Avian and Mammalian Acute Risk Quotients for 1 application of Bait Products (based on a Mallard LD50 of 7.78 mg ai/kg and Rat LD50 of 56 mg/kg).

	Granular Bait (1 application at 0.1 lbs/A) Acute RQ (LD50/ft ^{2})
Avian	
20 g bird	0.959***
100 g bird	0.151*
1000 g bird	0.011
Mammals	
15 g mammal	0.042
35 g mammal	0.022
1000 g mammal	0.002

*exceeds endangered species LOC (LOC = 0.1)
**exceeds endangered species and acute restricted use LOC (LOC = 0.2)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)

B. Risk Description - Interpretation of Direct Effects

1. Risks to Aquatic Animals

Summary of Major Conclusions

Acceptable data on dichlorvos indicates it is very highly toxic to freshwater fish (LC50 = 183 ppb for most sensitive species), moderately toxic to estuarine/marine fish (EC50 = 7350 ppb for the one species tested), very highly toxic to freshwater invertebrates (LC50 = 0.28 ppb for most sensitive species) and very highly toxic to estuarine invertebrates (LC50 = 19.1 ppb for most sensitive species). Chronic studies established NOAEL values of 5.2 ppb (rainbow trout), 960 ppb (sheepshead minnow), 0.0058 ppb (daphnid) and 1.48 ppb (mysid shrimp).

There is acute risk for freshwater invertebrates with RQs of 1.6 (FL turf) and 1.6 (PA turf) for one spray application. For 4 applications, the RQs are 2.41 (FL turf) and 2.1 (PA turf). These RQs exceeds the endangered species, restricted use, and acute risk LOC. In addition, the chronic level of concern is exceeded for freshwater invertebrates [egg production and growth

(length and weight) endpoint] for all of the turf scenarios (one and four applications). Based on these findings, there is a potential for acute and chronic risk to freshwater invertebrates from applications to turf.

For flying insect (including adult mosquitoes) use, EFED is unable to assess risk quantitatively. It may be assumed that the exposure to dichlorvos from flying insect use would be less than that expected from turf use. However, the potential risk to freshwater and marine/estuarine invertebrates can not be quantified and therefore can not be assessed nor discounted.

Exposure to aquatic animals from bait formulations applied around animal premises is expected to be minimal because treatment sites are small and localized. Therefore, the bait formulation scenario for aquatic animals was not addressed in this risk assessment.

2. Risks to Terrestrial Animals

Summary of Major Conclusions

Based on the results of acceptable ecotoxicity studies, dichlorvos is very highly toxic to birds on an acute oral basis (LD50= 7.8 mg/kg for most sensitive species), moderately toxic to birds on a subacute dietary basis (LC50 = 568 ppm for most sensitive species) and moderately toxic to mammals on an acute oral basis (LD50 = 56-80 mg/kg). Chronic toxicity studies established NOAEL values of 5 ppm (mallard), 20 ppm (rat) and 30 ppm (bobwhite).

The chronic risk endangered species LOCs are exceeded on turf applications (both 1 and 4 applications) for birds that consume short grass, tall grass, and broadleaf plants/small insects (with RQs ranging from 1.77 to 3.86). For the flying insect scenario, no acute LOCs are exceeded. Chronic LOCs are exceeded for birds that consume short grass, tall grass, and broadleaf plants/small insects.

For mammals, for both the 1 and 4 applications of dichlorvos to turf, the chronic LOC is exceeded for 15 g, 35 g, and 1000 g mammals that consume short grass, tall grass, and broadleaf plants/small insects. For turf application, there are acute endangered species LOC exceedences for the 15 g and 35 g mammals that consumes short grass.

The acute risk, acute restricted use, and acute endangered species LOCs for a small bird (20 g weight) are exceeded for the bait formulation scenario (Acute RQ = 0.959). The endangered species OC is exceeded for the 100 g mammals with the bait scenario. Chronic risk to birds from the bait formulation can not be assessed at this time.

There is a possibility of risk to birds and small mammals from ingestion of the bait product. Dichlorvos is highly toxic to birds on an acute oral basis (LD50 <10 mg/kg). The bait products appear to be of granular consistency and sugar-based *(e.g.,* front panel of product label for EPA Reg. No. 769-568 states FLY Bait Sugar Base With DDVP). Bait product labels carry directions for use both as a dry bait (sprinkle lightly where flies congregate) and wet bait (dissolve in water). Wet baits pose a minimal risk to terrestrial animals. Avian reproduction laboratory studies found that it is difficult to keep the material in the feed for a 24 hour period. Bait products of similar granular consistency also might have a very short life in the field. Some of the labels bear directions to reapply every 3 to 5 days until control is achieved.

C. Threatened and Endangered Species Concerns

1. Taxonomic Groups Potentially at Risk

The Agency's levels of concern for endangered and threatened freshwater invertebrates, birds, and mammals are exceeded for dichlorvos use. A summary of the endangered species taxonomic groups potentially at risk from dichlorvos use are listed in **Table 35.** Because turf , flying insect, and bait formulation use are available in all states, the endangered species listing encompasses all dichlorvos use areas..

The preliminary risk assessment for endangered species indicates that dichlorvos exceeds the endangered species LOCs for the following combinations of analyzed uses and species:

- Freshwater invertebrates (acute): use on turf (1 application and 4 applications, both FL and PA scenarios)
- Freshwater invertebrates (chronic): use on turf (1 application and 4 applications, both FL and PA scenarios)
- Birds (chronic): use on turf (1 application and 4 applications) for birds consuming short grass, tall grass, and broadleaf plants/small insects
- Birds (chronic): use as flying insect control for birds consuming short grass, tall grass,and broadleaf plants/small insects
- Birds (acute): use as bait formulation for 20 g and 100g bird
- Mammals (acute): use on turf (1 application and 4 applications) 15 g and 35 g mammals that consumes short grass.
- Mammals (chronic): use on turf (1 application and 4 applications) 15 g, 35 g, and 1000 g mammals that consume short grass, tall grass, and broadleaf plants/small insects.

Table 35. Tabulation by taxonomic group and total states of listed species that occur in dichlorvos use areas

	Taxonomic Group										
	Birds	Mammals	Reptiles	Amphibians	Fish	Crustaceans	Arachnids	Insects	Snails	Clams	Plants
Total Unique Species	57	61	28	19	113	20	12	44	30	70	548

Total States	49	47	19	12	40	12	4	27	15	28	49

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

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

2 .Probit Slope Analysis

The probit slope response relationship is evaluated to calculate the change of an individual event corresponding to the listed species acute LOCs. If information is unavailable to estimate a slope for a particular study, a default slope assumption of 4.5 is used as per original Agency assumptions of typical slope cited in Urban and Cook (1986).

Freshwater Invertebrates

Raw data is not provided in the daphnid acute EC50 study (MRID 40098001/ Mayer and Ellersieck 1986) to calculate a slope. RQ exceedances occur for freshwater invertebrate species for the turf scenario (1 application and 4 applications). Based on the default slope assumption of 4.5, the individual mortality associated with the minimum and maximum calculated RQ value (6.71 and 33.29) result in an estimated chance of individual mortality of 1 in 1 (100 %). The corresponding estimated chance of individual mortality associated with the listed species LOC of 0.05 is 1 in 4.17E+08.

Birds

Raw data is not provided in the mallard duck acute LD50 study (MRID 00160000/ Hudson *et al.* 1984) to calculate a slope. RQ exceedances occur for bird species for the flying insect and bait formulation scenario. Based on the default slope assumption of 4.5, the individual mortality associated with the calculated minimum and maximum RQ value (0.17 and 0.36) for flying insect scenario result in an estimated chance of individual mortality of 1 in 3.74E+03 to 1 in 4.36E+01 . For the bait scenario, RQ range of 0.151 to 0.959, result in an estimated chance of individual mortality of 1 in 9.08E+03 to 1 in 2.14 (50%). The corresponding estimated chance of individual mortality associated with the listed species LOC of 0.1 is 1 in 2.94 E+05.

Mammals
Raw data is not provided in the rat acute LD_{50} study (MRID 0005467) to calculate a slope. Therefore, the event probability was calculated for mammalian LOC based on a default slope of 4.5. RQ exceedances occur for mammalian species for the turf and flying insect scenario. The individual mortality associated with the calculated RQ values (0.13 and 0.26) for turf scenario result in an estimated chance of individual mortality of 1 in 2.99E+04 and 1 in 2.36E+02, respectively. For the flying insect scenario, RQ range of 0.33 to 1.58, result in an estimated chance of individual mortality of 1 in 6.61E+01 to 1 in 1.23E+0 (100%).

Based on an assumption of a probit dose response relationship with a mean estimated slope of 4.5, the corresponding estimated chance of individual mortality associated with the mammalian listed species LOC of 0.1 is 1 in 294,000.

It is recognized that extrapolation of very low probability events is associated with considerable uncertainty in the resulting estimates. To explore possible bounds to such estimates, the upper and lower values for the mean slope estimate can be used to calculate upper and lower estimates of the effects probability associated with the listed species LOC. However, since slope is based on a default assumption of 4.5, the 95 percent confidence intervals for the slopes are unavailable.

3. Critical Habitat

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the FWS and NMFS as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening level taxonomic analysis (risk quotients, RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening level risk assessment has identified potential concerns for indirect effects on listed species for those organisms dependent upon freshwater invertebrates, birds, and mammals. In light of the potential for indirect effects, the next step for EPA, FWS, and the NMFS is to identify which listed species and critical habitat are potentially implicated.

Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether the pesticide's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by the pesticide. Then EPA would determine whether use of the pesticide overlaps with the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that are potentially impacted directly by the use of the pesticide. EPA and the Service(s) are working together to conduct the necessary analysis.

This screening level risk assessment for critical habitat provides a listing of potential biological features that, if the are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include the following: freshwater invertebrates, birds, and mammals. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above, should additional work be necessary.

4. Indirect Effect Analyses

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of nesting habitat, creating gaps in the food chain, etc. In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-endangered organisms in these taxonomic groups as resources critical to their life cycle.

Because screening-level acute RQs for freshwater invertebrates, birds, and mammals exceed the endangered species acute LOCs, the Agency uses the dose response relationship from the toxicity study used for calculating the RQ to estimate the probability of acute effects associated with an exposure equivalent to the EEC. This information serves as a guide to establish the need for and extent of additional analysis that may be performed using Services-provided "species profiles" as well as evaluations of the geographical and temporal nature of the exposure to ascertain if a "not likely to adversely affect" determination can be made. The degree to which additional analyses are performed is commensurate with the predicted probability of adverse effects from the comparison of the dose response information with the EECs. The greater the probability that exposures will produce effects on a taxa, the greater the concern for potential indirect effects for listed species dependent upon that taxa, and therefore, the more intensive the analysis on the potential listed species of concern, their locations relative to the use site, and information regarding the use scenario (e.g., timing, frequency, and geographical extent of pesticide application).

Screening-level acute RQs for aquatic invertebrates, birds, and mammals are above the non-endangered species LOCs. The Agency considers this to be indicative of a potential for adverse effects to those listed species that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependent) for some important aspect of their life cycle. The Agency may determine if listed organisms for which plants are a critical component of their resource needs are within the pesticide use area. This is accomplished through a comparison of Service-provided "species profiles" and listed species location data. If no listed organisms that are either plant species obligates or plant dependent reside within the pesticide use area, a no effect determination on listed species is made. If plant species obligate or dependent organism may reside within the pesticide use area, the Agency may consider temporal and geographical nature of exposure, and the scope of the effects data, to determine if any potential effects can be determined to not likely adversely affect a plant species obligate or dependent listed organism.

a. Aquatic Species

Indirect effects to endangered/threatened fish that depend on freshwater invertebrates as a primary source of food, as well as larger aquatic animals that rely on aquatic (freshwater) invertebrate populations as a food source may be affected by the direct or chronic effects of dichlorvos use.

b. Terrestrial Species

Although RQs were not calculated for terrestrial plants, due to dichlorvos' mode of action, use, and the lack of aquatic plant risk, this assessment concludes that plant-dependent species will not be affected indirectly from dichlorvos use.

The Agency acknowledges that pesticides have the potential to exert indirect effects upon endangered or threatened species, by, for example, perturbing forage or prey availability, altering the extent of nesting habitat, etc. The screen for indirect effects includes using direct effect LOCs for non-endangered species to infer the potential for indirect effects upon listed species that rely upon non-endangered organisms as resources critical to their life cycle.

Because at intended use rates dichlorvos may cause mortality in exposed bird and mammal populations, there are potential concerns for indirect effects on those listed terrestrial organisms that are dependant upon vertebrate species (birds, mammals, reptiles) as prey items. Additionally, indirect effects to endangered/threatened fish, invertebrates, and mammals that depend on freshwater invertebrates as a primary source of food may occur.

The high acute toxicity of dichlorvos to honeybees may lead to mortality to this and other insect-pollinators. Listed plant species dependant upon insect pollination may be indirectly affected by the loss of all or part of such insect populations. Additionally, the potential risk to bird species from dichlorvos use could also affect bird-pollinated plant species.

A potential drop in both vertebrate and invertebrate biomass associated with dichlorvos use may reduce a significant portion of the prey base. If this prey base is removed at a critical life-cycle juncture, over a large area, or it if is removed for a long enough duration, some species may have difficulty meeting energy needs. Some species may be particularly sensitive during reproductive or developmental periods.

E. Description of Assumptions, Uncertainties, Strengths, and Limitations

1. **Assumptions and Limitations Related to Exposure for all Taxa**

a. Maximum Use Scenario

This screening-level risk assessment relies on labeled statements of the maximum rate of dichlorvos application, the maximum number of applications, and the shortest interval between applications (when applicable). Together, these assumptions constitute a maximum use scenario and can overestimate risk. However, the maximum use scenario must be considered because it is a reflection of the allowable use of dichlorvos.

2. **Assumptions and Limitations Related to Exposure for Aquatic Species**

a. Lack of Averaging Time for Exposure

For an acute risk assessment, there is no averaging time for exposure. An instantaneous peak concentration, with a 1 in 10 year return frequency, is assumed. The use of the instantaneous peak assumes that instantaneous exposure is of sufficient duration to elicit acute effects comparable to those observed over more protracted exposure periods tested in the laboratory, typically 48 to 96 hours. In the absence of data regarding time-to-toxic event analyses and latent responses to instantaneous exposure, the degree to which risk is overestimated cannot be quantified.

b. *Routes of exposure*

Screening-level risk assessments pesticide application for aquatic organisms consider exposure through the gills. Other potential routes of exposure, not considered in this assessment, are discussed below:

· ***Dietary consumption***

The screening assessment does not consider the ingestion pathway. This exposure may occur through ingestion of contaminated vegetation, invertebrates, or other exposed prey items.

· ***Dermal exposure***

The screening assessment does not consider dermal exposure. Dermal exposure may occur through one potential source: contact with contaminated water. The available measured data related to aquatic wildlife dermal contact with pesticides are extremely limited.

3. Assumptions and Limitations Related to Exposure for Terrestrial Species

a. The LD_{50}/sq. ft. Index

The LD_{50}/sq.ft. index was developed by Felthousen (1977). The concept was based upon field observations made by DeWitt (1966) who suggested that ecological effects are expected to occur when exposure residues that equal or exceed the LD_{50} value for a pesticide, as determined from laboratory studies, are reached in the field. The index was developed, in response to the Registration Divisions' request for guidance for classifying use patterns, involving granulated formulations, baits, and seed

treatments, for labeling purposes. At that time risk criteria considerations were typically based on the amount of residues likely to occur, immediately following application, in or on feed items likely to be consumed by non-target wildlife species. In so much as granular formulations, baits and seed treatments leave very little residue in or on non-target food items, a hazard index had to be developed to address theses routes of exposure. It's important to note that the LD_{50}/sq. ft. concept is an index to hazard that presumes exposure will occur on the treated areas (a deterministic assessment) rather than a tool that attempts to quantify the temporal and spatial relationship of exposure (i.e., a probabilistic assessment tool) to a non-target organism.

The LD_{50}/sq.ft. index used to predict risk to non-target wildlife species has been peer reviewed by numerous scientists, both within and outside of the Agency and, in general, has been accepted as a useful tool for addressing ecological hazard from the use of granulated formulations. In March of 1992, the Agency used this index in its "Comparative Analysis of Acute Avian Risk from Granular Pesticides" document. This document provided explanation, discussion and analysis of the index as well as specific examples of risk quotients derived from the index. In 1996 the FIFRA Science Advisory Panel (SAP) reviewed and approved the environmental assessments derived from the index for those chemicals evaluated in the corn cluster document. The SAP even suggested that the acute risk indices calculated from the index may actually underestimate risk.

Based on this long history of scientific peer review, which has repeatedly supported the use of the LD_{50}/sq. ft. risk index in ecological hazard assessments, we believe that the index is appropriate for determining and classifying ecological risk to terrestrial wildlife from the use of bait formulations.

b. Uncertainties Associated with the LD_{50}/sq. ft. Index

Risk quotients based on the LD_{50}/sq.ft. hazard index have been criticized as being too conservative and overestimating "real world" risk. It has been argued that the method greatly oversimplifies the exposure component to hazard assessment by not specifically addressing the temporal and spatial situations that non-target wildlife species experience under field conditions. Although this is somewhat correct there are still many other exposure related and toxicological factors that are not accounted for by the index which may actually underestimate risk from this method.

For example, the LD_{50}/sq.ft. index is based solely on acute mortality as derived from acute oral exposure from laboratory tests. It does not address subacute behavioral or physiological effects that may occur prior to mortality and yet can still have a profound sub-lethal effects on an organisms ability to survive and reproduce. As such, this index may underestimate ecological hazard from sub-lethal exposures. For instance, it is common in clinical observations, conducted during acute tests, to observe such symptoms as wing droop, goose-stepping ataxia, dyspnea (labored breathing), diarrhea, apnea, weight loss, salivation, convulsions and hyperactivity prior to mortality occurring. Even if an organism survives this exposure to the toxicant, these symptoms indicate the organism is under extreme stress that could greatly affect both its survival (susceptibility to disease and parasites, ability to avoid predation, nest desertion and abandonment) and ability to reproduce under actual field conditions. Necropsy data also indicate that many organisms are experiencing extreme physiological changes even though they may not die from exposure to the toxicant. Liver damage, renal failure, lesions, hemorrhage and other tissue damage are indications of severe physiological impairment that could adversely affect both the survival and reproductive capability of the organisms. These sub-lethal effects are not really addressed by the LD_{50}/sq. ft. index. In fact, although the SAP (1996) approved the LD_{50}/sq.ft. index as a method for determining and classifying ecological risk to terrestrial wildlife from the use of granular formulations, it questioned the use of mortality as the primary end-point for addressing ecological risk. The SAP stated that, "Many chemicals evoke toxicity through the interference with the physiological state of the animal including behaviors important to continued reproduction and survival. Each chemical may have certain unique qualities that may influence their potential hazard to wildlife." These comments suggest that basing ecological hazard assessments solely on direct effects, as determined by acute indices, may be under protective for predicting indirect effects from sub-lethal exposures.

Although it is presumed that the LD_{50}/sq.ft. index accounts for acute exposure from oral, dermal and inhalation exposure, it was not intended to address exposure from drinking water where runoff, from either rain events or irrigation, to low areas may create puddles that contain very high concentrations of the pesticide. The contribution of this route of exposure to overall body burden residues is unknown but it will clearly be additive to exposure from direct consumption of the bait formualtion and/or exposure from eating contaminated vegetation.

c. The Likelihood of Wildlife Presence at Time of Application

Birds and mammals may utilize outdoor areas and animal premise areas that have been treated with dichlorvos and therefore may be exposed. Also, birds and mammals foraging for seeds, insects, and annelids (e.g., earthworms) may be unable to avoid ingesting granular bait dichlorvos. Birds may also ingest granules in treated areas when foraging for grit.

d. Significance of Wildlife Utilization of Treatment Areas

Characterizing risk to non-target wildlife from the use of dichlorvos on the areas for which it is registered, requires a clear understanding of the many limitations of identifying exactly what species are most likely to use treated areas and for what purpose. The simple fact is, wildlife utilization of animal premise areas and general outdoor areas is highly variable and difficult to predict and, as such, there is a great deal of uncertainty surrounding this issue when conducting an ecological hazard evaluation.

e. *Routes of Exposure*

The risk assessment findings of acute risk to terrestrial animals is based on risk assessments where ingestion of contaminated food is considered as the primary route of exposure. The risk assessment did not consider the other possible routes of exposure, e.g., dermal, preening, and respiratory pathways. These other paths of exposure have been shown to contribute to acute toxicity of other organophosphate compounds (Driver *et al.* 1991). Other routes of exposure, not considered in this assessment, are discussed below:

· ***Incidental soil ingestion exposure***

This risk assessment does not consider incidental soil ingestion. Available data suggests that up to 15% of the diet can consist of incidentally ingested soil depending on the species and feeding strategy (Beyer et al., 1994).

· ***Inhalation exposure***

This risk assessment does not consider respiratory pathways. Since dichlorvos volatilizes rapidly, the inhalation route of exposure may contribute to acute toxicity. Incidence data reports avian toxicity due to inhalation exposure.

· ***Dermal Exposure***

The screening assessment does not consider dermal exposure, except as it is indirectly included in calculations of RQs based on lethal doses per unit of pesticide treated area. Dermal exposure may occur through two potential sources: (1) incidental contact with contaminated vegetation, or (2) contact with contaminated water or soil.

The available measured data related to wildlife dermal contact with pesticides are extremely limited. The Agency is actively pursuing modeling techniques to account for dermal exposure via incidental contact with vegetation.

· ***Drinking Water Exposure***

Drinking water exposure to a pesticide active ingredient may be the result of consumption of surface water or consumption of the pesticide in dew or other water on the surface of the treated area. For pesticide active ingredients with a potential to dissolve in runoff, puddles on the treated area may contain the chemical. Given its high water solubility, dichlorvos is expected to dissolve in dew and other water associated with plant surfaces. However, the likelihood of exposure to dichlorvos via drinking water is not quantified in the exposure modeling.

f. Incidental Pesticide Releases Associated with Use

This risk assessment is based on the assumption that the entire treatment area is subject to dichlorvos application at the rates specified on the label. In reality, there is the potential for uneven application of the pesticide through such plausible incidents as changes in calibration of application equipment, spillage, and localized releases.

4. Assumptions and Limitations Related to Effects Assessment

a. Age class and sensitivity of effects thresholds

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The screening risk assessment acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on recommended immature age classes (e.g., first instar for daphnids, second instar for amphipods, stoneflies and mayflies, and third instar for midges). Similarly, acute dietary testing with birds is also performed on juveniles, with mallard being 5-10 days old and quail 10-14 days old.

Testing of juveniles may overestimate toxicity at older age classes for pesticidal active ingredients, such as dichlorvos, that act directly because younger age classes may not have the enzymatic systems associated with detoxifying xenobiotics. The screening risk assessment has no current provisions for a generally applied method that accounts for this uncertainty. In so far as the available toxicity data may provide ranges of sensitivity information with respect to age class, the risk assessment uses the most sensitive life-stage information as the conservative screening endpoint.

b.. Use of the Most Sensitive Species Tested

Although the screening-level risk assessment relies on a selected toxicity endpoint from the most sensitive species tested, it does not necessarily mean that the selected toxicity endpoints reflect sensitivity of the most sensitive species existing in a given environment. The relative position of the most sensitive species tested in the distribution of all possible species is a function of the overall variability among species to a particular chemical. In the case of listed species, there is uncertainty regarding the relationship of the listed species' sensitivity and the most sensitive species tested.

The Agency is not limited to a base set of surrogate toxicity information in establishing risk assessment conclusions. The Agency also considers toxicity data on non-standard test species when available.

5. Assumptions Associated with the Acute LOCs

The risk characterization section of the assessment document includes an evaluation of the potential for individual effects at an exposure level equivalent to the LOC. This evaluation is based on the median lethal dose estimate and dose/response relationship established for the effects study corresponding to each taxonomic group for which the LOCs are exceeded.

6. Data Gaps and Limitations of the Risk Assessment

The following data gaps were identified:

g. Ecotoxicity Data Gaps

There is limited terrestrial and aquatic plant data for dichlorvos, which leads to uncertainty in the evaluation of plant risk.

c. Environmental Fate Information Gaps

re are no environmental fate data gaps.

Appendices A and B at the end of this document provides the summary status of all the environmental fate and ecotoxicological data requirement

REFERENCES

Bennett, R.S. and L. M. Ganio. 1991. Overview of methods for evaluating effects of pesticides on reproduction in birds. U.S.EPA, Off. Research and Development, Environ. Res. Lab., Corvallis, Oregon. 106 p.

Best, L.B., R.C. Whitmore and G.M. Booth. 1990. Use of cornfields by birds during the breeding season: the importance of edge habitat. American Midland Naturalist 123:84-99.

Driver *et al.* 1991. Routes of Uptake and their relative contribution to the toxicological response of northern bobwhite *(Colinus virginianus)* to an organophoshate pesticide. Environmental Toxicology and Chemistry Vol. 10, pp. 21-33.

Felthousen, R. 1977. Classification of Granulated Formulations. USEPA, September 9, 1977

Goh, K.S. *et al.* 1986. Dissipation of Dislodgeable Foliar Residues of Chlorpyrifos and Dichlorvos on Turf. Bull. Environ. Contam. Toxicol., 37:27-32.

Madrigal et al. 1996. Have to find the citation

Mayer, F. L. J. and Ellersieck, M. R. 1986. Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. *Resour.Publ.No.160, U.S.Dep.Interior, Fish Wildl.Serv., Washington, DC* 505 p. (USGS Data File) (EPA MRID # 40098001).

Urban D.J. and N.J. Cook. 1986. Hazard Evaluation Division Standard Evaluation Procedure Ecological Risk Assessment. EPA 540/9-85-001. U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC.

U.S. EPA. 1986. Acute Toxicity Handbook of Chemicals to Estuarine Organisms., *U.S.EPA, Gulf Breeze, FL* (US EPA MRID 40228401).

U.S. EPA. 1992. Comparative Analysis of Acute Avian Risk from Granular Pesticides. March, 1992.

U.S. EPA. 2004a. Interim Guidance of the Evaluation Criteria for Ecological Toxicity Data in the Open Literature, Phases I and II. July 16, 2004

U.S. EPA. 2004b. T-REX Version 1.1. December 7, 2004

APPENDIX A. ECOLOGICAL DATA REQUIREMENTS FOR DICHLORVOS

Data Requirements	Use Pattern [1]	Does EPA Have Data to Satisfy this Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
71-1(a) Acute Avian Oral, Quail/Duck	3,8,9,11,15	Yes	40818301, 00160000	No
71-2(a) Acute Avian Diet, Quail	3,8,9,11,15	Yes	00022923	No
71-2(b) Acute Avian Diet, Duck	3,8,9,11,15	Yes	00022923	No
71-4(a) Avian Reproduction Quail	3	Yes	43981701	No
71-4(b) Avian Reproduction Duck	3	Yes	44233401	No
72-1(a) Acute Fish Toxicity Bluegill	3,8,9,11,15	Yes	40094602	No
72-1(b) Acute Fish Toxicity Bluegill (TEP)	5	Yes	43284701	No[2]
72-1(c) Acute Fish Toxicity Rainbow Trout	3,8,9,11,15	Yes	40098001	No
72-1(d) Acute Fish Toxicity Rainbow Trout (TEP)	5	Yes	43284702	No[2]
72-2(a) Acute Aquatic Invertebrate	3,8,9,11,15	Yes	40098001	No
72-3(a) Acute Est/Mar Toxicity Fish	3	Yes	43571403	No
72-3(b) Acute Est/Mar Toxicity Mollusk	3	Yes	43571404	No
72-3(c) Acute Est/Mar Toxicity Shrimp	3	Yes	43571405	No
72-3(d) Acute	5	Yes	43571406	No[2]

Est/Mar Toxicity Fish (TEP)				
72-3(e) Acute Est/Mar Toxicity Mollusk (TEP)	5	Yes	43571407	No[2]
72-3(f) Acute Est/Mar Toxicity Shrimp (TEP)	5	Yes	43571408	No[2]
72-4(a) Early Life Stage Fish	3	Yes	43788001, 43790401	No
72-4(b) Life Cycle Aquatic Invertebrate	3	Yes	43890301, 43854301	No
141-1 Honey Bee Acute Contact	3, 11	Yes	00036935	No
141-2 Honey bee Residue on Foliage	3, 11	Yes	43366701	No

FOOTNOTES:

1. 1 = Terrestrial Food; 2 = Terrestrial Feed; 3 = Terrestrial Non-Food; 4 = Aquatic Food; 5 = Aquatic Non-Food (Outdoor); 6 = Aquatic Non-Food (Industrial); 7 = Aquatic Non-Food (Residential); 8 = Greenhouse Food; 9 = Greenhouse Non-Food; 10 = Forestry; 11 = Residential Outdoor; 12 = Indoor Food; 13 = Indoor Non-Food; 14 = Indoor Medicinal; 15 = Indoor Residential

2. Although data are available, there is no longer an Aquatic Non-Food (Outdoor) or Terrestrial Food use for this chemical.

APPENDIX B. ENVIRONMENTAL FATE DATA REQUIREMENTS FOR DICHLORVOS

Data Requirements	Use Pattern [1]	Does EPA Have Data to Satisfy this Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
161-1 Hydrolysis	3,8,9,11	Yes	41723101	No
161-2 Photodegradation in Water	3	Yes	43326601	No
161-3 Photodegradation On Soil	1	Yes	43642501	No[2]
162-1 Aerobic Soil	3,8,9,11	Yes	41723102	No
162-2 Anaerobic Soil	1	Yes	43835701	No[2]
163-1 Leaching - Adsorption/Desorp.	3,8,9,11	Yes	41723103, 40034904	No
164-1 Soil Dissipation	3,11	Yes	44386701, 44297701	No
201-1 Droplet Size Spectrum	3	Yes		No[3]
202-1 Drift Field Evaluation	3	Yes		No[3]

FOOTNOTES:

1. 1 = Terrestrial Food; 2 = Terrestrial Feed; 3 = Terrestrial Non-Food; 4 = Aquatic Food; 5 = Aquatic Non-Food (Outdoor); 6 = Aquatic Non-Food (Industrial); 7 = Aquatic Non-Food (Residential); 8 = Greenhouse Food; 9 = Greenhouse Non-Food; 10 = Forestry; 11 = Residential Outdoor; 12 = Indoor Food; 13 = Indoor Non-Food; 14 = Indoor Medicinal; 15 = Indoor Residential

2. Although data are available, there is no longer an Aquatic Non-Food (Outdoor) or Terrestrial Food use for this chemical.

3. Amvac is a member of the Spray Drift Task Force.

APPENDIX C. PRZM/EXAMS MODELING

FLORIDA TURF 1 APPLICATION at 0.2 lbs/A

stored as DVPtrf1.out
Chemical: DDVP
PRZM environment: FLturfC.txt modified Monday, 16 June
EXAMS environment: pond298.exv modified Thuday, 29 August
Metfile: w12834.dvf modified Wedday, 3 July 2002

Water segment concentrations (ppb)

Year	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
1961	0.112	0.0867	0.03732	0.01389	0.009268	0.002285
1962	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
1963	0.112	0.08675	0.03738	0.01392	0.009283	0.002289
1964	0.112	0.0867	0.03732	0.01389	0.009267	0.002279
1965	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
1966	0.112	0.08672	0.03733	0.0139	0.009272	0.002286
1967	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
1968	0.112	0.08671	0.03732	0.01389	0.009269	0.002279
1969	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
1970	0.112	0.0867	0.03731	0.01389	0.009265	0.002285
1971	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
1972	0.112	0.08671	0.03733	0.0139	0.00927	0.00228
1973	0.112	0.08671	0.03732	0.01389	0.009269	0.002286
1974	0.112	0.08671	0.03732	0.0139	0.009269	0.002286
1975	0.112	0.08671	0.03733	0.0139	0.00927	0.002286
1976	0.112	0.08717	0.0377	0.01404	0.009365	0.002303
1977	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
1978	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
1979	0.112	0.0867	0.03731	0.01389	0.009266	0.002285

1980	0.112	0.08677	0.03737	0.01391	0.00928	0.002282
1981	0.112	0.0867	0.03731	0.01389	0.009265	0.002285
1982	0.112	0.08671	0.03732	0.0139	0.009269	0.002286
1983	0.112	0.0867	0.03732	0.01389	0.009268	0.002286
1984	0.112	0.08691	0.0376	0.014	0.00934	0.002297
1985	0.1122	0.08721	0.03768	0.01403	0.009359	0.002308
1986	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
1987	0.112	0.0867	0.03732	0.01389	0.009267	0.002285
1988	0.112	0.0867	0.03732	0.01389	0.009268	0.002279
1989	0.112	0.0867	0.03731	0.01389	0.009265	0.002285
1990	0.112	0.0867	0.03731	0.01389	0.009266	0.002285

Sorted results

Prob.	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
0.03225806	0.1122	0.08721	0.0377	0.01404	0.009365	0.002308
0.06451613	0.112	0.08717	0.03768	0.01403	0.009359	0.002303
0.09677419	0.112	0.08691	0.0376	0.014	0.00934	0.002297
0.12903226	0.112	0.08677	0.03738	0.01392	0.009283	0.002289
0.16129032	0.112	0.08675	0.03737	0.01391	0.00928	0.002286
0.19354839	0.112	0.08672	0.03733	0.0139	0.009272	0.002286
0.22580645	0.112	0.08671	0.03733	0.0139	0.00927	0.002286
0.25806452	0.112	0.08671	0.03733	0.0139	0.00927	0.002286
0.29032258	0.112	0.08671	0.03732	0.0139	0.009269	0.002286
0.32258065	0.112	0.08671	0.03732	0.0139	0.009269	0.002286
0.35483871	0.112	0.08671	0.03732	0.01389	0.009269	0.002285
0.38709677	0.112	0.08671	0.03732	0.01389	0.009269	0.002285
0.41935484	0.112	0.0867	0.03732	0.01389	0.009268	0.002285

0.4516129	0.112	0.0867	0.03732	0.01389	0.009268	0.002285
0.48387097	0.112	0.0867	0.03732	0.01389	0.009268	0.002285
0.51612903	0.112	0.0867	0.03732	0.01389	0.009267	0.002285
0.5483871	0.112	0.0867	0.03732	0.01389	0.009267	0.002285
0.58064516	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
0.61290323	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
0.64516129	0.112	0.0867	0.03731	0.01389	0.009267	0.002285
0.67741935	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
0.70967742	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
0.74193548	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
0.77419355	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
0.80645161	0.112	0.0867	0.03731	0.01389	0.009266	0.002285
0.83870968	0.112	0.0867	0.03731	0.01389	0.009266	0.002282
0.87096774	0.112	0.0867	0.03731	0.01389	0.009266	0.00228
0.90322581	0.112	0.0867	0.03731	0.01389	0.009265	0.002279
0.93548387	0.112	0.0867	0.03731	0.01389	0.009265	0.002279
0.96774194	0.112	0.0867	0.03731	0.01389	0.009265	0.002279
0.1	0.112	0.086896	0.037578	0.013992	0.009334	0.002296

Average of yearly averages: 0.002286

Inputs generated by pe4.pl - 8-Aug-03

Description	Variable	Name	Value	Units	Comments
Data used for this run:					
Output File:		DVPtrf1			
Metfile:		w12834.dvf			
PRZM scenario:		FLturfC.txt			
EXAMS environment file:		pond298.exv			
Chemical Name:		DDVP			
Molecular	weight	mwt	220.9	g/mol	
Henry's Law Const.		henry	5.01E-08	atm-m^3/mol	
Vapor Pressure		vapr	1.20E-02	torr	

Solubility	sol		10000	mg/L			
Kd	Kd	mg/L					
Koc	Koc		37	mg/L			
Photolysis	half-life	kdp		10.2	days	Half-life	
Aerobic	Aquatic	Metabolism	kbacw		0	days	Halfife
Anaerobic	Aquatic	Metabolism	kbacs		0	days	Halfife
Aerobic	Soil	Metabolism	asm		0.42	days	Halfife
Hydrolysis:	pH		7	5.2	days	Half-life	
Method:	CAM		2	integer	See	PRZM	manual
Incorporation	Depth:	DEPI		0	cm		
Application	Rate:	TAPP		0.224	kg/ha		
Application	Efficiency:	APPEFF		0.99	fraction		
Spray	Drift	DRFT		0.01	fraction	of	applicatio
Application	Date	Date	20-05		dd/mm	or	dd/mmm
Record	17:00	FILTRA					
	IPSCND		1				
	UPTKF						
Record	18:00	PLVKRT					
	PLDKRT		2.64				
	FEXTRC		0.5				
Flag	for	Index	Res.	Run	IR	Pond	
Flag	for	runoff	calc.	RUNOFF	none	none,	

FLORIDA TURF 4 APPLICATIONS, 30 DAY INTERVAL, 0.2 lbs/A

stored	as	DVPFLtrf.out				
Chemical:	DDVP					
PRZM	environment:	FLturfC.txt	modified	Monday,	16 June	
EXAMS	environment:	pond298.exv	modified	Thuday,	29 August	
Metfile:	w12834.dvf	modified	Wedday,	3 July	2002	
Water	segment	concentrations	(ppb)			

Year	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
1961	0.114	0.09286	0.04047	0.02871	0.0284	0.009295
1962	0.1188	0.1001	0.04436	0.0302	0.0294	0.009537
1963	0.114	0.08831	0.03803	0.02781	0.02781	0.009148
1964	0.114	0.08833	0.03806	0.02782	0.02781	0.00912
1965	0.114	0.08831	0.03804	0.02781	0.02781	0.009143
1966	2.983	2.309	0.9941	0.3839	0.2653	0.06772

1967	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
1968	0.1247	0.09659	0.0416	0.02954	0.02897	0.009406
1969	0.114	0.08832	0.03813	0.02785	0.02783	0.00915
1970	0.114	0.08833	0.03805	0.02782	0.02781	0.009144
1971	0.114	0.08831	0.03804	0.02782	0.02781	0.009144
1972	2.374	1.838	0.7913	0.3083	0.2149	0.05513
1973	0.114	0.08832	0.03804	0.02782	0.02781	0.009145
1974	0.114	0.08832	0.03804	0.02782	0.02781	0.009145
1975	0.114	0.08835	0.03806	0.02783	0.02782	0.009147
1976	0.114	0.08831	0.03803	0.02781	0.02781	0.009142
1977	0.114	0.08831	0.03811	0.02784	0.02782	0.009148
1978	0.114	0.08831	0.03803	0.02781	0.0278	0.009143
1979	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
1980	0.114	0.08835	0.03812	0.02784	0.02784	0.009129
1981	0.114	0.08832	0.0381	0.02784	0.02782	0.009147
1982	0.1742	0.135	0.06278	0.03711	0.03401	0.01067
1983	0.114	0.08837	0.03809	0.02783	0.02782	0.009148
1984	0.1222	0.09999	0.04476	0.03035	0.0295	0.009552
1985	0.114	0.09034	0.0392	0.02825	0.0281	0.009239
1986	0.1143	0.09068	0.04065	0.02882	0.02848	0.009309
1987	0.114	0.08835	0.03806	0.02782	0.02781	0.009145
1988	0.114	0.08832	0.03804	0.02781	0.02781	0.009119
1989	0.114	0.08841	0.03808	0.02783	0.02781	0.009145
1990	0.114	0.08831	0.03803	0.02781	0.0278	0.009143

Sorted results

Prob.	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
0.03225806	2.983	2.309	0.9941	0.3839	0.2653	0.06772

0.06451613	2.374	1.838	0.7913	0.3083	0.2149	0.05513
0.09677419	0.1742	0.135	0.06278	0.03711	0.03401	0.01067
0.12903226	0.1247	0.1001	0.04476	0.03035	0.0295	0.009552
0.16129032	0.1222	0.09999	0.04436	0.0302	0.0294	0.009537
0.19354839	0.1188	0.09659	0.0416	0.02954	0.02897	0.009406
0.22580645	0.1143	0.09286	0.04065	0.02882	0.02848	0.009309
0.25806452	0.114	0.09068	0.04047	0.02871	0.0284	0.009295
0.29032258	0.114	0.09034	0.0392	0.02825	0.0281	0.009239
0.32258065	0.114	0.08841	0.03813	0.02785	0.02784	0.00915
0.35483871	0.114	0.08837	0.03812	0.02784	0.02783	0.009148
0.38709677	0.114	0.08835	0.03811	0.02784	0.02782	0.009148
0.41935484	0.114	0.08835	0.0381	0.02784	0.02782	0.009148
0.4516129	0.114	0.08835	0.03809	0.02783	0.02782	0.009147
0.48387097	0.114	0.08833	0.03808	0.02783	0.02782	0.009147
0.51612903	0.114	0.08833	0.03806	0.02783	0.02781	0.009145
0.5483871	0.114	0.08832	0.03806	0.02782	0.02781	0.009145
0.58064516	0.114	0.08832	0.03806	0.02782	0.02781	0.009145
0.61290323	0.114	0.08832	0.03805	0.02782	0.02781	0.009145
0.64516129	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
0.67741935	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
0.70967742	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
0.74193548	0.114	0.08832	0.03804	0.02782	0.02781	0.009144
0.77419355	0.114	0.08831	0.03804	0.02782	0.02781	0.009143
0.80645161	0.114	0.08831	0.03804	0.02781	0.02781	0.009143
0.83870968	0.114	0.08831	0.03804	0.02781	0.02781	0.009143
0.87096774	0.114	0.08831	0.03803	0.02781	0.02781	0.009142

0.90322581	0.114	0.08831	0.03803	0.02781	0.02781	0.009129
0.93548387	0.114	0.08831	0.03803	0.02781	0.0278	0.00912
0.96774194	0.114	0.08831	0.03803	0.02781	0.0278	0.009119
0.1	0.16925	0.13151	0.060978	0.036434	0.033559	0.010558

Average of yearly averages: 0.012728

Inputs generated by pe4.pl - 8-Aug-03

Data used for this run:						
Output File:	DVPFLtrf					
Metfile:	w12834.dvf					
PRZM scenario:	FLturfC.txt					
EXAMS environment file:	pond298.exv					
Chemical Name:	DDVP					
Description	Variable	Name	Value	Units	Comments	
Molecular	weight	mwt	220.9	g/mol		
Henry's	Law	Const.	henry	5.01E-08	atm-m^3/mol	
Vapor	Pressure	vapr	1.20E-02	torr		
Solubility	sol	10000	mg/L			
Kd	Kd	mg/L				
Koc	Koc	37	mg/L			
Photolysis	half-life	kdp	10.2	days	Half-life	
Aerobic	Aquatic	Metabolism	kbacw	0	days	Halfife
Anaerobic	Aquatic	Metabolism	kbacs	0	days	Halfife
Aerobic	Soil	Metabolism	asm	0.42	days	Halfife
Hydrolysis:	pH	7	5.2	days	Half-life	
Method:	CAM	2	integer	See	PRZM	manual
Incorporation	Depth:	DEPI	0	cm		
Application	Rate:	TAPP	0.224	kg/ha		
Application	Efficiency:	APPEFF	0.99	fraction		
Spray	Drift	DRFT	0.01	fraction	of	applicatio
Application	Date	Date	20-May	dd/mm	or	dd/mmm
Interval	1	interval	30	days	Set	to
Interval	2	interval	30	days	Set	to
Interval	3	interval	30	days	Set	to
Record	17:00	FILTRA				
	IPSCND	1				
	UPTKF					
Record	18:00	PLVKRT				
	PLDKRT	2.64				
	FEXTRC	0.5				
Flag	for	Index	Res.	Run	IR	Pond
Flag	for	runoff	calc.	RUNOFF	none	none,

PENNSYLVANIA TURF 1 APPLICATION at 0.2 lbs/A

stored	as	DVPtrfPA.out				
Chemical:	DDVP					
PRZM	environment:	PAturfC.txt	modified	Satday,	12 October	
EXAMS	environment:	pond298.exv	modified	Thuday,	29 August	
Metfile:	w14737.dvf	modified	Wedday,	3 July	2002	
Water	segment	concentrations	(ppb)			

Year	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
1961	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
1962	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
1963	0.112	0.08672	0.03733	0.0139	0.009273	0.002287
1964	0.112	0.08671	0.03733	0.0139	0.009271	0.00228
1965	0.112	0.08671	0.03733	0.0139	0.009272	0.002287
1966	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
1967	0.112	0.08672	0.03733	0.0139	0.009272	0.002287
1968	0.112	0.08672	0.03734	0.01391	0.009275	0.002281
1969	0.112	0.08671	0.03733	0.0139	0.009271	0.002286
1970	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
1971	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
1972	0.112	0.08672	0.03734	0.0139	0.009274	0.002281
1973	0.112	0.08672	0.03734	0.0139	0.009275	0.002287

1974	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
1975	0.112	0.08673	0.03735	0.01391	0.009276	0.002288
1976	0.112	0.08672	0.03733	0.0139	0.009273	0.00228
1977	0.112	0.08671	0.03733	0.0139	0.009271	0.002286
1978	0.112	0.08672	0.03734	0.0139	0.009275	0.002287
1979	0.112	0.08678	0.03742	0.01393	0.009295	0.002292
1980	0.112	0.08672	0.03734	0.0139	0.009273	0.002281
1981	0.112	0.08671	0.03733	0.0139	0.009272	0.002287
1982	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
1983	0.112	0.08686	0.03745	0.01394	0.009301	0.002294
1984	0.4776	0.3698	0.1592	0.05929	0.03955	0.009726
1985	0.112	0.08671	0.03733	0.0139	0.009272	0.002287
1986	0.112	0.08758	0.03798	0.01414	0.009435	0.002327
1987	0.112	0.08672	0.03733	0.0139	0.009272	0.002287
1988	0.112	0.08672	0.03734	0.0139	0.009274	0.002281
1989	0.112	0.08672	0.03734	0.0139	0.009275	0.002287
1990	0.112	0.08672	0.03734	0.0139	0.009273	0.002287

Sorted results

Prob.	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
0.03225806	0.4776	0.3698	0.1592	0.05929	0.03955	0.009726
0.06451613	0.112	0.08758	0.03798	0.01414	0.009435	0.002327
0.09677419	0.112	0.08686	0.03745	0.01394	0.009301	0.002294
0.12903226	0.112	0.08678	0.03742	0.01393	0.009295	0.002292
0.16129032	0.112	0.08673	0.03735	0.01391	0.009276	0.002288
0.19354839	0.112	0.08672	0.03734	0.01391	0.009275	0.002287
0.22580645	0.112	0.08672	0.03734	0.0139	0.009275	0.002287

0.25806452	0.112	0.08672	0.03734	0.0139	0.009275	0.002287
0.29032258	0.112	0.08672	0.03734	0.0139	0.009275	0.002287
0.32258065	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.35483871	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.38709677	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.41935484	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.4516129	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.48387097	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.51612903	0.112	0.08672	0.03734	0.0139	0.009274	0.002287
0.5483871	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
0.58064516	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
0.61290323	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
0.64516129	0.112	0.08672	0.03734	0.0139	0.009273	0.002287
0.67741935	0.112	0.08672	0.03733	0.0139	0.009273	0.002287
0.70967742	0.112	0.08672	0.03733	0.0139	0.009273	0.002287
0.74193548	0.112	0.08672	0.03733	0.0139	0.009272	0.002286
0.77419355	0.112	0.08672	0.03733	0.0139	0.009272	0.002286
0.80645161	0.112	0.08671	0.03733	0.0139	0.009272	0.002281
0.83870968	0.112	0.08671	0.03733	0.0139	0.009272	0.002281
0.87096774	0.112	0.08671	0.03733	0.0139	0.009272	0.002281
0.90322581	0.112	0.08671	0.03733	0.0139	0.009271	0.002281
0.93548387	0.112	0.08671	0.03733	0.0139	0.009271	0.00228
0.96774194	0.112	0.08671	0.03733	0.0139	0.009271	0.00228
0.1	0.112	0.086852	0.037447	0.013939	0.0093	0.002294

Average of yearly averages: 0.002535

Inputs generated by pe4.pl - 8-Aug-03

Data	used	for	this	run:		
Output	File:	DVPtrfPA				
Metfile:	w14737.dvf					
PRZM	scenario:	PAturfC.txt				
EXAMS	environment	file:	pond298.exv			
Chemical	Name:	DDVP				
Description	Variable	Name	Value	Units	Comments	
Molecular	weight	mwt	220.9	g/mol		
Henry's	Law	Const.	henry	5.01E-08	atm-m^3/mol	
Vapor	Pressure	vapr	1.20E-02	torr		
Solubility	sol	10000	mg/L			
Kd	Kd	mg/L				
Koc	Koc	37	mg/L			
Photolysis	half-life	kdp	10.2	days	Half-life	
Aerobic	Aquatic	Metabolism	kbacw	0	days	Halfife
Anaerobic	Aquatic	Metabolism	kbacs	0	days	Halfife
Aerobic	Soil	Metabolism	asm	0.42	days	Halfife
Hydrolysis:	pH	7	5.2	days	Half-life	
Method:	CAM	2	integer	See	PRZM	manual
Incorporation	Depth:	DEPI	0	cm		
Application	Rate:	TAPP	0.224	kg/ha		
Application	Efficiency:	APPEFF	0.99	fraction		
Spray	Drift	DRFT	0.01	fraction	of	applicatio
Application	Date	Date	20-05	dd/mm	or	dd/mmm
Record	17:00	FILTRA				
	IPSCND	1				
	UPTKF					
Record	18:00	PLVKRT				
	PLDKRT	2.64				
	FEXTRC	0.5				
Flag	for	Index	Res.	Run	IR	Pond
Flag	for	runoff	calc.	RUNOFF	none	none,

PENNSYLVANIA TURF 4 APPLICATIONS, 30 DAY INTERVAL, 0.2 lbs/A

stored	as	DVPPAtrf.out				
Chemical:	DDVP					
PRZM	environment:	PAturfC.txt	modified	Satday,	12 October	
EXAMS	environment:	pond298.exv	modified	Thuday,	29 August	
Metfile:	w14737.dvf	modified	Wedday,	3 July	2002	
Water	segment	concentrations	(ppb)			

Year	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
1961	0.1141	0.08833	0.03807	0.02784	0.02783	0.00915
1962	0.114	0.08832	0.03805	0.02783	0.02782	0.009149
1963	0.1141	0.08865	0.03822	0.02789	0.02786	0.009159
1964	0.1141	0.08833	0.03805	0.02783	0.02782	0.009123
1965	0.114	0.08833	0.03806	0.02783	0.02782	0.009148
1966	0.114	0.08832	0.03804	0.02782	0.02781	0.009147
1967	0.1141	0.08833	0.03806	0.02783	0.02782	0.009149
1968	0.114	0.08833	0.03805	0.02783	0.02782	0.009124
1969	0.1141	0.08833	0.03807	0.02783	0.02783	0.009149
1970	0.1262	0.1047	0.04681	0.03112	0.03001	0.00969
1971	0.114	0.08832	0.03804	0.02782	0.02782	0.009148
1972	0.1142	0.09017	0.04004	0.02893	0.02856	0.009307
1973	0.114	0.08833	0.03805	0.02782	0.02782	0.009149
1974	0.1141	0.08834	0.03806	0.02783	0.02782	0.00915
1975	0.1142	0.09152	0.03976	0.02847	0.02825	0.009256
1976	0.114	0.08832	0.03805	0.02782	0.02782	0.009123
1977	0.26	0.2014	0.08673	0.04596	0.03991	0.01213
1978	0.1141	0.08834	0.03806	0.02783	0.02782	0.00915
1979	0.1141	0.08833	0.03806	0.02783	0.02782	0.009155
1980	0.114	0.08833	0.03805	0.02782	0.02782	0.009123
1981	0.1141	0.08862	0.03827	0.02792	0.02789	0.009164
1982	0.114	0.08833	0.03805	0.02782	0.02782	0.009149
1983	0.1496	0.1192	0.05453	0.03402	0.03195	0.01017
1984	0.4776	0.3698	0.1592	0.07293	0.05792	0.01657
1985	0.114	0.08833	0.03805	0.02783	0.02782	0.009148
1986	0.1141	0.08833	0.03805	0.02785	0.02784	0.009188

1987	0.114	0.08833	0.03809	0.02784	0.02784	0.009152
1988	0.1141	0.09001	0.03895	0.02816	0.02804	0.009178
1989	0.1142	0.09185	0.03993	0.02864	0.02837	0.009285
1990	0.114	0.08832	0.03805	0.02782	0.02782	0.009148

Sorted results

Prob.	Peak	96 Hr	21 Day	60 Day	90 Day	Yearly
0.03225806	0.4776	0.3698	0.1592	0.07293	0.05792	0.01657
0.06451613	0.26	0.2014	0.08673	0.04596	0.03991	0.01213
0.09677419	0.1496	0.1192	0.05453	0.03402	0.03195	0.01017
0.12903226	0.1262	0.1047	0.04681	0.03112	0.03001	0.00969
0.16129032	0.1142	0.09185	0.04004	0.02893	0.02856	0.009307
0.19354839	0.1142	0.09152	0.03993	0.02864	0.02837	0.009285
0.22580645	0.1142	0.09017	0.03976	0.02847	0.02825	0.009256
0.25806452	0.1141	0.09001	0.03895	0.02816	0.02804	0.009188
0.29032258	0.1141	0.08865	0.03827	0.02792	0.02789	0.009178
0.32258065	0.1141	0.08862	0.03822	0.02789	0.02786	0.009164
0.35483871	0.1141	0.08834	0.03809	0.02785	0.02784	0.009159
0.38709677	0.1141	0.08834	0.03807	0.02784	0.02784	0.009155
0.41935484	0.1141	0.08833	0.03807	0.02784	0.02783	0.009152
0.4516129	0.1141	0.08833	0.03806	0.02783	0.02783	0.00915
0.48387097	0.1141	0.08833	0.03806	0.02783	0.02782	0.00915
0.51612903	0.1141	0.08833	0.03806	0.02783	0.02782	0.00915
0.5483871	0.1141	0.08833	0.03806	0.02783	0.02782	0.009149
0.58064516	0.1141	0.08833	0.03806	0.02783	0.02782	0.009149
0.61290323	0.114	0.08833	0.03805	0.02783	0.02782	0.009149
0.64516129	0.114	0.08833	0.03805	0.02783	0.02782	0.009149

0.67741935	0.114	0.08833	0.03805	0.02783	0.02782	0.009149
0.70967742	0.114	0.08833	0.03805	0.02783	0.02782	0.009148
0.74193548	0.114	0.08833	0.03805	0.02783	0.02782	0.009148
0.77419355	0.114	0.08833	0.03805	0.02782	0.02782	0.009148
0.80645161	0.114	0.08833	0.03805	0.02782	0.02782	0.009148
0.83870968	0.114	0.08832	0.03805	0.02782	0.02782	0.009147
0.87096774	0.114	0.08832	0.03805	0.02782	0.02782	0.009124
0.90322581	0.114	0.08832	0.03805	0.02782	0.02782	0.009123
0.93548387	0.114	0.08832	0.03804	0.02782	0.02782	0.009123
0.96774194	0.114	0.08832	0.03804	0.02782	0.02781	0.009123
0.1	0.14726	0.11775	0.053758	0.03373	0.031756	0.010122

Average of yearly averages: 0.009561

Inputs generated by pe4.pl - 8-Aug-03

Data used for this run:

Output	File:	DVPPAtrf				
Metfile:	w14737.dvf					
PRZM	scenario:	PAturfC.txt				
EXAMS	environment	file:	pond298.exv			
Chemical	Name:	DDVP				
Description	Variable	Name	Value	Units	Comments	
Molecular	weight	mwt	220.9	g/mol		
Henry's	Law	Const.	henry	5.01E-08	atm-m^3/mol	
Vapor	Pressure	vapr	1.20E-02	torr		
Solubility	sol	10000	mg/L			
Kd	Kd	mg/L				
Koc	Koc	37	mg/L			
Photolysis	half-life	kdp	10.2	days	Half-life	
Aerobic	Aquatic	Metabolism	kbacw	0	days	Halfife
Anaerobic	Aquatic	Metabolism	kbacs	0	days	Halfife
Aerobic	Soil	Metabolism	asm	0.42	days	Halfife
Hydrolysis:	pH	7	5.2	days	Half-life	
Method:	CAM	2	integer	See	PRZM	manual
Incorporation	Depth:	DEPI	0	cm		
Application	Rate:	TAPP	0.224	kg/ha		
Application	Efficiency:	APPEFF	0.99	fraction		
Spray	Drift	DRFT	0.01	fraction	of	applicatio
Application	Date	Date	20-05	dd/mm	or	dd/mmm

Interval		1 interval			30 days	Set	to
Interval		2 interval			30 days	Set	to
Interval		3 interval			30 days	Set	to
Record	17:00	FILTRA					
	IPSCND		1				
	UPTKF						
Record	18:00	PLVKRT					
	PLDKRT		2.64				
	FEXTRC		0.5				
Flag	for	Index	Res.	Run	IR	Pond	
Flag	for	runoff	calc.	RUNOFF	none	none,	

APPENDIX D. TERRESTRIAL EXPOSURE AND RQ CALCULATION - T-REX MODEL

T-REX Version 1.1

December 7, 2004

The T-REX spreadsheet has been developed by the Plant, Terrestrial Biology and Exposure Technical Teams.
For information or questions concerning this spreadsheet, please contact John Ravenscroft or Edward Odenkirchen.

****NOTE**:** Please save the spreadsheet file to you ***own*** computer first. Select 'File', then 'Save As' on the menu bar. Select the destination on your own hard drive (usually set to C:). ***Do not*** modify the spreadsheet on the F: drive.

Scroll down to next section for instructions.

Introduction and Background

This spreadsheet-based model calculates the decay of a chemical applied to foliar surfaces for single or multiple applications. It uses the same principle as the batch code models FATE and TERREEC that calculate terrestrial exposure concentration estimates on plant surfaces following pesticide application. A first order decay assumption is used to determine the concentration at each day after initial application based on the concentration resulting from the initial and additional applications. The decay is calculated from the first order rate equation:

$$CT = C_i e^{-kT}$$

or in log form:

$$\ln (CT/C_i) = kT$$

Where

CT =concentration at time T = day zero.

C_i =concentration, in parts per million (PPM), present initially (on day zero) on the surfaces. C_i is calculated by multiplying the application rate, in pounds active ingredient per acre, by 240 for short grass, 110 for tall grass, and 135 for broad-leafed plants/small insects and 15 for fruits/pods/large insects based on the Kenaga nomogram (Hoerger and Kenaga, 1972) as modified by Fletcher (1994). For maximum concentrations, additional applications are converted from pounds active ingredient per acre to PPM on the plant surface and the additional mass added to the mass of the chemical still present on the surfaces on the day of application.

k = If the foliar dissipation data submitted to EFED are found scientifically valid and statistically robust for a specific pesticide, the 90% upper confidence limit of the mean half-lives should be used. When scientifically valid, statistically robust data are not available, EFED recommends the using a default half-life value of 35 days. The use of the 35-day half-life is based on the highest reported value (36.9 days), as reported by Willis and McDowell (Pesticide persistence on foliage, Environ. Contam. Toxicol, 100:23-73, 1987).

T =time, in days, since the start of the simulation. The initial application is on day 0. The simulation is designed to run for 365 days.

The spreadsheet calculates the pesticide residue concentrations on each type of surface on a daily interval for one year. The maximum concentration during the year is calculated for both maximum and mean residues.

The calculated residue concentrations are used to calculate Avian and Mammalian risk quotient (RQ) values. The maximum calculated concentration is divided by user input values for acute and chronic endpoints to give RQs for each type of plant surface.

How to use TREX

TREX has been designed to be easy to use, yet maintain a level of flexibility needed for the multitude of chemicals and use patterns encountered by risk assessors. Throughout the spreadsheet, look for small red cell tags that contain additional information; just move the cursor over them to display the comment box. With the exception of the seed treatment exposure worksheet, all necessary data can be entered into the 'Input' worksheet.

Inputs

An 'Input' worksheet has been included to increase consistency and transparency in the terrestrial exposure estimation process. The inputs used to calculate the amount of chemical present and estimate exposure are highlighted in blue, as well as consist of various drop-down menus. These inputs include the following:

Chemical name: Enter either the chemical or common name used in the assessment
Use:Enter the crop name and type of use
Formulation:Enter the state of the chemical to be used (e.g., liquid, spray, WP, flowable, etc.)
% A.I.:Enter the % A.I. for the formulation (from the label)
Application Rate:The maximum label application rate (pounds ai/acre)
Half-life:The degradation half-life for the dominant process (days)
Application Interval:The interval between repeated applications, from the label (days)
Maximum # Application per year:From the label
Concentration of Concern:For graphing purposes, choose an endpoint (mg/kg-diet) that you wish to be overlaid onto the residue graph
Choose label:From the drop-down menu, choose the label that corresponds to the Concentration of Concern

NOTE: Pushing the 'reset model' button to the right of the first set of inputs will clear ALL of the user-supplied information. This button was included to allow the user to more quickly run multiple scenarios with TREX without having to manually clear each cell.

Endpoints

TREX requires that both the chosen endpoint (entered in the blue cell) ***and*** the test species to be included (chosen from the drop-down menu options). For example, one would enter an avian LD_{50} of 500 mg/kg-bw ***and*** that this endpoint was based on a Bobwhite quail study (i.e., chosen from the drop-down menu immediately to the right of the LD_{50} input cell). For now, this requirement is limited to the avian endpoints.

Avian endpoints

Enter the endpoints in the blue cells and choose the corresponding test species from the drop-down menus.

Mammalian endpoints

For acute endpoints, enter the data in the blue cells. For chronic endpoints, enter the reported number and then choose whether this datapoint was a dose- or diet-based endpoint from the drop-down menu. The other endpoint will then be calculated and displayed in the cell below.

LD_{50} ft^{-2}

TREX includes the capability to also calculate an LD_{50} ft^{-2} with the above-supplied information. Choose from the drop-down menu provided whether or not you wish to do so. If 'yes' is chosen, the type of application method (i.e., broadcast or rows) should be entered. If 'rows' is chosen, additional input parameters will be required (i.e., row spacing, bandwidth, and % incorporation) and appear to the right. Next, input whether the application is a granular or liquid application. If 'liquid' is chosen, enter the oz. product per 1000 ft row.

To see the results, choose the LD_{50} ft^{-2} worksheet tab. The print area has been pre-set, so choose the printer button in the toolbar to print.

Terrestrial Exposures

All calculated Estimated Environmental Concentration (EEC) and RQ values are presented in yellow. Intermediate calculations are displayed in red. Users may find these intermediate values useful in their assessment, so they are presented.

Upper Bound and Mean Kenaga Residue Worksheets

Both the upper bound and mean Kenaga residues for the various food categories are provided. Each includes RQs for birds and mammals. The upper bound residue worksheet is to be used for reporting RQ values in the risk assessment, while the mean residue worksheet is solely for risk description purposes. Mean residues are calculated exactly as the maximum residues are, except the corresponding Kenaga values are 85 for Short Grass, 36 for Tall Grass, and 45 for Broad-leafed plants/small insects and 7 for fruits/pods/large insects.

In both worksheets, dose-based RQs are calculated using a body weight-adjusted LD_{50} and consumption-weighted equivalent dose. The scaling factors (USEPA, 1993) used in the consumption-weighted (EECs) are:

Avian consumption

Mammal consumption

These consumption-weighted EECs (i.e., EEC equivalent dose) are sorted by food source and body size. There is a corresponding table for birds and mammals.

The LD_{50} values entered on the input form are adjusted for animal class (20, 100 and 1000 g birds and 15, 35, and 1000 g mammals) using the following equations:

Avian LD_{50}

Mammal LD_{50}

The dose-based RQs are calculated by dividing the daily dose (EEC equivalent dose) by the adjusted LD_{50} for each food category and animal class.

For dietary-based RQs, the Kenaga EEC is divided by the LC_{50} (acute RQ) or the NOAEC (chronic RQ).

Graphs

Each worksheet contains a graph of the calculated residues for the first 100 days and includes the 'Concentration of Concern' overlay from the input form. These can be copy/pasted individually into a word processing program and used in the risk assessment, if desired. Additionally, graphs displaying acute and chronic LOCs for both birds and mammals are displayed in the 'Graph' worksheet.

LD_{50} ft^{-2}

LD_{50} ft^{-2} values are calculated for both broadcast and banded (granular and liquid) applications using the adjusted LD_{50} method described above. The results are presented by class for both birds and mammals for each type of application.

Seed Treatments

Due to the difference in foliar application and seed treatment uses of pesticides, this worksheet can be used as a 'stand-alone' tool for estimating avian and mammalian RQs for the various crops listed. Efforts were made to make this crop list as complete as possible; however, there may be additional crops added in the future as the need arises. Only those seed treatments needed for the assessment need to be entered. For example, if rye is not an intended use, then leave it set to zero, as this will have no impact on the RQ calculations for the other crops.

The seed treatment worksheet contains additional input cells in blue separate from those in the Input worksheet including:

Name of seed treatment formulation: Labels for seed treatment products differ from foliar applied formulations.

Percent A.I. in formulation: Enter % A.I. as a whole number (e.g., 24% = 24)

Test body weights: Enter the test organism body weight from the avian and mammal studies

Application rate (fl oz./cwt): Provided on the label

NOTE: If a liquid rate is not available for a chemical, enter the dry weight application rate in the adjoining cell. Once this is done; however, the underlying equation in that cell has been replaced. It is preferable that users input the fl oz/cwt value.

RQs are calculated using the adjusted LD_{50} for the smallest weight class of animal. Acute RQs are calculated using two methods:

Method #1: Acute RQ = mg A.I. day^{-1}/adjusted LD_{50}

Method #2: Acute RQ = mg A.I. ft^{-2}/(adjusted LD_{50} * body weight)

Chronic RQs are calculated using the equation:

Chronic RQ = mg A.I. kg^{-1} seed/NOAEL

References

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

Hoerger, F. and E.E. Kenaga. 1972. Pesticide residues on plants: correlation of respresentative dada as a basis for estimation of their magnitude in the environment. IN: F. Coulston and F. Corte, eds., Environmental Quality and Safety: Chemistry, Toxicology and Technology. Vol 1. Georg Theime Publishers, Stuttgart, Germany. pp. 9-28

USEPA. 1993. Wildlife Exposure Factors Handbook. Volume I of II. EPA/600/R-93/187a. Office of Research and Development, Washington, D. C. 20460.

Willis and McDowell. 1987. Pesticide persistence on foliage. Environ. Contam. Toxicol. 100:23-73

TURF - 1 APPLICATION AT 0.2 LBS/A

Chemical Name:	**Dichlorvos**	
Use	Turf	
Formulation	Liquid spray	
Application Rate	**0.0804**	lbs a.i./acre
Half-life	**0.0875**	days
Application Interval	**0**	days
Maximum # Apps./Year	**1**	
Length of Simulation	**1**	year
Concentration of Concern	**0.00**	(ppm)
Name of Concentration of Concern	**FALSE**	

Endpoints

Avian	**Mallard duck LD50 (mg/kg-bw)**	**7.78**
	Mallard duck LC50 (mg/kg-diet)	**568**
	Bobwhite quail NOAEL (mg/kg-bw)	**0**
	Mallard duck NOAEC (mg/kg-diet)	**5**
Mammals	**LD50 (mg/kg-bw)**	**56**
	LC50 (mg/kg-diet)	**0**
	NOAEL (mg/kg-bw)	**1**
	NOAEC (mg/kg-diet)	**20**

EECs (ppm)	**Kenaga Values**
Short Grass	**19.30**
Tall Grass	**8.84**
Broadleaf plants/sm Insects	**10.85**
Fruits/pods/seeds/lg insects	**1.21**

Avian Results

Avian Class	Body Weight	% body wgt consumed	Adjusted LD50
Small	20	114	4.04
Mid	100	65	5.14
Large	1000	29	7.26

EEC equivalent dose (mg/kg-bw)	Avian Classes and Body Weights		
	small 20 g	mid 100 g	large 1000 g
Short Grass	22	13	6
Tall Grass	10	6	3
Broadleaf plants/sm Insects	12	7	3
Fruits/pods/lg insects	1	1	0

Dose-based RQs (daily dose/LD50)	Avian Acute RQs		
	20 g	100 g	1000 g
Short Grass	5.45	2.44	0.77
Tall Grass	2.50	1.12	0.35
Broadleaf plants/sm insects	3.06	1.37	0.43
Fruits/pods/lg insects	0.34	0.15	0.05

Dietary-based RQs (EEC/LC50 or NOAEC)	RQs	
	Acute	Chronic
Short Grass	0.03	3.86
Tall Grass	0.02	1.77
Broadleaf plants/sm Insects	0.02	2.17
Fruits/pods/lg insects	0.00	0.24

Mammalian Results

Mammalian Class	Body Weight	% body wgt consumed	Adjusted LD50	Adjusted NOAEL
Herbivores/ insectivores	15	95	123.08	2.20
	35	66	99.58	1.78
	1000	15	43.07	0.77
Grainvores	15	21	123.08	2.20
	35	15	99.58	1.78
	1000	3	43.07	0.77

EEC equivalent dose (mg/kg-bw)	Mammalian Classes and Body weight					
	Herbivores/ insectivores			Granivores		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short Grass	18	13	3			
Tall Grass	8	6	1			
Broadleaf plants/sm Insects	10	7	2			
Fruits/pods/seeds/lg insects	1	1	0	0	0	0

Dose-based RQs (daily dose/LD50 or NOAEL)	15 g mammal		35 g mammal		1000 g mammal	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
Short Grass	0.15	8.34	0.13	7.16	0.07	3.76

Tall Grass	**0.07**	**3.82**	**0.06**	**3.28**	**0.03**	**1.72**
Broadleaf plants/sm insects	**0.08**	**4.69**	**0.07**	**4.03**	**0.04**	**2.12**
Fruits/pods/lg insects	**0.01**	**0.52**	**0.01**	**0.45**	**0.00**	**0.24**
Seeds (granivore)	**0.00**	**0.12**	**0.00**	**0.10**	**0.00**	**0.05**

Dietary-based RQs (EEC/LC50 or NOAEC)	**Mammal RQs**					
	Acute	**Chronic**				
Short Grass		**0.96**				
Tall Grass		**0.44**				
Broadleaf plants/sm insects		**0.54**				
Fruits/pods/seeds/lg insects		**0.06**				

TURF - 4 APPLICATION, 30 DAY APPLICATION INTERVALS, AT 0.2 LBS/A

Chemical Name:	**Dichlorvos**	
Use	Turf	
Formulation	Liquid spray	
Application Rate	**0.0804**	lbs a.i./acre
Half-life	**0.0875**	days
Application Interval	**30**	days
Maximum # Apps./Year	**4**	
Length of Simulation	**1**	year
Concentration of Concern	**0.00**	(ppm)
Name of Concentration of Concern	**FALSE**	

Endpoints

Avian	**Mallard duck LD50 (mg/kg-bw)**	**7.78**
	Mallard duck LC50 (mg/kg-diet)	**568**
	Bobwhite quail NOAEL (mg/kg-bw)	**0**
	Mallard duck NOAEC (mg/kg-diet)	**5**
Mammals	**LD50 (mg/kg-bw)**	**56**
	LC50 (mg/kg-diet)	**0**
	NOAEL (mg/kg-bw)	**1**
	NOAEC (mg/kg-diet)	**20**

EECs (ppm)	**Kenaga Values**
Short Grass	**19.30**
Tall Grass	**8.84**
Broadleaf plants/sm Insects	**10.85**
Fruits/pods/seeds/lg insects	**1.21**

Avian Results

Avian	**Body**	**% body**	**Adjusted**

Class	Weight	wgt consumed	LD50
Small	20	114	4.04
Mid	100	65	5.14
Large	1000	29	7.26

EEC equivalent dose (mg/kg-bw)	Avian Classes and Body Weights		
	small 20 g	mid 100 g	large 1000 g
Short Grass	22	13	6
Tall Grass	10	6	3
Broadleaf plants/sm Insects	12	7	3
Fruits/pods/lg insects	1	1	0

Dose-based RQs (daily dose/LD50)	Avian Acute RQs		
	20 g	100 g	1000 g
Short Grass	5.45	2.44	0.77
Tall Grass	2.50	1.12	0.35
Broadleaf plants/sm insects	3.06	1.37	0.43
Fruits/pods/lg insects	0.34	0.15	0.05

Dietary-based RQs (EEC/LC50 or NOAEC)	RQs	
	Acute	Chronic
Short Grass	0.03	3.86
Tall Grass	0.02	1.77
Broadleaf plants/sm Insects	0.02	2.17

Fruits/pods/lg insects	**0.00**	**0.24**

Mammalian Results

Mammalian Class	Body Weight	% body wgt consumed	Adjusted LD50	Adjusted NOAEL
Herbivores/ insectivores	15	95	123.08	2.20
	35	66	99.58	1.78
	1000	15	43.07	0.77
Grainvores	15	21	123.08	2.20
	35	15	99.58	1.78
	1000	3	43.07	0.77

EEC equivalent dose (mg/kg-bw)	Mammalian Classes and Body weight					
	Herbivores/ insectivores			Granivores		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short Grass	18	13	3			
Tall Grass	8	6	1			
Broadleaf plants/sm Insects	10	7	2			
Fruits/pods/seeds/lg insects	1	1	0	0	0	0

Dose-based RQs (daily dose/LD50 or NOAEL)	15 g mammal		35 g mammal		1000 g mammal	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
Short Grass	0.15	8.34	0.13	7.16	0.07	3.76
Tall Grass	0.07	3.82	0.06	3.28	0.03	1.72
Broadleaf plants/sm insects	0.08	4.69	0.07	4.03	0.04	2.12
Fruits/pods/lg insects	0.01	0.52	0.01	0.45	0.00	0.24
Seeds (granivore)	0.00	0.12	0.00	0.10	0.00	0.05

Dietary-based RQs (EEC/LC50 or NOAEC)	Mammal RQs					
	Acute	Chronic				
Short Grass		0.96				
Tall Grass		0.44				
Broadleaf plants/sm insects		0.54				
Fruits/pods/seeds/lg insects		0.06				

FLYING INSECT - 0.2 LBS/A

Chemical Name:	**Dichlorvos**	
Use	Flying Insect	
Formulation	Liquid spray	
Application Rate	**0.0804**	lbs a.i./acre
Half-life	**0.0875**	days
Application Interval	**5**	days
Maximum # Apps./Year	**75**	
Length of Simulation	**1**	year
Concentration of Concern	**0.00**	(ppm)
Name of Concentration of Concern	**FALSE**	

Endpoints

Avian	**Mallard duck LD50 (mg/kg-bw)**	**7.78**
	Mallard duck LC50 (mg/kg-diet)	**568**
	Bobwhite quail NOAEL (mg/kg-bw)	**0**
	Mallard duck NOAEC (mg/kg-diet)	**5**
Mammals	**LD50 (mg/kg-bw)**	**56**
	LC50 (mg/kg-diet)	**0**
	NOAEL (mg/kg-bw)	**1**
	NOAEC (mg/kg-diet)	**20**

EECs (ppm)	**Kenaga Values**
Short Grass	**19.30**
Tall Grass	**8.84**
Broadleaf plants/sm Insects	**10.85**
Fruits/pods/seeds/lg insects	**1.21**

Avian Results

Avian	**Body**	**% body**	**Adjusted**

Class	Weight	wgt consumed	LD50
Small	20	114	4.04
Mid	100	65	5.14
Large	1000	29	7.26

EEC equivalent dose (mg/kg-bw)	Avian Classes and Body Weights		
	small 20 g	mid 100 g	large 1000 g
Short Grass	22	13	6
Tall Grass	10	6	3
Broadleaf plants/sm Insects	12	7	3
Fruits/pods/lg insects	1	1	0

Dose-based RQs (daily dose/LD50)	Avian Acute RQs		
	20 g	100 g	1000 g
Short Grass	5.45	2.44	0.77
Tall Grass	2.50	1.12	0.35
Broadleaf plants/sm insects	3.06	1.37	0.43
Fruits/pods/lg insects	0.34	0.15	0.05

Dietary-based RQs (EEC/LC50 or NOAEC)	RQs	
	Acute	Chronic
Short Grass	0.03	3.86
Tall Grass	0.02	1.77
Broadleaf plants/sm Insects	0.02	2.17

Fruits/pods/lg insects	**0.00**	**0.24**

Mammalian Results

Mammalian Class	Body Weight	% body wgt consumed	Adjusted LD50	Adjusted NOAEL
Herbivores/ insectivores	15	95	123.08	2.20
	35	66	99.58	1.78
	1000	15	43.07	0.77
Grainvores	15	21	123.08	2.20
	35	15	99.58	1.78
	1000	3	43.07	0.77

EEC equivalent dose (mg/kg-bw)	Mammalian Classes and Body weight					
	Herbivores/ insectivores			Granivores		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short Grass	18	13	3			
Tall Grass	8	6	1			
Broadleaf plants/sm Insects	10	7	2			
Fruits/pods/seeds/lg insects	1	1	0	0	0	0

Dose-based RQs (daily dose/LD50 or NOAEL)	15 g mammal		35 g mammal		1000 g mammal	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
Short Grass	0.15	8.34	0.13	7.16	0.07	3.76
Tall Grass	0.07	3.82	0.06	3.28	0.03	1.72
Broadleaf plants/sm insects	0.08	4.69	0.07	4.03	0.04	2.12
Fruits/pods/lg insects	0.01	0.52	0.01	0.45	0.00	0.24
Seeds (granivore)	0.00	0.12	0.00	0.10	0.00	0.05

Dietary-based RQs (EEC/LC50 or NOAEC)	Mammal RQs					
	Acute	Chronic				
Short Grass		0.96				
Tall Grass		0.44				
Broadleaf plants/sm insects		0.54				
Fruits/pods/seeds/lg insects		0.06				

BAIT- 1 APPLICATION, 0.1 LBS/A

Chemical:	Dichlorvos			
LD50 ft-2				
INPUTS	Do not overwrite these numbers.			
Application Rate:		0.1	lbs ai/acre	
% A.I.:		0.0744		
Avian LD50 (20g):		4.04	mg/kg bw	
(100g)		5.14		
(1000g)		7.26		
Mammalian LD50 (15g):		123.08	mg/kg bw	
(35g)		99.58		
(1000g)		43.07		
Row Spacing:		0	inches	
Bandwidth:		0	inches	
Unincorporation:		100%		

Broadcast applications		
Granular		
Intermediate Calculations		
mg ai/ft2:	0.08	
LD50 ft-2		
	wgt class	
Avian	20 g	0.959
	100 g	0.151
	1000 g	0.011
Mammal	15 g	0.042
	35 g	0.022
	1000 g	0.002