



# US Environmental Protection Agency Office of Pesticide Programs

## Reregistration Eligibility Decision for Diazinon

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

Combined PDF document consists of the following:

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



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

OFFICE OF  
PREVENTION, PESTICIDES AND TOXIC  
SUBSTANCES

**MEMORANDUM**

**DATE:** July 31, 2006

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

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

**TO:** Jim Jones, Director  
Office of Pesticide Programs

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

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<sup>1</sup> 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](http://www.epa.gov/pesticides/cumulative) and in the docket (EPA-HQ-OPP-2006-0618).

**Attachment A:**  
Organophosphates included in the OP Cumulative Assessment

<b>Chemical</b>	<b>Decision Document</b>	<b>Status</b>
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-04-006  
May 2004

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# **Interim Reregistration Eligibility Decision**

## **Diazinon**



# I.R.E.D. FACTS

## Pesticide Reregistration

## Diazinon

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EPA has assessed the risks of diazinon and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Without mitigation, diazinon poses unacceptable risks to agricultural workers and to birds and other wildlife species. To increase protection for workers, birds, and the environment, the Agency's decision includes provisions to phase out and cancel certain agricultural crop uses, the granular formulation, and aerial applications; reduce the amount and frequency of use; and employ engineering controls and other protective measures. These changes in diazinon use were developed through discussions with the technical registrants and were based on extensive stakeholder input.

Diazinon has been one of the most widely used insecticides in the U.S. for household as well as agricultural pest control. A December 2000 agreement with the technical registrants phased out and cancelled all indoor and outdoor residential uses in order to reduce risks to children and others.

Diazinon residues in food and drinking water resulting from agricultural uses do not pose human dietary risks of concern. While residues attributed to agricultural and residential uses have been detected frequently in surface waters, previous mitigation measures for residential products should result in less frequent detections in water. Without further mitigation limiting children's and others' exposure through food and drinking water, diazinon fits into its own "risk cup." Even with the recommended mitigation measures, diazinon's worker and ecological risks still will be above levels of concern, but these risks are offset by strong benefits of diazinon use in fruit and vegetable production.

EPA's next step is to consider the cumulative effects of the OP pesticides, which share a common mechanism of toxicity. The interim decision on diazinon will not be final until the Agency completes a cumulative evaluation of the OPs. Further risk mitigation may be warranted at that time.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs require decisions about their eligibility for reregistration under FIFRA. OPs with food, drinking water, residential, and any other non-occupational exposures must be reassessed to make sure they meet the new FFDCSA safety standard, brought about by the Food Quality Protection Act of 1996 (FQPA).

The IRED concludes EPA's review of diazinon through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in the Agency's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in the Diazinon IRED. During the past several years, the Agency has exchanged information on diazinon's uses, risks, and benefits with USDA, other federal and state agencies, registrants, users, the environmental community, concerned citizens, and others. This significant input from stakeholders and interested parties helped EPA reach a decision that diazinon is eligible for reregistration and meets the FQPA safety standard.

### **Use Profile**

Diazinon is registered to control foliage and soil insects and pests of many fruit, nut, vegetable, and ornamental crops. Diazinon also is used in cattle ear tags. All residential uses have been cancelled.

Approximately 4 million pounds of the active ingredient diazinon are used annually on agricultural sites. Use is highest on almonds and stone fruits.

### **Health Effects**

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

### **Risks**

! Dietary risks from exposure to diazinon residues in food and drinking water do not exceed the Agency's level of concern.

! Occupational exposure to diazinon is of concern to EPA for handlers and applicators of diazinon as well as to workers entering fields after applications.

! EPA has identified ecological risks of concern from diazinon use, particularly to birds, mammals, bees, fish, and aquatic invertebrates.

### **Residential Risk Mitigation**

Known as Spectracide and other trade names, diazinon was one of the most widely used insecticides in the U.S. for household lawn and garden pest control (up to 70% of the 13 million pounds used each year), indoor residential crack and crevice treatments and pet collars (up to 5% of all use), and agricultural pest control (about 30% of all use). To reduce risks to children and others, the December 2000 agreement phased out and cancelled all residential uses. All indoor residential use product registrations were cancelled and retail sale of these products ended as of December 31, 2002. All outdoor residential use product registrations must be cancelled and retail sale must end by December 31, 2004. After that time, a buy-back program will help remove remaining outdoor diazinon residential use products from the market and prevent further sale.

## **Agricultural and Ecological Risk Mitigation**

To mitigate risks to agricultural workers, birds and other wildlife, the following mitigation measures are required by the Diazinon IRED. All deletions and cancellations will be phased in during the next 2 to 5 years.

**! Cancellation of all granular registrations**, except for use on lettuce in California and Arizona and two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler.

**! Deletion of aerial application for all uses**, except for one application per crop for lettuce.

**! Deletion of foliar application on all vegetable crops**, except for treatment of leafhopper on honeydew melons in California and one application per crop for lettuce.

**! Application rate reduction for ornamentals and lettuce.**

**! Establishment of crop specific REIs.** REIs of 2 days to 18 days will be established for all crops.

**! Cancellation of all seed treatment uses.**

**! Require engineering controls for all uses.** All application equipment must use lock and load engineering controls. All wettable powder formulations must be packaged in water soluble bags. Closed cabs are required all ground equipment, except for applications to apples.

**! Reduce the number of applications of diazinon per growing season.** For most uses, only one application per growing season will be allowed. Crops with dormant season and in season uses (e.g., stone fruits) will have one application per season, for a total of two applications per year. Other exceptions are noted in the Labeling Summary Table in Chapter 5 of the IRED.

**! Cancellation of the following uses:**

**Section 3 registrations:** Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugarbeets, walnuts, and watercress.

**Section 24(c) registrations:** Control of cranberry girdler for grass grown for seed (Oregon); dipping of pineapple seed pieces (Hawaii); drenching around residential fruit trees for control of Mediterranean fruit fly (California).

## **Benefits Analysis**

Benefits information was required for diazinon based on its risks to workers and wildlife. Complete benefits assessments, evaluating the economic and agricultural effects of cancellation of diazinon, were prepared for crops with over 5% of the crop treated with diazinon. In issuing the Diazinon IRED, EPA is requesting public comment on these uses, including almonds, apricots, blueberries, broccoli, Brussels sprouts, cabbage, caneberry crop group, carrots, cauliflower, cherries (sweet), cranberries, hops, lettuce, melons,



nectarines, onions, peaches, pears, plums, prunes, radishes, strawberries, and tomatoes. The benefits assessments can be found on EPA's website in the diazinon electronic docket at

[http://cascade.epa.gov/RightSite/dk\\_public\\_home.htm](http://cascade.epa.gov/RightSite/dk_public_home.htm) (OPP Docket # OPP-2002-0251) and through the diazinon web page, <http://www.epa.gov/oppsrrd1/op/diazinon.htm>.

## **Next Steps**

The Diazinon IRED was issued for 60 days of public comment through a September 25, 2002, Federal Register notice. This comment period was extended in December 2002 for an additional 30 days, closing January 8, 2003. EPA has amended the IRED document in accordance with comments received. The letter to registrants listing amendments is available with the IRED document.

May 13, 2004



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

The Interim Reregistration Eligibility Decision (IRED) document for diazinon was signed on July 31, 2002. In accordance with the NRDC consent decree, a public comment period for the IRED and the supporting benefit assessments was conducted. This comment period opened September 25, 2002 and closed January 1, 2003. The risk assessments, benefit assessments, and public comments can be found on the EPA EDOCKET system, available at <http://www.epa.gov/edocket> (docket # OPP-2002-0251). The Environmental Protection Agency has reviewed the public comments submitted and has responded to those that related specifically to the diazinon IRED. These responses are also available for viewing on the EDOCKET system (docket # OPP-2004-0129). As a result of its review of the public comments, the Agency is revising the diazinon IRED, where appropriate. These revisions are listed below.

- For use on lettuce in California and Arizona only, one granular soil pre-plant application per crop will be allowed, in addition to the one liquid foliar application per crop allowed in all states. The application rate will be lowered to 2 lbs ai/A instead of 1 lb ai/Acre. When this is taken into consideration, risks to applicators resulting from soil applications are at acceptable levels.
- Liquid and wettable powder foliar applications may be made by aerial equipment for lettuce only. Lettuce growers provided the Agency with data showing that actual daily acreage treated is less than that assumed in the original risk assessment. When that is taken into consideration, risks to mixers/loaders and applicators from aerial applications are considered acceptable with maximum PPE.
- For use on melons (except honeydew melons), a five-year phase-out is being granted, instead of two, for foliar applications, so foliar applications of diazinon to melons will be allowed to continue until December 31, 2008. EPA acknowledges that one year may be an insufficient phase-out time for growers to adjust to newer alternatives, such as thiamethoxam and pymetrozine.
- Foliar treatment of honeydew melons will remain on the label after 2008 for all currently listed foliar pests, not just leafhoppers, and for all states, not only California. Given comments from melon growers, EPA acknowledges the need of honeydew melon growers (not only those in California) for foliar applications of diazinon to control aphids, as well as leafhoppers.

- Two foliar applications per year will be allowed for apples (or one foliar and one dormant application per year) for control of woolly apple aphids and San Jose scale. The only available alternative for control of San Jose scale is pyriproxyfen, and the Agency believes it is important to allow more than one available tool on the market for management of a pest.
- The requirement of closed cab equipment for application of diazinon to apples is being waived; instead, applicators will be required to wear maximum personal protective equipment. Apples are a high benefit use, and use of closed cabs is infeasible in narrow orchard rows.
- The requirement of closed cab equipment for application of diazinon to lettuce is being waived; instead, applicators will be required to wear maximum personal protective equipment. Lettuce growers provided the Agency with data showing that actual daily acreage treated is less than that assumed in the original risk assessment. When the new data were incorporated into the assessment, risks to workers were found to be acceptable with maximum PPE.
- Until spray drift issues are resolved between stakeholders and the Agency, the instructions for revising spray drift language will be changed to the following:

“The Agency is currently working with stakeholders to develop appropriate generic label statements to address spray drift risk. Once this process has been completed, diazinon product labels will need to be revised to include this additional language.”

- The SLN registration for drenching residential fruit trees for control of the Mediterranean Fruit Fly (CA960016) will be retained based on the high benefits for this quarantine use, and the use will remain on the label. The registrant, California Department of Health Services, and the USDA Animal and Plant Health Inspection Service informed the Agency that this is a necessary public health use.

Additionally, there are some clarifications that need to be made to the IRED that was posted on the internet in August 2002. These clarifications include (but are not limited to):

- Update of contact information.
- The list of cancelled seed treatment uses on page 41 will be revised to include corn.
- The PHI for melons in Table 7 was corrected to read as 3 days instead of 7 days.
- The REI for strawberries in Table 18 was corrected to read as 3 days instead of 5 days.
- Labels will be changed to say that trunk wraps may be used in agricultural settings only.

A number of updates have also been made to the label table (Table 18), for purposes of clarification. This updated table is included with the IRED. Among the updates are the following:

- The following have been added to the MUP section of the table: end-use dates for those use deletions being granted a phase-out that is longer than two years, instructions regarding water soluble bags for wettable powders, special instructions for granular formulations, and an explanation regarding SLN registrations.
- Handler PPE requirements have been divided by formulation type.
- Under the application restrictions for apricots, the requirement to delete the statement “Do not

apply more than 12 pts of product per acre per season.” has been replaced with the more general statement “Delete all references to multiple applications per season.”

- Instructions for ginseng, ornamentals, rutabagas, and watercress have been added to the table.
- REIs for endive, ginseng, pineapples, radishes, rutabagas, and watercress have been added to the table.
- All crops being deleted from labels have been placed together on the label.
- A section with directions for SLN registrations has been added.
- Engineering control precautions have been added for pilots making aerial application of liquid or wettable powder products to lettuce.
- Instructions to “combine all foliar or soil pests and directions for use” have been deleted to allow for appropriate pest specific rate and timing variations.

If you have questions on the diazinon IRED or any of the revisions listed above, please contact the Chemical Review Manager, Stephanie Plummer at (703) 305-0076. For questions about product reregistration and/or the Product Data Call-In that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Sincerely,

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

Attachment

July 31, 2002



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide diazinon. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on January 31, 2001. Additionally, the Agency held a Technical Briefing on December 5, 2000, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on January 31, 2001, and closed on April 2, 2001.

Based on its review, EPA has identified risk mitigation measures it believes are necessary to address the human health and environmental risks associated with the current use of diazinon. EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of diazinon and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for diazinon will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for diazinon," which was approved on July 31, 2002, contains the Agency's decision on the individual chemical diazinon.

A Notice of Availability for this Interim Reregistration Eligibility Decision for diazinon is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/op>. A 60-day public comment period on the risk management decision, including the benefits assessments considered in making this decision, will begin with the publication of the Notice of Availability.

The interim RED is based on the updated technical information found in the diazinon public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for diazinon (the Health Effects Division Human Health Risk Assessment revised as of December 5, 2000 and the Environmental Fate and Ecological Risk Assessment revised as of February 19, 2002), and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For diazinon, comments on the risk assessment were submitted by Makhteshim-Agan of North America, Inc., the technical registrant. Comments on mitigation or mitigation suggestions were submitted by environmental organizations, agricultural extension agents, various other organizations, and private citizens.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

Please note that the diazinon risk assessments and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to diazinon alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of diazinon. Because the FQPA directs the Agency to consider available information on the cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will consider the cumulative risk posed by the entire organophosphate class of chemicals after evaluating the risks for the individual organophosphates. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of diazinon. The Agency will issue the final tolerance reassessment decision for diazinon and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophosphates are considered.

This document describes further data requirements for this chemical. Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants separately. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

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

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Stephanie Plummer at (703) 305-0076. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Attachment

**Interim Reregistration Eligibility Decision  
for  
Diazinon**

**Case No. (0238)**



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## Glossary of Terms and Abbreviations

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

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

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

## **Executive Summary**

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for diazinon. The decisions outlined in this document do not include the final tolerance reassessment decision for diazinon; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. For enforcement purposes, the tolerance expression will be diazinon per se as is currently listed in 40 CFR 180.153. A 40 CFR 180.6(a)(3) condition exists (“no reasonable expectation of finite residues”), and tolerances for cattle meat and meat byproducts will be revoked, and a milk tolerance is not required. Existing tolerances of 0.7 ppm in sheep tissues (meat and meat byproducts) are adequate. However, the existing tolerance for diazinon in sheep, fat should be raised from 0.7 ppm to 5.0 ppm. The existing tolerance for cattle (beef) fat should be decreased from 0.7 ppm to 0.5 ppm. EPA intends to propose revocation of the following tolerances because there are currently no registered or supported uses: alfalfa, clover, coffee, cottonseed, cowpeas, dandelions, kiwi, lespedeza, olives, and sorghum. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for diazinon once cumulative risks are considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on diazinon. After considering the revised risks, as well as mitigation proposed by Makhteshim-Agan of North America, Inc. and Syngenta Crop Protection, Inc., the technical registrants of diazinon, and comments and mitigation suggestions from other interested parties including the United States Department of Agriculture, agricultural grower groups, state and local government agencies, etc., EPA developed its risk management decision for uses of diazinon that pose risks of concern. This decision is discussed fully in this document.

Diazinon is an organophosphate insecticide, acaricide, and nematicide used on a variety of pests. It was first registered in 1956 for control of soil insects and pests of fruit, vegetables, and forage and field crops. Based on available usage information, for 1987 through 1997, total annual domestic usage of diazinon is over 13 million pounds active ingredient. Most of this is allocated to outdoor residential uses by homeowners (39%), lawn care operators (19%), pest control operators (11%), and agricultural uses (31%).

## **Overall Risk Summary**

EPA’s human health risk assessment for diazinon indicates some risk concerns. Food risks, both acute and chronic, are below the Agency’s level of concern. Similarly, drinking water risk estimates based on monitoring data and screening models, from both ground and surface water for acute and chronic exposures, is not of concern for all populations. In 1999 the Agency expressed concerns for residential applicators and for children exposed to diazinon residues inside and outside the home.



These residential risks are being mitigated by a phase out of all residential uses by December 2004. However, there are risk concerns for workers who mix, load, and apply diazinon to agricultural sites. Also, EPA has identified acute and chronic risk to birds and risk to aquatic species that are of concern. The Agency also evaluated benefits associated with these uses of diazinon that pose occupational and ecological risks of concern for the Agency.

To mitigate risks of concern posed by the uses of diazinon, EPA considered mitigation proposals submitted by technical registrants, as well as comments and mitigation ideas from other interested parties, and has decided on a number of mitigation measures that, when implemented would address the occupational and ecological concerns. Results of the risk assessments and mitigation measures, including label amendments, are presented in this interim RED.

### Dietary Risk

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

### Occupational Risk

Occupational exposure to diazinon is of concern to the Agency. For agricultural uses of diazinon, most mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than 100 for dermal exposure and MOEs are less than 300 for inhalation exposure). Taking into consideration both the risks and benefits of these uses, EPA has determined that most agricultural uses may continue with the adoption of the following mitigation measures: (1) deletion of aerial application; (2) engineering controls for mixers and loaders and closed cabs for applicators for all application scenarios; (3) deletion of all granular formulations; and (4) setting crop specific re-entry intervals (REIs) for post application exposure ranging from 2 to 18 days. The Agency has also identified uses that cannot continue because of the risks and little benefit associated with them. Therefore, with the adoption of the above mentioned mitigation measures and use deletions, mostly through label and formulation changes detailed in this document, the Agency has determined that, until the outcome of cumulative risks for all of the organophosphates has been considered, the use of pesticides containing diazinon may continue.

### Residential Risk

Prior to December 5, 2000, Memorandum of Agreement with the basic manufacturers, diazinon had a wide variety of residential uses including lawns, home gardens and ornamentals, indoor crack and crevice, and pet collars. Diazinon could be applied by professional pest control operators or, in most cases, by homeowners. Application methods included aerosol cans, spray equipment and granular spreaders. All residential applicator and post application scenarios pose risks of concern to applicators and children. To mitigate these risks diazinon registrants agreed to phase out and cancel all residential

indoor uses including pet collars and outdoor residential products. Production of indoor use products ended June 30, 2001, and all product registrations must be canceled and retail sales must end by December 31, 2002. Production of all outdoor residential products will end by June 30, 2003, and all registrations of such products will be canceled and retail sales will end by December 31, 2004. A buy back program will assist in the removal of all outdoor residential diazinon products from the retail market after December 31, 2004. Therefore, after December 31, 2004, no diazinon products with residential uses will be registered or sold.

### Ecological Risk

Ecological risks are of concern to the Agency. Diazinon is extremely toxic to birds. On March 29, 1988, diazinon uses on golf courses and sod farms were canceled due to numerous bird kills. Acute lethal and reproductive effect levels for birds occur at residue levels well below those measured in the field. Diazinon is also highly toxic to honey bees and other beneficial insects. Mammals are less sensitive than birds orally, but diazinon is highly toxic to mammals dermally and very highly toxic to them based on inhalation exposure. Diazinon is very highly toxic to freshwater fish and invertebrates following acute exposure. The endangered species levels of concern are exceeded for wildlife, aquatic life and terrestrial plants in semi-aquatic areas for all registered use rates of diazinon. Sublethal effects are an increasing concern in the Pacific Northwest and are relevant to endangered salmonids nationally.

Taking into account both the risks and benefits of the agricultural uses of diazinon, the Agency has determined that with the adoption of all of the mitigation measures, mostly through label amendments noted in this document, most of these uses may continue until the outcome of the cumulative risks of all organophosphates has been considered. The Agency believes that the adoption of the mitigation measures will reduce, but not eliminate, risks to wildlife; however, continuing use is allowed based on the assessed benefits of the uses which are to be continued.

### Benefits Summary

Based on occupational and ecological risks, benefits assessments were conducted on crops that have greater than five percent crop treated with diazinon. Diazinon's major benefits are: (1) control of foliar pests on fruits and orchard crops; and (2) control of soil pests in vegetable and certain fruit crops.

The Agency is issuing this Interim Reregistration Eligibility Decision (IREED) document for diazinon, as announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for submitting any necessary label changes for products containing diazinon. The Notice of Availability also announces the beginning of a 60 day public comment period. During this comment period, interested parties may submit additional information on diazinon's benefits, usage, risks to workers and/or the environment, etc. The Agency will review all comments and if warranted, will make amendments to the regulatory decisions contained within this document. Neither the tolerance reassessment, nor the Interim Reregistration Eligibility Decision for diazinon, can be considered final, however, until the cumulative risks for all organophosphate pesticides are considered. The cumulative assessment may result in further risk mitigation measures for diazinon.

## **I. Introduction**

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

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

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

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

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

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

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

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

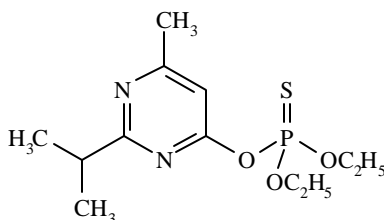
This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice.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

## II. Chemical Overview

### A. Regulatory History

Diazinon was first registered in the United States in 1956 as an organophosphate insecticide, acaricide, and nematicide used on a variety of pests, for control of soil insects and pests of fruit, vegetables, and forage and field crops.

### B. Chemical Identification



- **Common Name:** Diazinon
- **Chemical Name:** O,O-Diethyl O-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate
- **Chemical family:** Organophosphate
- **Case number:** 0238
- **CAS registry number:** 333-41-5
- **OPP chemical code:** 057801
- **Empirical formula:** C<sub>12</sub>H<sub>21</sub>N<sub>2</sub>O<sub>3</sub>PS
- **Molecular weight:** 304.3
- **Trade and other names:** Spectracide, D.Z.N., Knox-Out, Diazol
- **Basic manufacturers:** Makhteshim-Agan of North America Inc.  
Syngenta Crop Protection
- **Vapor pressure:** 1.40 x 10<sup>-4</sup> mm Hg @ 20 C

Pure diazinon is a colorless oil which is formulated into “stabilized” technical diazinon. Technical diazinon (≥ 90% pure) is an amber to brown liquid with a boiling point of 83-84°C. Technical diazinon is not very soluble in water (40 ppm at 20°C) but is completely miscible in acetone, benzene, dichloromethane, ethanol, 1-octanol, toluene, and xylene, and is soluble in petroleum oils.

## C. Use Profile

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

**Type of Pesticide:** Insecticide, acaricide, nematicide.

### **Summary of Use Sites:**

Food: almonds, apples, apricots, bananas\*, beets (red, table), blackberries, blueberries, cabbage, carrots, cauliflower, celery\*, cherries, collards, sweet corn, cranberries, cucumbers\*, endive (escarole), figs, filberts, ginseng, grapes, hops, kale, lettuce, loganberries, melons, mushrooms, nectarines, onions, parsley\*, parsnips\*, peaches, pears, peas\*, peppers\*, pineapples, plums, Irish potatoes\*, prunes, radishes, radishes (Chinese), raspberries, rutabagas, squash (winter and summer)\*, spinach, strawberries, sugar beets, sweet potatoes\*, Swiss chard, tomatoes, turnips (roots and tops)\*, vegetables (Brassica leafy group), walnuts, and watercress.

Crops designated with an (\*) appear only on 24(c) Special Local Need registrations.

Other agricultural sites: seed treatment on beans (except soybeans), field corn, sweet corn, lima beans, peas, and snap beans; use on non-lactating cattle as an ear-tag.

Residential: All indoor residential product registrations, including pet collars will be canceled and retail sale will end by December 31, 2002. All outdoor residential product registrations will be phased out and canceled by December 31, 2004. Outdoor residential use sites include: outdoor ornamentals, home lawns, window and door screens, window sills, the house foundation, unenclosed porches (but not underneath porches), patios, entrance ways, walks, outdoor garbage cans and outdoor garbage can storage areas, tree trunks, into cracks and other places where insects hide, around the outside of the house next to the foundation, and use as an additive to paints or stains for application outside on exterior surfaces of homes. Additionally, as part of the phase out, for all lawn, garden and turf uses, manufacturing amounts will be decreased over time (25 percent decrease in production for 2002 and 50 percent decrease in production for 2003). California currently holds a 24(c) Special Local Need registration for soil drenching around residential citrus trees for control of Mediterranean fruit fly.

Public Health: Diazinon is currently labeled for control of fire ants in blueberry fields. California holds a Section 24(c) registration for the control of plague infected fleas on squirrels.

Other Nonfood: range, pasture, grasslands, ornamentals, food/feed handling establishments, and livestock areas.

**Target Pests:** Registered for use to control soil insects and pests of fruit, vegetables, forage and field crops. Diazinon has veterinary uses for fleas and ticks and is also used for control of household insects, grubs, nematodes in turf, seed treatments and fly control.

**Formulation Types Registered:** Dusts, emulsifiable concentrates, granules, impregnated materials, liquid, microencapsulated, pressurized sprays, soluble concentrates, flowable concentrates, wettable powders, ready-to-use solutions, and seed dressings.

#### **Method and Rates of Application:**

Equipment - Liquid diazinon (liquid formulations or formulated from wettable powder) can be applied by airblast sprayer, aircraft, airless sprayer, backpack sprayer, backpack/low pressure handwand equipment, chemigation, handheld spray equipment, hydraulic sprayer with handgun, groundboom sprayer, high pressure handwand, and paint brush. Granular diazinon can be applied by a belly grinder, push-type granular spreader, and tractor drawn spreader.

Method and Rate - Diazinon can be applied as a foliar or soil treatment via aerial application, airblast, groundboom, tractor and push-type granular spreaders and hand-held spray equipment. Rates vary according to method and type of application and pest. Typical vegetable crop rates range from foliar application of 0.5 lb ai/acre to soil incorporated rates up to 4 lb ai/acre; granular applications up to 4 lb ai/acre; and fruit and nut trees with 1 to 3 lb ai/acre.

Timing - For most orchard crops, application is made only during the dormant season. For other crops, foliar applications are made as infestations occur. For control of soil pests, application is made just prior to planting and immediately incorporated into the soil. In most cases multiple applications are allowed to maintain pest control.

**Use Classification:** Commercial agriculture products (excluding cattle ear tags) are restricted use due to avian and aquatic toxicity.

#### **D. Estimated Usage of Pesticide**

This section summarizes the best estimates available for many of the pesticide uses of diazinon, based on available pesticide usage information for 1987 - 1997. A full listing of all uses of diazinon, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 13 million lbs a.i. of diazinon are used annually, according to Agency and registrant estimates.

**Table 1. Diazinon Estimated Usage for Representative Sites**

Crop	Lbs. Active Ingredient Applied (000) (Wt. Avg.) <sup>1</sup>	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Almonds	170	30	20
Apples	37	6	4
Apricots	29	68	52
Beans (snap)	10 - 12	5	NA <sup>2</sup>
Beans (lima)	<5	3	NA
Blackberries	1	23	18
Blueberries	3	11	6
Broccoli	12	21	11
Brussel Sprouts	2	100	90
Cabbage, fresh	13	17	11
Cabbage, processed	1	31	13
Cantaloupes	7	18	12
Carrots	18	20	10
Cauliflower	5	31	16
Cherries (sweet)	18	29	17
Cherries (tart)	1	6	2
Collards	2	28	19
Corn (field and sweet)	26	0.1	0.1
Cranberries	35	73	48
Figs	5	26	17
Grapes	21	7	3
Ginseng	NA	NA	NA
Green Onions	1	23	8
Green Peas	8	8	4
Greens (turnip)	0.2	39	20
Hazelnuts	3	12	6
Honeydew melons	1	10	5
Hops	41	84	63
Kale	20	2.2	0.2
Lettuce, head	45	39	28
Lettuce, other	14	52	32
Lettuce, Romaine	1	68	45
Nectarines	51	100	54
Onions	25	16	11



Crop	Lbs. Active Ingredient Applied (000) (Wt. Avg.) <sup>1</sup>	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Peaches	61	20	12
Pears	16	19	11
Pineapples	NA	100	NA
Plums	64	54	39
Prunes	66	64	36
Radishes	2	7	4
Raspberries	4	45	25
Spinach, fresh	6	44	22
Spinach, processing	2	60	24
Strawberries	8	16	9
Sugar beets	34	6	2
Tomatoes, fresh	7	7	4
Tomatoes, processing	18	21	9
Walnuts	33	14	7
Watercress	NA	NA	NA
Watermelon	5	5	2

<sup>1</sup> Weighted Average is based on data for 1987 - 1997; the most recent years and more reliable data are weighted more heavily.

<sup>2</sup> "NA" designates "Not Assessed".

### III. Summary of Diazinon Risk Assessment

The following is a summary of EPA's revised human health and ecological risk findings and conclusions for diazinon, as fully presented in the documents, "Revised HED Human Health Risk Assessment" dated December 5, 2000, and "Environmental Fate and Ecological Risk Assessment Chapter for the Reregistration Eligibility Decision on Diazinon," dated November 16, 2000 (revised on February 19, 2002). The purpose of this summary is to assist the reader to better understand the conclusions reached in the assessments by identifying the key features and findings of these risk assessments.

The risk assessments for diazinon were presented at a December 5, 2000, Technical Briefing, which was followed by a public comment period. The risk assessments presented here form the basis of the Agency's risk management decision for diazinon only; the Agency must consider cumulative risks of all the organophosphate pesticides before any final decisions can be made.

#### A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for diazinon on April 12, 2000 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined.

## 1. Dietary Risk from Food

### a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of diazinon can be found in the December 5, 2000, Human Health Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

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

Assessment	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor <sup>1</sup>	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary	NOAEL = 0.25 LOAEL = 2.5	Plasma cholinesterase inhibition	Acute Neurotoxicity Study in Rat (MRID 43132201)	100	1X	0.0025
Chronic Dietary	NOAEL = 0.02	Consistent pat-tern of no adverse effects on cholinesterase inhibition.	Various <sup>2</sup>	100	1X	0.0002

<sup>1</sup>Uncertainty factor of 100 is the result of a 10x for interspecies and a 10x factor for intraspecies variability.

<sup>2</sup>4-week, 90-day and 1-year studies in dog (MRIDs 40815004, 40815004, and 41942001 respectively); 4-week, 90-day feeding, 90-day neurotoxicity and 2-year studies in rat (MRIDs 43543901, 40815003, 43543802, and 41942002 respectively).

### b. FQPA Safety Factor

The FQPA safety factor is intended to provide an additional safety factor (10X) to safeguard against potential special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The Agency reduced the FQPA safety factor to 1X after evaluating the hazard and exposure data for diazinon. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses, as compared to maternal animals, following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups, as compared to adults, in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the 10X factor as required by FQPA was reduced to 1X.

### c. Population Adjusted Dose (PAD)

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

#### Acute PAD:

The acute PAD is the dose an individual could be exposed to on any given day and no adverse health effects would be expected to occur. A rat acute neurotoxicity study resulted in a NOAEL of 0.25 mg/kg/day based on plasma cholinesterase inhibition. The uncertainty factors selected were 10X for intra-species uncertainty and 10X for inter-species uncertainty for a total uncertainty factor (UF) of 100X.

Acute RfD = 0.25 mg/kg/day (NOAEL) ÷ 100 (UF) = 0.0025 mg/kg/day.

Acute PAD = Acute RfD ÷ FQPA Safety Factor (1) = 0.0025 mg/kg/day.

#### Chronic PAD:

A chronic reference dose was derived from the results *in toto* from seven oral feeding studies (in dogs from 4 week, 90-day, and 1 year feeding studies, and in rats from a 28-day feeding study, a 90-day feeding study, a 90-day neurotoxicity study and a 2 year feeding study). Results from these studies demonstrated that the 0.02 mg/kg/day dose level was consistent with a pattern of no adverse effects on cholinesterase inhibition. The uncertainty factors selected were 10X for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100X.

Chronic RfD = 0.02 mg/kg/day (NOAEL) ÷ 100 (UF) = 0.0002 mg/kg/day.

Chronic PAD = Chronic RfD ÷ FQPA Safety Factor (1) = 0.0002 mg/kg/day.

### d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for diazinon were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92. This analysis is refined in that it uses monitoring data for USDA's Pesticide Data Program (PDP) and FDA Surveillance Monitoring Program to calculate anticipated residues for use in the acute dietary analysis. Controlled field trial data are also used for anticipated residues but monitoring data are preferred because samples are more reflective of residues that may occur on foods as consumed. Data on percent of a crop-treated were incorporated for all commodities with diazinon tolerances included in the acute dietary assessment.

The PDP program has reported analyses for diazinon per se for almost all commodities up through 1998. For the 1997 data, out of eleven crops and more than 7,000 samples analyzed, no detectable diazoxon residues were reported with the exception of one spinach sample. The preliminary 1998-1999 data on five crops show no detectable diazoxon residues in any of the more than 1,400 samples analyzed. There were no reports of detectable residues of the metabolites of diazinon for 1992-1998 in either domestic or imported foods. The preponderance of residue data from metabolism studies, residue field trial and monitoring data indicated that the metabolites, diazoxon and hydroxy diazinon, are infrequently to never detected for the majority of crops. Therefore, these metabolites are not included in the dietary assessment.

In the acute dietary assessment, exposure was compared to the acute Population Adjusted Dose (aPAD) based on the acute reference dose (RfD) and a 1X FQPA Safety Factor. In the chronic dietary assessment, exposure was compared to the chronic PAD based on the chronic RfD and a 1X FQPA Safety Factor. The Agency considers dietary residue contributions greater than 100% of the PAD to be of concern.

#### **e. Food Risk Characterization**

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The acute dietary risk from diazinon residues on food is below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized. For the most exposed subgroup, children (1-6 years), the percent acute PAD value is 63 at the 99.9<sup>th</sup> percentile of exposure. The chronic dietary risk from food alone is not of concern. For the most exposed subgroup, children (1 to 6 years old), the percent chronic PAD value is 22.

Refinements to the dietary analyses can be made using monitoring data for the chronic dietary analysis, and a probabilistic assessment for acute dietary analysis. Refinements will be conducted when cumulative risks for all of the organophosphates are considered.

## **2. Dietary Risk from Drinking Water**

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks.

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than the other two. Ground water monitoring studies were also used to estimate concentrations.

Environmental fate data indicate that diazinon and its degradates may occur in both ground water and surface waters to varying degrees. Therefore, consideration is being given to the probability of residues and toxicologically significant metabolites of diazinon appearing in ground water. Diazinon is only moderately mobile and persistent. Laboratory data indicate that diazinon will not persist in acidic

water; however, in neutral and alkaline waters, residues may be quite persistent. Oxyprymidine is the main soil and water degradate. Diazoxon, a toxic degradate, was not found in laboratory fate studies but was found in the field dissipation studies. Modeling and monitoring data for drinking water do not consider diazinon degradates. There is evidence that degradates may be formed by water treatment such as chlorination. The toxicity of these degradates is uncertain.

#### **a. Surface Water**

The Tier II PRZM-EXAMS screening model is used to estimate the upper-bound concentrations in drinking water derived from surface water. Model estimates from a scenario representing diazinon use on peaches using the index reservoir was selected for use in the human health risk assessment as it represented a high end use pattern. A maximum diazinon concentration of 70 ug/L, and a 90<sup>th</sup> percentile (i.e. 1 in 10 year) annual diazinon concentration of 9.4 ug/L were recommended for use in acute and chronic risk assessments, respectively.

Diazinon was the most frequently detected insecticide in surface water monitoring studies conducted by the United States Geological Survey under the National Water Quality Assessment Program (NAWQA) and Stream Quality Network programs, California state regulatory agencies, and other sources. It is detected more frequently and at higher concentrations in samples from urban sites than at agricultural sites. Surface waters sampled include rivers, streams, and creeks from areas with both agricultural and urban pesticide use. For example, diazinon was detected frequently (35% of NAWQA samples) at concentrations ranging from below the level of quantitation up to 3.8 µg/L.

#### **b. Ground Water**

Results from a variety of ground water monitoring studies that include diazinon as an analyte were used. No metabolites were included in the analyses. In general, diazinon has been detected in groundwater from a variety of sources, drinking water wells, monitoring wells, and agricultural wells. Many of the studies conducted have been located in areas where pesticide use and agricultural production are considered to be high. The concentrations of diazinon detected in ground water (all wells) ranged from non-detectable (ND) to 1.0 ug/L.

Much of the ground water data provided comes from the United States Geological Survey National Water Quality Assessment Program (NAWQA), which assesses ambient water quality. Approximately 2% of the ground water samples collected through this program from 1992 to 1996 had positive detections of diazinon. However, the maximum concentration value was below the limit of quantitation for all wells sampled, and the median value was ND or <0.002 ug/L. Results from the NAWQA database indicate that diazinon was detected more frequently in shallow ground water in urban areas than in agricultural areas.

The relative percentage of samples with detections to total wells sampled from studies in which rural drinking water wells were sampled ranged from 5 to 22.5%. The maximum concentration detected in the rural drinking water wells sampled was 1.0 ug/L, and the 95<sup>th</sup> percentile concentration

values ranged from ND to <0.3 ug/L. Average (mean) concentrations as determined from all samples analyzed were reported to range from 0.012 to <0.3 ug/L. Since most wells were sampled one time only, an average concentration value for diazinon per well is not available.

The SCI-GROW model was used to provide a 90-day average concentration of 0.8 ug/L as an upper bound estimate of diazinon concentrations in shallow ground water.

**c. Drinking Water Levels of Comparison (DWLOCs)**

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

The results of the Agency’s drinking water analysis are summarized here. Details of this analysis, which used screening models and actual monitoring data, are found in the HED Human Health Risk Assessment, dated December 5, 2000.

For acute risk, the potential drinking water exposure derived from ground water is not of concern for all populations. Although the acute DWLOC is exceeded for all reported populations for surface water, the Agency has determined that these exceedances are probably not of concern. The PRZM-EXAMS model that is used to estimate diazinon concentrations is a Tier II model and a screening-level assessment. The results of the model are expected to be higher than the diazinon concentrations actually found in drinking water; in other words, these are likely an overestimate of residues. There are several sources of conservatism built into the model estimates. In particular, the site chosen to represent a particular crop is chosen because it is expected to produce concentrations greater than 90% of the sites used for that crop. The value represents a concentration that was equaled or exceeded only once every 10 years in the model simulation. The use rate used in the simulation was the maximum label rate for that crop. Both groundwater and surface water monitoring data support the conclusion that drinking water residues will likely be lower than the modeled concentrations. The table below presents the calculations for the acute drinking water assessment.

**Table 3. Summary of DWLOC Calculations for Acute Risk**

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb) (SCI-GROW)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.0025	0.00067	0.0018	0.8	70	55
Females 13-50 yrs	0.0025	0.00060	0.0019	0.8	70	48
Children 1-6 yrs	0.0025	0.00119	0.0013	0.8	70	9

For chronic risk, potential exposure to drinking water derived from groundwater is not of concern for all populations.

For the same reasons the acute drinking water risk exceedances are not of concern, the Agency has determined that diazinon's chronic drinking water risk estimate is not of concern, even though the DWLOC is exceeded for all populations.

**Table 4. Summary of DWLOC Calculations for Chronic Risk**

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.0002	0.000028	0.00017	0.8	9	6
Females 13 - 50 yrs	0.0002	0.000024	0.00018	0.8	9	6
Children 1-6 yrs	0.0002	0.000045	0.00016	0.8	9	2

### 3. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Occupational handlers of diazinon include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators, and lawncare and turf management professionals. It should be noted that indoor, residential use products are being phased out and cancelled and cannot be sold after December 31, 2002. Outdoor lawn and garden diazinon products are being phased out and cancelled and cannot be sold after December 31, 2004. Therefore, only agricultural occupational risk is discussed in this IRED. For information on residential risk, consult the HED risk assessment.

Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

#### a. Toxicity

The toxicity of diazinon is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for diazinon, including a 21-day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for diazinon are listed below. Because route specific toxicity studies are available, dermal and inhalation adsorption factors are not necessary.

**Table 5a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Assessments for Diazinon.**

Assessment	Dose	Endpoint	Study
Short-term dermal (MOE $\geq$ 100)	NOAEL = 1 mg/kg/day LOAEL = 5 mg/kg/day	significant serum and brain cholinesterase inhibition at 5 mg/kg/day	21 day dermal (rabbit) MRID 40660807
Intermediate- term dermal (MOE $\geq$ 300)*	NOAEL = 1 mg/kg/day LOAEL = 5 mg/kg/day	significant serum and brain cholinesterase inhibition at 5 mg/kg/day	21 day dermal (rabbit) MRID 40660807
Short-term, intermediate and long-term inhalation (MOE $\geq$ 300)**	LOAEL= 0.1: g/L (0.026 mg/kg/day)	significant serum and RBC cholinesterase inhibition at 0.026 mg/kg/day	21 day whole body rat inhalation study (6 hours/day) MRID 40815002

\* Target MOE is 300 since the length of the study may not be adequate to address the concern for achieving a steady state following longer exposure.

\*\* Target MOE is 300 because a NOAEL was not established for cholinesterase inhibition, and additional 3X factor is required for inhalation exposure risk assessments.

Diazinon has moderate acute toxicity and is classified as Category III for all routes of exposure. It is not a skin sensitizer. Table 5b summarizes the acute toxicity of the active ingredient.

**Table 5b. Acute Toxicity Profile for Occupational Exposure for diazinon.**

Route of Exposure	Category Basis	Toxicity Category
Oral	LD <sub>50</sub> = 1340 mg/kg - male rat; 1160 mg/kg - female rat; combined sex = 1250 mg/kg; 95% confidence limit (MRID 41407218)	III
Dermal	LD <sub>50</sub> > 2020 mg/kg (MRID 41407219); rabbit	III
Inhalation	LC <sub>50</sub> > 2.33 mg/L/4 hours (MRID 41407220); rat	III
Eye Irritation	Minimally irritating (MRID 41407221); rabbit	III
Dermal Irritation	Maximum irritation score = 2.8; slight irritant (MRID 41407222); rabbit	III
Dermal Sensitizer	Buehler assay; not a sensitizer (MRID 41407223); guinea pig.	Negative

### b. Exposure

A chemical specific applicator study was used to evaluate the application of a 2% diazinon dust formulation by a pest control operator indoors (MRID 44348801). All indoor uses have been canceled; therefore this study's results are not relevant for the occupational exposure assessment results presented below. No other chemical-specific occupational mixer/loader/applicator data were available for supporting the reregistration of diazinon. However, seed treatment data from a lindane seed treatment study (dust formulation, MRID 44405802) were used for screening level assessment of the diazinon seed treatment scenario.



Analyses were also performed for short and intermediate term exposures using the *Pesticide Handlers Exposure Database* (PHED) Version 1.1. Standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc., were used to calculate risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates (in most cases the maximum rate was used) and the amount applied in a single day are derived directly from diazinon labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality, while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for diazinon, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on diazinon labels range from 0.5 to 4 pounds of active ingredient per acre in agricultural settings. The Agency typically uses “acres treated per day” values that are thought to represent eight solid hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures, using a tiered approach, to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest suite of PPE is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation (PPE) are applied. If MOEs are still less than 100, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from diazinon activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves and a respirator if risk is driven by inhalation.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a closed mechanical transfer system for liquids or a packaged based system (e.g., Lock N Load for granulars or water soluble packaging for wettable powders). Some engineering controls are not applicable for

certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures). For the purpose of this risk assessment, the Agency has determined that the frequency and duration of diazinon uses by occupational handlers result in short-term (1- 30 days) and intermediate term (30 - 180 days) exposures. The Agency believes that no uses of diazinon would result in chronic exposures (more than 180 days).

Finally, post application exposure to workers through entry into agricultural fields treated with diazinon were also considered. These activities result in potential short-term and intermediate-term dermal diazinon post application exposures. Two dislodgeable foliar residue (DFR) studies submitted by the registrant that address the dissipation of diazinon on cabbage and broccoli (MRID 40202902) and citrus (40466601). These studies were used to evaluate potential post application worker risks. The occupational risk assessment also includes information from the Agricultural Reentry Task Force (ARTF) on transfer coefficients. This information has been summarized by HED's Exposure Science Advisory Council (ExpoSAC) in interim Policy 3.1.

### **c. Occupational Handler Risk Summary**

Based on the use patterns and potential exposures, 32 major occupational exposure scenarios (including agricultural, animal premise, greenhouse, and/or commercial handler exposures) are identified to represent the extent of diazinon uses. The registrant is not supporting the belly grinder and airless sprayer methods of application and all residential uses are being phased out. However, these scenarios were included for completeness, since they currently appear on labels.

For the agricultural handlers, the estimated exposures considered baseline (long pants, long sleeved shirt, no gloves), personal protective equipment (PPE, which includes a double layer of clothing and gloves and/or a dust/mist respirator), and engineering controls (closed mixing/loading systems for liquids and granulars and enclosed cabs/trucks). The scenarios presented in Table 6 are only for engineering controls because risk estimates were unacceptable at baseline and with PPE. The potential exposures within the 32 identified exposure scenarios are assessed using the toxicological endpoints and uncertainty factors associated with the active ingredient. Therefore, the PPE and engineering controls are determined by the assessment of the active ingredient and not the currently required PPE/engineering control measures on diazinon labels.

For the dermal and inhalation risk assessments, risk estimates are expressed in terms of MOE, which is the ratio of the NOAEL and LOAEL selected for the risk assessment to the exposure. Target MOEs for short-term dermal risk assessments are 100 resulting from the following uncertainty factors: a 10X for interspecies variability and 10X for intraspecies extrapolation. A target MOE of 300 is applicable for the intermediate and long term dermal endpoints based on the interspecies (10X) and intraspecies (10X) factors, in addition to a 3X to extrapolate from a 21 day dermal study to longer term

exposures. For inhalation risk assessments (all time periods) the target MOE is 300 resulting from the interspecies (10X) and intraspecies (10X) factors, and for lack of a NOAEL in the critical study and consequent use of a LOAEL (3X). MOEs below the target level would represent a risk concern.

Dermal and inhalation exposures were combined because of a common toxicity endpoint (i.e., cholinesterase inhibition), and because dermal and inhalation exposures may occur simultaneously. An aggregate risk index (ARI) was used to combine short term dermal and inhalation risk estimates because the dermal and inhalation target MOEs are different (i.e., 100 for dermal and 300 for inhalation). An ARI of less than 1 exceeds HED's level of concern. However, a total MOE was calculated for intermediate and long-term exposures because the target MOE is 300 for both dermal and inhalation exposure. For intermediate and long term aggregate exposure, an MOE of 300 is the target MOE.

As described in the January 15, 2002, memorandum HED's Development of Handler Risks for the Diazinon Risk Benefit Analysis, modifications have been made to the exposure factors affecting the MOEs presented in Table 6. Modifications include the ratio of the dermal surface area to body weight, as well as the changes to the inhalation rates. The ratio of the body surface area to the body weight used in dermal calculations to estimate potential dose overestimates exposure by a factor of 1.1. The ratio is not physiologically matched in that the surface area used in the calculations is for an average male while the body weight is the median for both male/female. The inhalation exposure is modified by the adaptation of NAFTA recommended values for breathing rates. NAFTA recommends inhalation rates of 8.3, 16.7, and 26.7 L/min for sedentary activities (e.g., driving a tractor), light activities (e.g., flaggers and mixers/loaders < 50 lb containers), and moderate activities (e.g., loading > 50 lb containers, handheld equipment in hilly conditions), respectively. These inhalation reduction factors reduce the estimated dose and increase corresponding MOEs by factors of 3.5 for tractor drivers, 1.7 for mixer/loaders and flaggers, and 1.1 for handheld equipment. A complete copy of this document can be found in the public docket.

Only three of the short term scenarios evaluated using engineering controls have acceptable ARIs (i.e.,  $\geq 1$ ) for mixers/loaders: loading granulars for tractor-drawn spreaders at 1.00 lb ai/acre and 3.00 lb ai/acre with ARIs of 3.56 and 1.17 respectively and sprays (liquid formulation) for groundboom application at 0.50 lb ai/acre with an ARI of 1.29. For applicators, only one short term scenario had an acceptable ARI: applying liquid formulations by groundboom at 0.50 lb ai/acre with an ARI of 2.97. ARIs for all other scenarios for mixers/loaders and applicators ranged from 0.02 to 0.70 and 0.05 to 0.59 respectively.

### **(1) Agricultural Handler Risk**

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use patterns associated with diazinon. The Occupational and Residential Exposure Assessment and Recommendations for the RED Document for Diazinon dated November

30, 2000, includes 32 major occupational and exposure scenarios (including agricultural animal premise, green house, and/or commercial handler exposures). For purposes of this IRED discussion, we are focusing on currently registered use patterns. Based on current use patterns and potential exposures, these major occupational exposure scenarios for agricultural uses are identified to represent the extent of diazinon uses.

- (1) Mixing/loading liquids to support:
  - (a) aerial applications;
  - (b) groundboom applications;
  - (c) airblast applications.
  
- (2) Mixing/loading wettable powders to support:
  - (a) aerial applications;
  - (b) groundboom applications;
  - (c) airblast applications;
  
- (3) Loading granules to support tractor-drawn broadcast spreaders applications.
  
- (4) Applying sprays or liquids with:
  - (a) an airblast;
  - (b) a groundboom;
  - (c) aerial equipment
  
- (5) Applying granules with a tractor drawn spreader

The results of the short term handler assessments are summarized in Table 6 below. Shaded boxes indicate acceptable MOEs. Only the short term (less than 30 days) handler assessment was used to determine appropriate occupational handler risk mitigation. Although information is not available to determine what percentage of applicators apply diazinon continuously for more than 30 days, it is reasonable to believe that those individuals will represent a very small segment of agricultural applicators. The intermediate term handler assessment can be found in the Occupational and Residential Exposure Assessment and Recommendations for the RED Document for Diazinon. No chronic exposure durations (more than 180 days per year) for agricultural handlers have been identified. All risk estimates using baseline and PPE were unacceptable; therefore, only the scenarios with engineering controls are presented.

**Table 6. Agricultural Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs) with Engineering Controls.**

Crop	App. Rate (lb ai/A) <sup>1</sup>	Acres treated	Application method / formulation	Short-Term ARI		Dermal MOE Mixer-Loader/Applicator	Inhalation MOE Mixer-Loader/Applicator
				Mixer/Loader	Applicator		
Almonds	3.00	350	aerial / liquid	0.042	0.052	8.6 / 14.3	35.7 / 87.5
		40	airblast / liquid	0.43	0.082	74.8 / 34.1	<b>306</b> / 119
		350	aerial / WP	0.026	0.052	7.48 / 14.3	12.24 / 87.5
		40	airblast / WP	0.23	0.082	66 / 34.1	107.1 / 119
Apples Pears	2.00	350	aerial / WP	0.040	0.15	11 / 22	18.7 / 133
		40	airblast / WP	0.35	0.27	97.9 / 50.6	161.5 / 178.5
Apricots Nectarines Peaches Plums Prunes Walnuts	2.00	350	aerial / liquid	0.075	0.15	13.2 / 22	52.7 / 38
		40	airblast / liquid	0.64	0.27	<b>110</b> / 50.6	<b>459</b> / 178.5
		350	aerial / WP	0.040	0.15	11 / 22	18.7 / 38
		40	airblast / WP	0.35	0.27	97.9 / 50.6	161.5 / 178.5
Beets (red) Onions Spinach	.5	350	aerial / liquid	0.30	0.59	51.7 / 88	221 / <b>525</b>
		80	groundboom / liquid	<b>1.29</b>	<b>2.97</b>	<b>220 / 385</b>	<b>935 / 3850</b>
		350	aerial / WP	0.16	0.59	45.1 / 88	73.1 / <b>525</b>
		80	groundboom / WP	0.70	<b>2.97</b>	<b>198 / 385</b>	<b>323 / 3850</b>
	4	80	tractor-drawn spreader / granular	0.90	0.24	<b>1430 / 121</b>	289 / 91
Blackberries Boysenberries Dewberries Loganberries Raspberries Cherries (sweet)	2.00	350	aerial / liquid	0.075	0.15	13.2 / 22	52.7 / 133
		40	airblast / liquid	0.64	0.12	<b>110</b> / 50.6	<b>459</b> / 178.5
		350	aerial / WP	0.040	0.15	11 / 22	18.7 / 133
		40	airblast / WP	0.35	0.12	97.9 / 50.6	161.5 / 178.5
Blueberries Grapes Hops	1.00	350	aerial / liquid	0.15	0.29	25.3 / 44	107.1 / 126.6
		40	airblast / liquid	<b>1.29</b>	0.54	<b>220 / 101.2</b>	<b>935 / 350</b>
		350	aerial / WP	0.080	0.29	22 / 44	37.4 / 126.6
		40	airblast / WP	0.70	0.54	<b>198 / 101.2</b>	<b>323 / 350</b>
Broccoli Brussels Sprouts Cabbage	.5	350	aerial / liquid	0.30	0.59	51.7 / 88	221 / <b>525</b>
		80	groundboom / liquid	<b>1.29</b>	<b>2.97</b>	<b>220 / 385</b>	<b>935 / 3850</b>
		350	aerial / WP	0.16	0.59	45.1 / 88	73.1 / <b>525</b>
		80	groundboom / WP	0.70	<b>2.97</b>	<b>198 / 385</b>	<b>323 / 3850</b>
	3	80	tractor drawn spreader / granular	<b>1.17</b>	0.32	<b>1870 / 154</b>	<b>374</b> / 119

Crop	App. Rate (lb ai/A) <sup>1</sup>	Acres treated	Application method / formulation	Short-Term ARI		Dermal MOE Mixer- Loader/ Applicator	Inhalation MOE Mixer- Loader/ Applicator
				Mixer/Load er	Applicato r		
Cantaloupes Crenshaw Melons Endive Honeydew Melons Muskmelons Persian Melons Watermelon	4	350	aerial / liquid	0.037	0.074	6.38 / 11	27.2/66.5
		350	aerial / WP	0.020	0.074	5.61 / 11	9.18/66.5
	4	80	tractor drawn spreader / granular	0.90	0.24	<b>1430 / 121</b>	289/91
Carrots Cauliflower Collards Kale Radishes Rutabagas Tomatoes	4	350	aerial / liquid	0.037	0.074	6.38 / 11	27.2/66.5
		80	groundboom / liquid	0.16	0.37	27.5 / 48.4	117.3 / <b>455</b>
		350	aerial / WP	0.020	0.074	5.61 / 11	9.18 / 66.5
		80	groundboom /WP	0.087	0.37	24.2 / 48.4	40.8 / <b>455</b>
	4	80	tractor drawn spreader / granular	0.90	0.24	<b>1430 / 121</b>	289 / 91
Corn (sweet)	.5	350	aerial / liquid	0.30	0.59	51.7 / 88	221 / <b>525</b>
		80	groundboom / liquid	<b>1.29</b>	<b>2.97</b>	<b>220 / 385</b>	<b>935 / 3850</b>
	4	350	aerial / WP	0.020	0.039	5.61 / 88	9.18 / <b>525</b>
		80	groundboom / WP	0.087	0.22	24.2 / <b>385</b>	40.8 / <b>3850</b>
	4	80	tractor drawn spreader / granular	0.90	0.24	<b>1300 / 121</b>	170 / 91
Cranberries	3	350	aerial / liquid	0.042	0.052	8.6 / 14.3	35.7 / 87.5
		80	groundboom / liquid	0.43	0.082	74.8 / 34.1	<b>306</b> / 119
		350	aerial / WP	0.026	0.052	7.48 / 14.3	12.2 / 87.5
		80	groundboom / WP	0.23	0.082	66 / 34.1	107.1 / 119
Ginseng	.5	350	aerial / liquid	0.30	0.59	51.7 / 88	221 / <b>525</b>
		80	groundboom / liquid	<b>1.29</b>	<b>2.97</b>	<b>220 / 385</b>	<b>935 / 3850</b>
	4	80	tractor drawn spread / granular	0.90	0.24	<b>1430 / 121</b>	289 / 91
Lettuce	0.50	350	aerial / liquid	0.30	0.59	51.7 / 88	221 / <b>525</b>
		80	groundboom / liquid	<b>1.29</b>	<b>2.97</b>	<b>220 / 385</b>	<b>935 / 3850</b>
	4.0	350	aerial / liquid	0.037	0.074	6.38 / 11	27.2 / 66.5
		80	groundboom / liquid	0.16	0.37	27.5 / 48.4	117.3 / <b>455</b>
		350	aerial / WP	0.020	0.074	5.61 / 11	9.18 / 66.5
		80	groundboom /WP	0.087	0.37	24.2 / 48.4	40.8 / <b>455</b>
	1.00	80	tractor drawn spread / granulars	<b>3.56</b>	0.90	<b>5610 / 1430</b>	<b>1139</b> / 289

Crop	App. Rate (lb ai/A) <sup>1</sup>	Acres treated	Application method / formulation	Short-Term ARI		Dermal MOE Mixer- Loader/ Applicator	Inhalation MOE Mixer- Loader/ Applicator
				Mixer/Load er	Applicato r		
Mustard greens	4.00	350	aerial / liquid	0.037	0.074	6.38 / 11	27.2 / 66.5
		80	groundboom / liquid	0.16	0.37	27.5 / 48.4	117.3 / <b>455</b>
		350	aerial / WP	0.020	0.074	5.61 / 11	9.18 / 66.5
		80	groundboom / WP	0.087	0.37	24.2 / 48.4	40.8 / 455
	1.00	80	tractor drawn spreader / granulars	<b>3.56</b>	0.90	<b>5610 / 1430</b>	<b>1139</b> / 289
Pineapples	2.00	350	aerial / liquid	0.075	0.15	13.2 / 22	52.7 / 133
		40	airblast / liquid	0.64	0.27	<b>110</b> / 50.6	<b>459</b> / 178.5
	1.00	350	aerial / WP	0.080	0.29	22 / 44	37.4 / 26.6
		40	airblast / WP	0.70	0.25	<b>180</b> / 92	190 / 100
Strawberries	1.00	350	aerial / liquid	0.15	0.29	25.3 / 44	107.1 / 126.6
		80	groundboom / liquid	0.64	<b>1.50</b>	<b>110 / 198</b>	<b>459 / 1855</b>
		350	aerial / WP	0.080	0.29	22 / 44	37.4 / 126.6
		80	groundboom / WP	0.35	<b>1.50</b>	97.9 / <b>198</b>	161.5 / <b>1855</b>

<sup>1</sup>The application rates presented here are only a small sample of the range of rates available on product labels. In general, if application rates, treatment method and acres treated are the same, the same MOEs will apply regardless of the crop.

<sup>2</sup>The highlighted values indicate MOEs that are not of concern.

## (2) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture. Workers may be exposed to diazinon on a short term or intermediate term basis upon entering treated areas. All of the post application scenarios and post-application risk calculations for handlers completed in this assessment are included in the Occupational and Residential Exposure Assessment and Recommendations for the RED Document for Diazinon dated November 30, 2000.

The following ten crop groupings are used to assess the post application exposures to diazinon:

- (1) Low berry;
- (2) Field row crop, low & medium
- (3) Field-grown nursery ornamentals;
- (4) Deciduous tree fruit;
- (5) Nut trees;
- (6) Root vegetables;
- (7) Cucurbit vegetables;
- (8) Fruiting vegetables;
- (9) Brassica vegetables; and
- (10) Leafy vegetables.

The Agency has incorporated two post application exposure studies (i.e., dislodgeable foliar residue) on cabbage and oranges and determined the transfer coefficients to calculate restricted entry intervals (REIs). These transfer coefficients were derived from Agency data and transfer coefficient studies submitted by the Agricultural Reentry Task Force (ARTF) and summarized by OPP's Health Effects Division into an interim policy document (Policy 3.1) developed in August 2000. Data from two crop-specific residue studies are used in HED's risk assessment as surrogates to represent other crops not monitored but currently registered.

The results of the short term post application assessments indicated that REIs need to be established. The REIs are presented in Table 7. The results of the dermal post application assessments for workers exposed to diazinon for most agricultural activities indicate that MOEs are less than 100 (i.e., unacceptable) at the current Worker Protection Standard (WPS) required restricted entry level (REI) of 24 hours. For high end exposure activities (i.e., hand harvesting in most instances) the short term MOEs for post application workers did not reach 100 for 2- 4 days after treatment for most vegetable crops, 4 days for fruit trees, 3 days for field crops, 3 - 5 days for berries, 2 - 7 days for ornamentals and 7 - 18 days for tree nuts. The REIs were based exclusively on dermal exposures. The potential for dermal contact during post application activities (e.g., harvesting) is assessed using a matrix or potential contact rates by activity and associated crops. This assessment is believed to be reasonably representative of diazinon uses, except for nut trees and cut flowers, which lack adequate transfer coefficient data.

**Table 7. Summary of “The Days After Treatment” to Reach the Target MOE for Hand Harvesting<sup>1</sup>.**

Crop Grouping	Diazinon Specific Crops	Max Foliar Rate (lb ai/acre)	Days After Treatment Short-term (Target MOE 100) <sup>2</sup>	PHI (days)
Low berry	Blackberries, raspberries, blueberries, cranberries	2-3	5	5 to 7
	strawberries	1	3	5
Field row crop, low & medium	beans, peas	0.75	3	7
Field grown nursery ornamentals	carnation, chrysanthemum (cut flowers)	2	7	NA
	ball/burlap other types of ornamentals such as azalea, boxwood, dogwood, juniper	1	2	NA
Deciduous tree fruit	apples, apricots, cherries, figs, nectarines, peaches, pears, plums	2	4	21
Tree nuts	hazelnuts	3	18	45
	almonds (dormant spray only)	3	7	NA
Root vegetables	beets, carrots, onions, parsnips, potatoes, radishes	0.5	3	14+



Crop Grouping	Diazinon Specific Crops	Max Foliar Rate (lb ai/acre)	Days After Treatment Short-term (Target MOE 100) <sup>2</sup>	PHI (days)
Cucurbit vegetables	cucumbers	0.75	3	7
	melons	0.75	3	3
Fruiting vegetables	peppers, tomatoes	0.75	2	1 to 5
Brassica vegetables	cole crops	0.5	4	7
Leafy vegetables	lettuce, parsley, spinach, Swiss chard	0.5	3	10+

- (1) Results are for the high end exposure activity of hand harvesting.
- (2) Short-term dermal NOAEL = 1 mg/kg/day (21-day rabbit dermal study with a 100 target MOE).

## B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division (EFED) chapter, dated February 19, 2002, available in the public docket. In December 2000, EPA reached an agreement with the diazinon technical registrants to phase out all outdoor, non-agricultural uses and certain agricultural uses. However, the EFED risk assessment was originally conducted prior to this agreement and includes some of the deleted uses.

### 1. Environmental Fate and Transport

Diazinon is moderately persistent and mobile in the environment. Diazinon appears to degrade by hydrolysis in water and by photolysis and microbial metabolism and to dissipate by volatilization from impervious surfaces. Diazinon degrades by hydrolysis at all pH's tested. Hydrolysis is rapid under acidic condition, with a half-life of 12 days at pH 5. Under neutral and alkaline conditions, diazinon hydrolyzed more slowly with abiotic hydrolysis half-lives of 138 days at pH 7 and 77 days at pH 9. Diazinon is stable to photolysis in water, but was shown to degrade with a half-life of less than two days on soil indicating that photodegradation may be important under certain circumstances.

Diazinon was shown to be moderately mobile in five soils with reported Freundlich adsorption coefficients ranging from 3.7 to 23.4 mL/g. In a soil column leaching study, aged (30 days) diazinon residues were mobile with parent diazinon, and less mobile than oxypyrimidine, the major degradate of diazinon.

In several supplemental terrestrial field dissipation studies submitted to the Agency, diazinon dissipated with apparent field half-lives ranging from 5 to 20 days in the top 6 inch soil layer. These dissipation half-lives are consistent with a compound which is registered for multiple applications for adequate pest control. These studies measure dissipation resulting from degradation, dilution and movement from site. In two studies diazinon was detected to a depth of 48 inches; however, in most studies, diazinon was recovered at a maximum of 18 inches. Diazinon is not expected to bioaccumulate in fish based on rapid depuration of residues.

## 2. Exposure Assessment

### Terrestrial exposure

For pesticides applied as liquids, the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk with a Risk Quotient (RQ) method. Estimates of maximum and average residue levels of diazinon on wildlife food was based on the model of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). EECs resulting from multiple applications are calculated from the maximum number of applications, minimum application interval, and foliar half-life data. For pesticides applied as granulars, EECs are calculated as the number of lethal doses ( $LD_{50}$ s) that are available within one square foot immediately after application ( $LD_{50}/ft^3$ ). Applications which are incorporated are assumed to leave one percent of the granules on the soil surface (i.e., 99% is incorporated). Risk quotients are calculated for three separate weight classes of birds and mammals: 1000 g (e.g., waterfowl), 180 g (e.g., upland game bird), and 20 g (e.g., songbird).

### Surface Water

For exposure to aquatic animals, EPA considers surface water only, since most organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater aquatic animals, since monitoring data are generally not targeted studies on small water bodies and primary streams, where many aquatic animals are found. The modeling results are summarized here. Refer to the EFED chapter for a detailed discussion of the water models.

The Agency used PRZM-EXAMS to calculate refined Estimated Environmental Concentrations (EECs). The Pesticide Root Zone Model (PRZM, version 3.1) simulates pesticides in field runoff and erosion, while the Exposure Analysis Modeling System (EXAMS, version 2.97-5) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep). EECs in surface water resulting from the highest application rate on seven crop types (berries, tubers/bulbs, nuts, stone fruits, pome fruits, vegetables, and other) were calculated. The crops were chosen based on the uses for which the greatest amount of diazinon was applied according to usage data from 1992 - 1997.

These estimates for ecological risk differ from the drinking water EEC's, since the ecological aquatic EECs were estimated with the farm pond and not the Index Reservoir amendment to the model. EEC's are tabulated below in Table 8.

**Table 8. Estimated Environmental Concentrations (EECs) Used in PRZM-EXAMS.**

Crop and Application Method	Application Rate (lbs ai/A)	# of Applications	Peak EEC (ppb)	21-day Average EEC (ppb)	60-day Average EEC (ppb)
almond; aerial spray	3.0	1	8.89	7.94	6.39
potatoes; broadcast	4.0	1	72.7	58.9	45.7
blueberries; aerial spray	1.0	5	37.7	32.8	22.4
peaches; aerial spray	2.0	3	91.2	80.5	67.2
apples; aerial spray	2.0	3	25.1	20.5	15.4
cucumbers; broadcast	4.0	1	429	356	258

These values reflect an aerial application of diazinon which may result in direct spray drift deposition into surface waters adjoining target use sites. For modeling purposes, the drift potential for aerial and ground spray is assumed to be equivalent to 5% of applied and 1% of applied, respectively.

### 3. Toxicity (Hazard) Assessment

#### a. Avian, Mammalian and Honeybee Toxicity

Diazinon is very highly toxic to birds and has been linked to a number of bird kills. The diazinon acute oral toxicity LD<sub>50</sub>, administered as a single dose by oral intubation, ranges from 1.44 (mallard duck) to 69 (brown-headed cowbird). Nearly all studies found that diazinon is very highly toxic by the acute oral route. Subacute dietary studies estimate the quantity of diazinon mixed in the diet that causes 50% mortality. LC<sub>50</sub> values for technical diazinon ranged from 32 to 3,912 ppm. Almost all studies found that diazinon is very highly toxic or highly toxic. The toxicity values used to calculate the acute avian risk quotients (RQ) can be found in Table 9.

**Table 9. Technical Diazinon Acute Oral Toxicity to Birds**

Study/Type	Species	LD <sub>50</sub> (mg/kg)	Toxicity Category
MRID 40895301 Acute Oral (Single dose by gavage)	Mallard duck	1.44	very highly toxic
MRID 40895302 Subacute dietary <sup>1</sup> (five days of treated feed)	Mallard Duck	32	very highly toxic

<sup>1</sup> Test organisms observed an additional three days while on untreated feed.

Chronic effects are measured by avian reproduction studies that estimate the quantity of toxicant required to adversely affect the reproductive capabilities of a test population of birds. Technical diazinon is administered to the breeding bird's diet throughout the breeding cycle. The toxicity value (NOAEC) used to calculate the chronic avian risk quotient is presented in Table 10.

**Table 10. Technical Diazinon - Reproductive Toxicity to Birds**

Study/Species	NOEC (ppm ai)	LOEC (ppm ai)	LOEC Endpoints
MRID 41322901 Mallard Duck	8.3	16.33	Significant reduction in the number of 14-day hatchling survivors.

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammal 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. Diazinon is characterized as moderately to practically nontoxic to small mammals on an acute oral basis (LD<sub>50</sub> for combined sexes was 1250 mg/kg). In a multi generation reproduction study (MRID 41158101), for parental/systemic toxicity, the NOAEL is 0.67 mg/kg/day and the LOAEL is 6.69 mg/kg/day based on decreased parental weight gain. For offspring toxicity, the NOAEL is 0.67 mg/kg/day and LOAEL is 6.69 mg/kg/day based on pup mortality and decreased weight gain.

Diazinon is highly toxic to bees and other beneficial insects on an acute contact basis. The LD<sub>50</sub> for technical diazinon is 0.22 µg ai/bee (MRID 05004151).

#### b. Toxicity to Aquatic Animals

Technical diazinon has been shown to be moderately toxic to very highly toxic to freshwater fish with LC<sub>50</sub>s ranging from 90 to 7,800. A freshwater fish life cycle test is designed to estimate the quantity of toxicant required to adversely affect the reproductive capabilities of a test population of fish. The toxicity values appearing in Table 11 will be used to calculate the acute and chronic aquatic risk quotients.

**Table 11. Acute and Chronic Toxicity of Diazinon to Fish**

Study /Type	Species	LC <sub>50</sub> (ppb)		Toxicity Category
MRID 40094602 Acute Toxicity	Rainbow Trout	90.0		very highly toxic
MRID ROODI007 Chronic Toxicity	Brook Trout	NOEC (ppm ai)	LOEC (ppm ai)	Endpoints Affected
		<0.55	<0.55	inhibited growth first 3 months, neurological symptoms, reduced growth in progeny

A freshwater aquatic invertebrate toxicity test is used to establish the acute toxicity of diazinon to aquatic invertebrates. Diazinon is very highly toxic to freshwater aquatic invertebrates on an acute basis with an EC<sub>50</sub> of 0.2. A freshwater aquatic invertebrate life cycle test is used to determine chronic effects. The toxicity values appearing in Table 12 are used to calculate the acute and chronic risk quotients for aquatic invertebrates.

**Table 12. Acute and Chronic Toxicity of Diazinon to Aquatic Invertebrates**

Study/Type	Acute Toxicity - Species	EC <sub>50</sub> (ppb)		Toxicity Category
MRID 40094602 Acute Toxicity	Scud	0.20		very highly toxic
MRID 40782302 Chronic Toxicity	Daphnid ( <i>Daphnia magna</i> )	21 day NOEC/LOEC (ppb)		Endpoints Affected
		0.17	0.32	mortality of all test organisms at two highest concentrations (0.32 and 0.83 ppb)

Acute toxicity testing with estuarine and marine fish and invertebrates is required for diazinon because end-use products are expected to reach the marine and estuarine environment because of its use in coastal counties. The LC<sub>50</sub>s from several studies range from 150 to 1,500 ppb categorizing diazinon as highly to moderately toxic to estuarine and marine fish on an acute basis. An estuarine and marine fish early life-stage toxicity study measures chronic toxicity. The toxicity values appearing in Table 16 are used to calculate the acute and chronic risk quotients for estuarine and marine invertebrates.

For estuarine and marine invertebrates the LC<sub>50</sub>/EC<sub>50</sub> fall in the range of 4.2 to >1000.0 ppb, diazinon is categorized as very highly to moderately toxic on an acute basis. An estuarine and marine life cycle study measures chronic toxicity. The toxicity values appearing in Table 13 are used to calculate the acute and chronic risk quotients for estuarine and marine invertebrates.

**Table 13. Acute and Chronic Toxicity of Diazinon to Estuarine and Marine Invertebrates**

Study/Type	- Species	LC <sub>50</sub> /EC <sub>50</sub> (ppb)		Toxicity Category
MRID 40625501 Acute Toxicity	Mysid shrimp	EC <sub>50</sub> = 4.2; NOAEC = <2.7		highly toxic
MRID 44244801 Chronic Toxicity	Mysid shrimp	NOEC (ppb ai)	LOEC (ppb ai)	Endpoints Affected
		0.23	0.42	growth (weight)

### c. Toxicity to Plants

A greater than 25% detrimental effect level on radical length was observed in oat, carrot and tomato seedling emergence and a 25% or greater detrimental effect on vegetative vigor, as measured in plant height, was observed on onion, cucumber and tomato. Aquatic plants are also affected by diazinon.

Aquatic plant testing is required for diazinon because of its terrestrial outdoor use pattern, its ability to move offsite in both surface and ground water, and its demonstrated phytotoxicity, as determined in the terrestrial plant testing. The toxicity values appearing in Table 14 are used to calculate acute risk quotients.

**Table 14. Nontarget Terrestrial Plant Toxicity**

Study	Result Type	Result
Plant seedling emergence	Endpoint affected	EC <sub>25</sub> /EC <sub>05</sub> (lbs ai/A)
Monocot - Oat	Shoot height	5.26 / 0.17
Vegetative vigor	Endpoint affected	EC <sub>25</sub> /EC <sub>05</sub> (lbs ai/A)
Dicot - cucumber	Shoot height	3.23 / 1.27
Aquatic plant	Endpoint affected	EC <sub>50</sub> /EC <sub>05</sub>
Green Algae ( <i>Selenastrum capricornutum</i> )	Growth	3.7 / <0.06

#### 4. Ecological Risk Calculations

##### a. Levels of Concern

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects by using risk quotients (RQs). RQs are calculated by dividing exposure estimates by acute and chronic ecotoxicity values:

$$RQ = \text{EXPOSURE} / \text{TOXICITY}$$

RQs are then compared with OPP's levels of concern (LOCs). These LOCs are used by OPP to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. Risk presumptions, along with the corresponding LOCs are summarized in Table 15. The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies.

**Table 15. Risk Presumptions for Terrestrial and Aquatic Animals**

Risk Presumption	LOC terrestrial animals	LOC aquatic animals
<b>Acute Risk</b> there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification,	0.5	0.5
<b>Acute Restricted Use</b> -there is potential for acute risk, but may be mitigated through restricted use classification,	0.2	0.1
<b>Acute Endangered Species</b> -endangered species may be adversely affected; regulatory action may be warranted,	0.1	0.05
<b>Chronic Risk</b> -there is potential for chronic risk; regulatory action may be warranted.	1	1

**b. Risk to Birds and Mammals**

Diazinon has acute and chronic risk to birds. Diazinon acute RQs for birds exceeded the acute risk LOC (0.5), restricted use LOC (0.2), and endangered species LOC (0.1) for all uses evaluated. Also, practically all chronic RQs exceeded the chronic LOC (1.0). This was true for single and multiple applications, nongranular and granular applications, banded/in-furrow, as well as broadcast application methods, and for seed treatments. The table below provides ranges of RQs for the various formulation and application types. RQs for non-granular products are calculated based on residues on particular types of foodstuffs. RQs for granular products are calculated based on the number of lethal doses (LD50s) that are available within one square foot immediately after application (LD50s/sq. ft.). Birds may be exposed to granular pesticides by ingesting granules when foraging for food and grit or drinking contaminated water.

**Table 16. Ranges of Avian Acute and Chronic Risk Quotients for Various Formulation and Application Types.**

Formulation/application scenario	acute RQ	chronic RQ
Non-granular formulation, single application	0.23 - 30	0.90 - 115.66
Non granular formulation, multiple applications	0.37 - 46.82	1.41 - 180.50
Granular, broadcast,	1.08 - 1446.25	Not calculated
Granular, banded, incorporated	95 - 4725	Not calculated
Seed treatment	0.03 - 1.58	Not calculated
Granular and seed treatment RQ's are based on differing weights of various types of birds		

Risk quotients for mammals are calculated for three separate weight classes of mammals (15, 35, and 1000g), each presumed to consume four different kinds of foods (grass, forage, insects, and seeds). The concentration of diazinon in the diet that is expected to be acutely lethal to 50% of the test population (LC<sub>50</sub>) is determined by dividing the LD<sub>50</sub> value (usually the acute oral rat LD<sub>50</sub>) by the percent body weight consumed. The RQ is then determined by dividing the EEC by the derived LC<sub>50</sub> value. By dietary and oral routes, diazinon is classified as moderately acutely toxic to small mammals.

For single and multiple applications of non-granular diazinon products, the mammalian high acute level of concern is exceeded for many of the uses evaluated. RQs range up to 1.8 for a 35 g mammal. For applications of diazinon granular products (broadcast and banded) the mammalian high acute level of concern is exceeded for many of the uses evaluated with RQs ranging up to 5.5 for small mammals from the use on apples.

Diazinon is chronically toxic to mammals, and the chronic RQs for mammals exceeded the LOC (1.0) for all uses of diazinon at maximum application rates with chronic RQs ranging from 1.2 from use on bananas up to 85.7 for use on cranberries.

### **c. Risk to Aquatic Species**

Because of diazinon's widespread use in the U.S., and documented widespread presence in water bodies at concentrations of concern to aquatic life, there is a high level of certainty that aquatic organisms will be exposed to potentially toxic levels of diazinon in surface water. Since diazinon and its major degradate oxypyrimidine are mobile and persistent in the environment and found at significant levels in surface water, it is quite probable that they will be available in quantity and for times that will exceed acute and chronic toxicity endpoints.

Aquatic invertebrates appear to be highly sensitive to diazinon on an acute and chronic basis. Acute freshwater invertebrate risk quotients range from 53.5 for grapes to 2,145 for cucumbers. Chronic RQs range from 53.5 to 2094 for the same crops. These risk quotients indicate great risk potential to aquatic invertebrates at all use sites. Populations of aquatic invertebrates may recover over time, but their lowered numbers can potentially have an effect on the health of animals that prey on them, depending on alternative food sources and the overall health of the ecosystem prior to the introduction of the toxicant.

Although diazinon does not appear to be as acutely toxic to fish as it is to freshwater aquatic invertebrates, the estimated environmental concentrations from the water modeling are within the range of acute toxicity to fish for some application rates. Acute mortality to fish is thus a possibility, even though there are no reported fish kills incidents in EIIS that have been clearly linked to diazinon. Chronic RQs from freshwater fish range from 11.6 for almonds to 469 for cucumbers, indicating that chronic effects to fish are clearly possible.

### **d. Risks to Nontarget Plants**

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff, spray drift, or volatilization. Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from such uses as aquatic weed or mosquito larvae control. Diazinon does not have any aquatic uses. EECs are calculated for the following application methods: unincorporated ground applications; incorporated ground application; and aerial, airblast, forced-air, and chemigation applications. For single and multiple applications, acute high risk levels of concern are not exceeded for terrestrial and semi-aquatic plants for the registered application rates of diazinon. For single applications, endangered species levels of concern are exceeded for terrestrial and semi-aquatic plants for vegetable crops. For single or multiple applications, the non-vascular acute high aquatic plant risk levels of concern are not exceeded for the registered application rates of diazinon.

## **5. Ecological Incidents**

Based on EPA's Ecological Incident Information System (EIIS), diazinon has caused the second largest number of total known incidents of bird mortality of any pesticide. Diazinon has the highest number of bird mortality incidents (58) caused by any pesticide from 1994 to 1998 and it has the highest total number per million acres treated. There has been a trend in EIIS of steadily increasing



numbers of diazinon related incidents over the years. Diazinon has high use on lawns and other turf, and the majority of incidents on known sites have occurred here, with the remaining incidents on a variety of residential, agricultural, or unknown sites. Incidents have occurred with both liquid and granular formulations of diazinon. The largest kills are generally with waterfowl. Waterfowl frequently travel in larger flocks and are attracted to turf areas, particularly if water is nearby.

In conclusion, diazinon has caused widespread and repeated mortality of birds. The mortality has been well documented over many years and there is high certainty regarding diazinon's risk to birds. In 1988, diazinon was cancelled for use on golf courses and sod farms due to its high risk to birds. The risk to birds is very high on other sites as well, since birds can be attracted to a wide range of turf and agricultural sites. The continued mortalities over the years indicate that neither lower application rates on turf sites, nor the various added label environmental hazard statements, have been adequate to prevent bird mortalities. Mortality is likely to continue in the future if diazinon continues to be used on sites where birds can be exposed.

## **6. Endangered Species**

Endangered species LOCs are exceeded for multiple taxonomic groups of organisms on most application sites. The USFWS has determined that diazinon is likely to jeopardize multiple aquatic and terrestrial species. The 9/14/89 Biological Opinion, for example, lists a total of 88 federally-listed endangered/threatened aquatic and terrestrial species that the USFWS considers to be in jeopardy due to diazinon use. Corn, sorghum, cotton, and soybeans covered by this Biological Opinion are among the use sites listed in the January 22, 1999 Use Closure memo that were included in this environmental risk assessment.

In 1989 the USFWS issued a biological opinion on diazinon in response to EPA's request for consultation. In issuing its opinion, the USFWS considered the following factors: (1) potential for exposure of the listed species to the pesticide; (2) information on the chemical toxicity relative to estimated environmental concentrations; (3) potential for secondary impacts; and (4) special concerns not specifically addressed in the preceding factors or unique to the situation being evaluated. Given the evaluation criteria, a total of 132 species (5 bird, 6 amphibian, 77 fish, 32 mussel, 6 crustacean, 4 miscellaneous aquatic invertebrates, and 2 snake) were considered potentially affected by the use of diazinon. Of these organisms potentially affected, the USFWS listed 84 aquatic species as jeopardized, of which the majority (56%) were endangered/threatened species of freshwater fish. Four terrestrial (avian) species were also classified as being in jeopardy. The remaining potentially affected organisms were listed either as having no potential for exposure or as not being in jeopardy.

For all of the species listed as jeopardized the USFWS lists reasonable and prudent alternatives (RPA) to mitigate the effects of diazinon use. For some of the species listed as not jeopardized, the USFWS lists reasonable and prudent measures (RPM) and incidental take (IT) to mitigate effects. For details on the RPA and RPM recommendations, the reader is referred to a USFWS 1989 publication.

Many additional species, especially aquatic species, have been federally listed as endangered/threatened since the biological opinion of 1989 was written, and determination of jeopardy to these species has not been assessed for diazinon. Additionally, recent literature does document direct biological effects on a species, i.e., chinook salmon, with populations subsequently listed as threatened and/or endangered (USFWS Species Profile 10/13/2000) or proposed for listing, e.g. Atlantic salmon (USFWS Service Species Profile 10/13/2000). As noted earlier, sublethal effects could reduce reproductive success, diminish the genetic “purity” of specific fish stocks, increase vulnerability to predation and thereby adversely impact threatened/endangered species.

When the regulatory changes recommended in the IRED are implemented and the ecological effects and environmental fate data are submitted and accepted by the Agency, the Reasonable and Prudent Alternatives and Reasonable and Prudent Measures in the Biological Opinion(s) may need to be reassessed and modified based on the new information.

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

## **7. Risk Characterization**

Diazinon is an organophosphate that works by inhibiting cholinesterase enzymes. The toxic effect is the disruption of normal neuromuscular control. Death can occur rapidly, due primarily to asphyxiation as muscles associated with respiration undergo tetany. Organophosphate exposure can also result in chronic effects in animals such as reproductive impairment and delayed neuropathy.

### **a. Terrestrial Organisms**

There are several reasons why risk assessments may underestimate risk for those organisms exposed to pesticides. Compared to animals in the laboratory, animals in the wild might be more susceptible because they are exposed to multiple stressors in addition to the chemical (e.g., extreme environmental conditions, predation pressure, and disease). Furthermore, terrestrial vertebrates including birds, mammals, reptiles, and amphibians may be exposed to diazinon not only through oral and dermal exposure, but also through inhalation exposure. The Agency’s assessment only considered risks from oral exposure.

An extensive amount of data demonstrate diazinon's high acute toxicity to birds. Practically all avian acute and chronic RQs exceed the LOCs for all calculated uses. Among pesticides, diazinon is the cause of the second most documented avian mortality incidents. The majority of incidents on known sites have occurred on lawns and other turf, but incidents have also been reported on a variety of other residential and agricultural sites. Many documented bird kills have occurred on (residential) turf sites. As part of the mitigation required in the December 2000 Memorandum of Agreement signed by the diazinon technical registrants, outdoor, non-agricultural uses (including home and garden, lawn, and turf sites) will be phased out and cancelled by December 31, 2004. The Agency believes that these new use restrictions will significantly reduce risk to birds. However, bird kills have also been reported on agricultural sites.

By dietary and oral routes, diazinon is classified as moderately acutely toxic to small mammals and is, therefore, considerably less toxic to mammals than to birds. In addition, diazinon has demonstrated chronic toxicity to mammals at low levels. There are no wild mammal incident reports in the Ecological Incident Information System (EIS) that clearly document diazinon as the cause of death, either directly or through scavenging the carcass of a bird or other organism killed by diazinon.

#### **b. Aquatic Organisms**

Because of diazinon's widespread use and documented presence in water bodies at concentrations of concern to aquatic life, there is a high level of certainty that aquatic organisms can be exposed to potentially toxic levels of diazinon in surface water. Since diazinon and its major degradate oxydimeton-methyl are mobile and persistent in the environment, and found at significant levels in surface waters; it is quite probable that they will be available in quantity and for times that will exceed acute and chronic toxicity endpoints. Aquatic invertebrates are highly sensitive to diazinon on an acute and chronic basis. Measured levels of diazinon from monitoring studies exceed lethal levels, and populations of invertebrates may be severely reduced or eliminated in these areas. Populations of aquatic invertebrates may recover over time but their lowered numbers can potentially have an effect on the health of animals that prey on them and the overall health of the aquatic ecosystem prior to the introduction of the toxicant.

Although diazinon does not appear to be as acutely toxic to fish as it is to freshwater aquatic invertebrates, the EECs from the water modeling are within the range of acute toxicity to fish for some application rates. Acute mortality to fish is thus a possibility, even though there are no reported fish kill incidents which have been clearly linked to diazinon. Following acute exposure to diazinon, fish have exhibited lethargy when undisturbed, abnormal forward extension of the pectoral fins, darkened areas on the posterior part of the body, and when startled, sudden rapid swimming in circles followed by severe muscular contractions. Chronic RQs indicate that chronic effects to fish are clearly possible. There are reports of reduced reproduction rates, malformed fry, and lowered cholinesterase levels in fish exposed to low levels of organophosphates in water.

Studies on sublethal effects indicate that diazinon inhibits olfactory function in salmon. Salmon exposed to environmentally relevant concentrations were significantly less cognizant of a threat of predation and had diminished ability in detecting natal waters. Sublethal effects including lethargy and unusual movements in the water stemming from scoliosis, lordosis and poor fin coordination are likely to increase vulnerability to predation..

There is high certainty that in all urban and suburban areas where diazinon is applied outdoors and where irrigation or rainfall cause runoff, there will be negative impacts on aquatic biota from the diazinon use. The Agency believes that the phase out and eventual cancellation of outdoor, non-agricultural uses by December 31, 2004 will significantly reduce the amount of diazinon contamination in aquatic environments. However, runoff from treatment of agricultural sites has also been linked to aquatic contamination.

In conclusion, diazinon use has been shown to affect terrestrial and aquatic wildlife. The risk assessment shows high risk to avian species and this conclusion is supported by bird kill incidents. Although most bird incidents are linked to residential and turf uses, agricultural uses have also caused adverse effects to birds.

To date, diazinon has been detected in the rivers, creeks, and/or streams of 30 states and the District of Columbia. Environmental fate data predict that water contamination will occur from diazinon use. Because of diazinon's widespread use and documented widespread presence in water bodies at concentrations of concern to aquatic life, there is a high level of certainty that aquatic organisms will be exposed to potentially toxic levels of diazinon in surface water.

#### **IV. Interim Risk Management and Reregistration Decision**

##### **A. Determination of Interim Reregistration Eligibility**

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient diazinon, as well as a diazinon-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient diazinon, EPA has sufficient information on the human health and ecological effects of diazinon to make interim decisions as part of the tolerance reassessment process under FFDCFA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that agricultural use of diazinon, based on

currently approved labeling, pose occupational and ecological risks. However, the Agency believes that these risks can likely be acceptably mitigated through changes to pesticide labeling and formulations. Accordingly, the Agency has determined that products containing diazinon are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this interim decision (ii) the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. Label changes are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of diazinon and lists the submitted studies that the Agency found acceptable. The additional data that the Agency intends to require are described in Section V.

Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of diazinon. Based on its current evaluation of diazinon alone, the Agency has determined that diazinon products, when used in accordance with the current labeling, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of diazinon.

The Agency will address any outstanding risk concerns when the cumulative assessment is conducted. For diazinon, if all changes outlined in this document are incorporated into the labels, all current risks identified in this document will be acceptably mitigated. But because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for diazinon after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate individually and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

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

If the Agency determines, before finalization of the RED, that any of the determinations described in this interim RED are no longer appropriate, the Agency will pursue appropriate action, including, but not limited to, reconsideration of any portion of this interim RED.

## **1. Summary of Phase 5 Comments and Responses**

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket.

Among others, comments were received from the following: pesticide manufacturers (e.g., Makhteshim-Agan of North America Inc., Syngenta Crop Protection Inc., etc.) various local municipal governments (e.g., Seattle City Council, City of Roswell, Georgia, etc.), other government agencies (e.g., USDA, Texas Department of Agriculture, etc.), agricultural groups (e.g., National Potato Council, Almond Hullers & Processors Associated, etc.), environmental advocacy groups (e.g., American Bird Conservancy, Washington Toxics Coalition, etc.), regional water quality groups (e.g., California Regional Water Quality Board, California Stormwater Quality Task Force, etc.), and private citizens.

Many of the municipal governments, environmental advocacy groups, and private citizens commented in favor of further restrictions on diazinon use. Agricultural groups tended to stress the benefits of diazinon for their crops. Many parties provided EPA with data or information on the use of diazinon.

### **B. Regulatory Position**

#### **1. FQPA Assessment**

##### **a. “Risk Cup” Determination**

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

EPA has determined that risk from exposure to diazinon is within its own “risk cup.” In other words, if diazinon did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for diazinon meet the FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water. Results of this aggregate assessment indicate that the

human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to diazinon “fit” within the individual risk cup. Therefore, the diazinon tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered.

**b. Tolerance Summary**

In the individual assessment, tolerances for residues of diazinon in/on plant commodities [40 CFR §180.153] are presently expressed in terms of the parent compound only (*O,O*-diethyl *O*-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl]phosphorothioate).

**Table 17. Tolerance Summary for Diazinon.**

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment
<b>Tolerances Listed Under 40 CFR § 180.153</b>			
Alfalfa, fresh	40.0	NA	propose revocation; no registered uses
Alfalfa, hay	10.0	NA	propose revocation; no registered uses
Almonds	0.5	0.5	
Almonds, hulls	3.0	3.0	
Apples	0.5	0.5	
Apricots	0.5	0.5	
Bananas	0.2	0.2	NMT 0.1 ppm shall be present in the pulp after peel is removed
Beans, guar	0.1	0.1	propose revocation; no registered uses
Beans, lima	0.5	0.5	
Beans, snap	0.5	0.5	
Beets, roots	0.75	0.75	
Beets, sugar, roots	0.5	0.5	
Beets, sugar, tops	10.0	10.0	
Beets, tops	0.7	0.7	
Blackberries	0.5	0.5	
Blueberries	0.5	0.5	
Boysenberries	0.5	0.5	
Carrots	0.75	0.75	
Cattle, fat	0.7	0.5	pre-slaughter application
Cattle, meat	0.7	0.7	fat basis, pre-slaughter application; proposed for revocation on 7/11/2002
Cattle, mbyp	0.7	0.7	fat basis, pre-slaughter application; proposed for revocation on 7/11/2002

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment
<b>Celery</b>	0.7	0.7	
<b>Cherries</b>	0.75	0.75	
<b>Chicory, red (tops)</b>	0.7	0.7	also known as radicchio
<b>Citrus</b>	0.7	0.7	
<b>Clover (fresh)</b>	40.0	NA	propose revocation; no registered uses
<b>Clover, hay</b>	10.0	NA	propose revocation; no registered uses
<b>Coffee beans</b>	0.2	NA	propose revocation; no registered uses
<b>Corn, forage</b>	40.0	40.0	
<b>Corn (sweet K=CWHR)</b>	0.7	0.7	
<b>Cottonseed</b>	0.2	NA	propose revocation; no registered uses
<b>Cowpeas</b>	0.1	NA	propose revocation; no registered uses
<b>Cowpeas, forage</b>	0.1	NA	propose revocation; no registered uses
<b>Cranberries</b>	0.5	0.5	
<b>Cucumbers</b>	0.75	0.75	
<b>Dandelions</b>	0.7	NA	propose revocation; no registered uses
<b>Dewberries</b>	0.5	0.5	
<b>Endive (escarole)</b>	0.7	0.7	
<b>Figs</b>	0.5	0.5	
<b>Filberts</b>	0.5	0.5	
<b>Ginseng</b>	0.75	0.75	
<b>Grapes</b>	0.75	0.75	
<b>Hops</b>	0.75	0.75	
<b>Kiwi fruit</b>	0.75	NA	propose revocation; no registered uses
<b>Lespedeza</b>	1.0	NA	propose revocation; no registered uses
<b>Lettuce</b>	0.7	0.7	
<b>Loganberries</b>	0.75	0.75	
<b>Melons</b>	0.75	0.75	
<b>Mushrooms</b>	0.75	0.75	
<b>Nectarines</b>	0.5	0.5	
<b>Olives</b>	1.0	NA	propose revocation; no registered uses
<b>Onions</b>	0.75	0.75	



Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment
Parsley	0.75	0.75	
Parsnips	0.5	0.5	
Peaches	0.7	0.7	
Pears	0.5	0.5	
Peavine, hay	10.0	10.0	
Peavines	25.0	25.0	
Peas with pods	0.5	0.5	determined on peas after removing any shell present when marketed
Peppers	0.5	0.5	
Pineapples	0.5	0.5	
Plums	0.5	0.5	fresh prunes
Potatoes	0.1	0.1	
Potatoes, sweet	0.1	0.1	
Radishes	0.5	0.5	
Raspberries	0.5	0.5	
Rutabagas	0.75	0.75	
Sheep, fat	0.7	0.7	pre-slaughter application
Sheep, meat	0.7	0.7	fat basis; pre-slaughter application
Sheep, mbyb	0.7	0.7	fat basis; pre-slaughter application
Sorghum, forage	10.0	NA	propose revocation; no registered uses
Sorghum, grain	0.75	NA	propose revocation; no registered uses
Spinach	0.7	0.7	
Squash, summer	0.5	0.5	
Squash, winter	0.75	0.75	
Strawberries	0.5	0.5	
Swiss chard	0.7	0.7	
Tomatoes	0.75	0.75	
Turnips, roots	0.5	0.5	
Turnips, tops	0.75	0.75	
Vegetables, leafy	0.7	0.7	Brassica (cole)
Walnuts	0.5	0.5	
Watercress	0.7	0.7	

\* The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon completion of the cumulative risk assessment of all organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data.

The following commodities, for which all uses have been previously canceled and tolerance revocations have been recommended, are not included in this dietary assessment: olives, beans (guar), and cowpeas. The potential for transfer of residues to meat, milk, poultry and eggs from animal feeds have been reassessed. It has been determined that measurable secondary residues in these tissues are not likely as a result of diazinon residues in animal feed items. Dermal treatments are not being supported for any livestock or poultry except cattle (ear tags). Therefore, the following commodities are not included in this dietary assessment: milk, all poultry meats and meat byproducts, eggs, and livestock meats and meat byproducts - except for the meat, meat byproducts and fat of sheep and the fat of beef. Though there is no registered use for dermal treatment of sheep, the tolerance is not being revoked because residues may be found in imported sheep commodities. There are also regulations permitting diazinon applications in food handling and animal feed-handling establishments.

## **2. Endocrine Disruptor Effects**

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

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

## **C. Regulatory Position**

### **1. Labels**

Label amendments, in addition to the existing label requirements, are necessary in order for diazinon products to be eligible for reregistration. Provided the risk mitigation measures identified in this document are adopted, the Agency finds that pesticides containing diazinon are eligible for reregistration, pending consideration of cumulative risks of the organophosphates. These mitigation measures will reduce, but not totally eliminate all risk; however, the Agency believes the benefits of use outweigh the risks that would remain after the implementation of the mitigation measures. The regulatory rationale for each of the mitigation measures outlined below is discussed in Section E. The other mitigation measures are not individually discussed below, but can be found in Section V of this document.

### a. Mitigation for Agricultural Uses

The Agency has identified the following mitigation measures that reduce risks to agricultural workers and wildlife to levels the Agency considers reasonable:

- **Cancellation of all granular registrations.**  
The only exception are two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler. Three other Section 24(c) registrations held by Massachusetts, New Jersey, and Wisconsin will be phased out in 5 years in order to give cranberry growers in these states adequate time to implement cultural practices to control cranberry girdler.  
Granular use on lettuce will only be allowed in California with a five year phase out in order to give lettuce growers adequate time to adapt to liquid application or to find alternatives to diazinon.
- **Deletion of aerial application for all uses.**
- **Deletion of foliar application on all vegetable crops.**  
The only exception will be for treatment of leafhopper on honeydew melons in California.  
  
Foliar treatment on leaf lettuce will only be allowed in California with a five year phase out to give growers adequate time to investigate alternatives to diazinon.
- **Application rate reduction.**  
The maximum rate for ornamentals (except cut flowers) will be reduced from 2 lb ai/acre to 1 lb ai/acre. The maximum granular rate for lettuce (during the five year phase out) will be reduced from 4 lb ai /acre to 1 lb ai/acre.
- **Establishment of crop specific REIs.**  
REIs of 2 days to 18 days will be established for all crops.
- **Cancellation of all seed treatment uses.**  
Five uses will be cancelled: beans (snap), beans (lima), corn (field), corn (sweet), and green peas.
- **Require engineering controls for all uses.**  
All application equipment must use lock and load engineering controls. All wettable powder formulations must be packaged in water soluble bags. Closed cabs are required for all ground equipment.
- **Reduction in the number of applications of diazinon per growing season.**  
On most uses only one application per growing season will be allowed. Crops with dormant season and in season uses (e.g., stone fruits) will have one application per season - for a total of two applications per year. Other exceptions are noted in the Labeling Summary Table in Chapter 5.

- **Application limitations and labeling on orchard crops.**  
For all orchard crops (nuts, stone fruits, pome fruits, etc) with dormant season uses, label language will be added to labeling suggesting that applications should be made every other year unless pest pressures are such that consecutive, annual treatments are necessary.
- **Cancelled uses.**  
Section 3 uses: Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugar beets, walnuts, and watercress. Watercress use will be phased out over 4 years.  
Section 24(c) uses: control of cranberry girdler for grass grown for seed (Oregon); dipping of pineapple seed pieces (Hawaii); drenching around residential fruit trees for control of Mediterranean fruit fly (California).

In light of the necessary adjustments that need to be made, such as replacing equipment and investigating diazinon alternatives, the Agency believes that it is reasonable to allow two years, except as noted above, to put these mitigation measures in place.

#### **D. Benefits Assessment Summary**

Benefits information was required for diazinon based on risks to workers and wildlife. Benefits assessments evaluating the economical and agricultural effects of cancellation of diazinon were prepared for the following crops because over five percent of the crop is treated with diazinon: almonds, apricots, blueberries, broccoli, Brussels sprouts, cabbage, caneberry crop group, carrots, cauliflower, cherries (sweet), cranberries, hops, lettuce, melons, nectarines, onions, peaches, pears, plums, prunes, radishes, strawberries, and tomatoes. These assessments can be found in the diazinon docket and will be posted on OPP's website.

Diazinon is used mainly to control foliar pests (aphids, leafhoppers, mites, scale, etc.) on orchard crops, fruits and vegetables, and soil pests (cutworms, wireworms, root maggots, mole crickets, etc.) on vegetables. Foliar pests on vegetable crops can be controlled with effective, registered alternatives. Certain foliar pests on fruits (e.g., Raspberry Crown Borer on caneberries) and orchard crops (e.g., scale on almonds) cannot be effectively controlled with alternative insecticides. One of diazinon's most important benefits is the control of soil pests in vegetable and certain fruit crops. No effective alternatives are available for control of these soil pests.

#### **E. Regulatory Rationale**

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

## **1. Human Health Risk Mitigation**

### **a. Dietary Mitigation**

#### **(1) Dietary (Food)**

Acute and chronic dietary risk from food alone is below the Agency's level of concern. No mitigation is necessary.

#### **(2) Drinking Water**

Drinking water risk estimates based on a combination of screening level models and monitoring data for ground and surface waters are also below the Agency's level of concern. No mitigation is necessary for dietary risk from drinking water. In general, diazinon has been detected in ground water from a variety of sources including drinking water wells, monitoring wells, and agricultural wells. Also, diazinon is one of the most frequently detected insecticides in surface water in a NAWQA monitoring program. However, the highest monitoring value cited is below the DWLOC, which indicates that the screening level estimates are conservative. Furthermore, the Agency believes that the elimination of residential uses, elimination of aerial applications, reduction in the dormant season use (almonds and other orchard crops), and overall use reduction through other mitigation measures should reduce the amount of diazinon found in ground water and surface water.

### **b. Occupational Risk Mitigation**

#### **(1) Agricultural Uses**

The highest occupational risk for mixers, loaders, and applicators of diazinon is associated with aerial applications because of the amount of product handled. Therefore, eliminating aerial applications removes the handler scenario of greatest concern. Risks to mixers, loaders, and applicators for aerial application are of concern even when engineering controls are factored into the assessment. Short term ARIs (values above one are considered acceptable risk) for aerial application range from 0.037 to 0.30 for mixers/loaders and 0.074 to 0.59 for applicators. When cancellation was proposed to diazinon users and stakeholders, the Agency did not receive any compelling benefits for aerial application. Most diazinon is applied by ground equipment so the aerial prohibition will not pose an undue burden on users.

Deletion of nearly all granular formulations also eliminates a worker scenario of potential concern. Short term ARIs range from 0.24 to 0.90 for applicators. The range in ARIs is directly related to the application rate (higher the rate, lower the ARI). Granulars are basically used to control soil pests and the application rate tends to be high (e.g., 4 lb ai/acre). Given that diazinon liquid formulations are registered for the same uses and pests, and with the same application rates, most occupational risk associated with granulars is not justified by the benefits from their use.

For handlers involved in ground application (the only remaining method of application for diazinon), the use of engineering controls such as closed mixing/loading systems and closed cabs would reduce risks from dermal and inhalation exposures to levels the Agency considers reasonable. To achieve such risk reduction, the closed system must meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], for dermal protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize dripping.

The level of protection resulting from use of these engineering controls cannot be quantified. The Agency is requiring worker exposure studies in order to quantify the additional protection from these engineering controls.

## **(2) Post-Application Risk**

EPA has determined that short-term post application dermal exposures following typical use patterns are associated with diazinon in occupational settings. Intermediate exposures are not anticipated for post application workers. Current REIs for diazinon are 24 hours for fruit and nut crops, vegetable crops, and field crops and 12 hours for ornamentals. In order to reduce all re-entry worker risks for short term exposure, REIs are increased from 2 days (for root vegetables) to 18 days (for nut trees). A range of typical label application rates and the assumption that workers will be exposed for 8 hours/day (the upper bound for some activities) is used in the post application assessment.

One exception is the REI for almonds. Diazinon is applied to almonds only in the dormant season, when no foliage is present. The exposure route of concern for post application is dermal. Based on these two reasons, the REI for almonds is seven days. The 18 day REI remains for hazelnuts, which has in season, foliar uses.

## **2. Environmental Risk Mitigation**

The current use of diazinon poses acute and chronic risks to birds and aquatic wildlife. The mitigation measures that are expected to lower expected risks to wildlife from use of diazinon are: deletion of granular formulations, deletion of seed treatment use, deletion of aerial application, reduction of allowable applications for some crops, and deletion of foliar applications to vegetable crops. This mitigation will reduce, but not entirely eliminate risks to wildlife from diazinon use. Additionally, label language will recommend that growers limit dormant season applications to orchards to every other year.

Because of their widespread use, deletion of granular formulations should have the most significant impact on avian wildlife. Diazinon is highly toxic to birds. The assessed acute avian risk quotients for granular formulations range from 1.08 to 4,725 (see section III B). Almost all granular formulations are pre-plant, soil incorporated. However, not all granules become incorporated, and birds will also forage below the surface of the soil leading to the possible consumption of buried granules.

Elimination of seed treatment will also have an impact on avian wildlife. A diazinon treated seed can contain 2.5 times the amount of diazinon found on a single 14G granule. A single diazinon 14G granule could contain a toxic dose for song birds. Seeds are an attractive food source for birds.

While deleting aerial applications and reducing rate and number of applications do not directly eliminate the assessed risks to wildlife, they do affect the potential for exposure. Deleting aerial application will reduce drift to wildlife areas including water bodies adjacent to the field, and will also lower the amount of area that may be treated at one time. Reduction in application rate and number of applications will reduce total diazinon load to the ecosystem.

### **3. Other Labeling**

In addition to the mitigation measures identified above, the Agency's interim decision documented in this IRED is also based on the incorporation of other use and safety information into the labeling of all end-use products containing diazinon. For the specific labeling statements, refer to Section V of this document

### **4. Endangered Species Statement**

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for interim REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will include consideration of the regulatory changes recommended in this interim RED. 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.

At present, the program is being implemented on an interim basis as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989). A final program, which may be altered from the interim program, will be proposed in a *Federal Register* notice scheduled for publication in 2002.

## 5. Spray Drift Management

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

Until EPA decides upon, and publishes the final label guidance for spray and dust drift, registrants (and applicants) may choose to use the statements proposed in the draft PR notice. Registrants should refer to and read the draft PR notice to obtain a full understanding of the proposed guidance and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

For diazinon labels submitted in response to this document, registrants (and applicants) may also elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.

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

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

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

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

For overhead chemigation:

“Apply only when wind speed is 10 mph or less.”

On all product labels:

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



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

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

“Do not allow this product to drift.”

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

## **V. What Registrants Need to Do**

The Agency has determined that diazinon is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this interim decision; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section V.D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

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

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

- (1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant’s response form); and
- (2) submit any time extension and/or waiver requests with a full written justification.

### **Within the time limit specified in the generic DCI:**

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

Please contact Stephanie Plummer at (703) 305-0076 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:

Document Processing Desk (DCI/SRRD)  
Stephanie Plummer  
US EPA (7508C)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)  
Stephanie Plummer  
Office of Pesticide Programs (7508C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

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

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

- (1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- (2) submit any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:**

- (1) two copies of the confidential statement of formula (EPA Form 8570-4);
- (2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
- (3) five copies of the draft label incorporating all label amendments outlined in Table 18 of this document;
- (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
- (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- (6) the product-specific data responding to the PDCI.

Please contact Venus Eagle at (703) 308-8045 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:

Document Processing Desk (PDCI/PRB)  
Venus Eagle  
US EPA (7508C)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)  
Venus Eagle  
Office of Pesticide Programs (7508C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

## **A. Manufacturing Use Products**

### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of diazinon for the above eligible uses has been reviewed and determined to be substantially complete. However the following data requirements are necessary to confirm the interim reregistration eligibility decision documented in this IRED.

#### Toxicology

- 870.3250 90 - day repeated dose dermal study in rats.

#### Product Chemistry

- 830.6313 Stability
- 830.7050 UV/visible absorption
- Additional product chemistry data for MUPs

#### Residue Chemistry

- 860.1500 Additional residue data required for blueberries, celery, spinach, and Swiss chard.

#### Occupational Exposure

Worker exposure study associated with “super” lock and load systems including:

- 875.1100 Dermal exposure
- 875.1300 Inhalation exposure
- 875.1500 Biological Monitoring.

#### Environmental Fate

- 835.1230 Mobility -- adsorption and desorption studies.
- 835.1410 Laboratory volatility study.
- 835.6100 Terrestrial field dissipation information on diazoxon.

#### Ecological Effects:

- 850.1400 Early life-stage fish study for freshwater fish.
- 850.1500 Fish life cycle study for both freshwater and estuarine/marine species.
- 850.2100 Acute avian oral studies on the degradates, diazoxon and oxypyrimidine.
- 850.2200 Subacute avian dietary studies on the degradates, diazoxon and oxypyrimidine.
- 850.2300 Avian chronic tests on the degradates are reserved pending results of the acute oral and dietary studies.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies. Protocols have been submitted to the Agency and the studies are in progress.

## **2. Labeling for Manufacturing Use Products**

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 18 at the end of this section.

### **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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria, and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

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

#### **2. Labeling for End-Use Products**

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 18.

### **C. Existing Stocks**

The Agency has determined that it is reasonable to allow the growers two years, except where noted above, to adopt the mitigation measures outlined in this IRED. In other words, products bearing the current labels/labeling may continue to be sold for two years.

### **D. Labeling Changes Summary Table**

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

**Table 18. Summary of Labeling Changes for Diazinon**

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
<p>Formulation instructions required on all MUPs</p>	<p>“Only for formulation into an insecticide for the following use(s) [<i>insert only those uses that are being supported by MUP registrant</i>]. After December 31, 2005, this product may not be used to formulate any end-use product labeled for application to mushrooms, including mushroom houses. After December 31, 2007, this product maynot be used to formulate any end-use product labeled for application to watercress. After December 31, 2008, this product may not be used to formulate any end-use product labeled for foliar application to melons, other than honeydew melons. Wettable powder formulations must be marketed in water-soluble packaging. Granular formulations must be marketed in closed loading system (engineering control) packaging. Granular formulations may be labeled for Section 3 product only for preplant soil-incorporated applications to lettuce grown in California and Arizona. After December 31, 2008, this product may not be used to formulate any granular end-use product. In addition, Special Local Need (SLN) registrations are active for granular use on cranberries in Oregon (OR970002), Washington (WA970001 and WA900027), Massachusetts (MA970001), New Jersey (NJ970001), and Wisconsin (WI010001 and WI980003). All other SLNs for granular products expire as soon as possible. The only Special Local Need registrations for granular products allowed to continue after December 31, 2008, are uses on cranberries in Oregon (OR970002) and Washington (WA900027, and WA970001), or replacements thereof. After December 31, 2008, the Special Local Need registrations for cranberries in Massachusetts (MA970001), New Jersey (NJ970001), and Wisconsin (WI010001and WI980003) expire. Registrants should immediately contact the issuing states about changing their SLN labels to reflect theupcoming expiration and should send a copy of the letter to ProductManager 13, Insecticide Branch, Registration Division (7505C) in EPA’s Office of Pesticide Programs.”</p>	<p>Directions for Use</p>
<p>One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.</p>	<p>“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).”</p> <p>“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).”</p>	<p>Directions for Use</p>

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>“This pesticide is highly toxic to birds, fish and aquatic organisms, and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and, the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.”</p>	Directions for Use
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide (excluding cattle ear tags)	<p>“RESTRICTED USE PESTICIDE”</p> <p>“Due to Avian and Aquatic Toxicity”</p> <p>“For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator’s certification.”</p>	Top of front panel.
Handler PPE considerations	<p>Note the following information when preparing labeling for all end use products:</p> <p>For <b>sole active ingredient</b> end-use products that contain diazinon the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For <b>multiple active ingredient</b> end-use products that contain diazinon, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	Precautionary Statements Under PPE Requirements

Description	Amended Labeling Language	Placement on Label
<p>Handler PPE requirements for wettable powder formulations in water soluble packaging and liquid formulations</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers using engineering controls must wear:  Long-sleeved shirt and long pants  Shoes plus socks,  Chemical-resistant gloves, if mixing or loading  Chemical resistant apron, if mixing or loading</p> <p>See engineering controls for additional requirements.</p> <p>Handlers performing tasks, such as cleaning equipment or spill clean-up, for which engineering controls are not feasible must wear:  Coveralls over long-sleeved shirt and long pants,  Chemical-resistant gloves,  Chemical resistant shoes footwear plus socks,  Chemical-resistant apron, if exposed to the concentrate.  A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or HE prefilter.”</p> <p><i>(Note: Drop the N type prefilter from the respirator statement if the pesticide product contains or is used with oil.)</i></p>	<p>Immediately following/below  Precautionary Statements:  Hazards to Humans and  Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>Handler PPE requirements for granular formulations in closed loading (engineering control) system packaging</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F, G or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers using engineering controls must wear:  Long-sleeved shirt and long pants  Shoes plus socks,  Chemical-resistant gloves, if loading  Chemical-resistant apron, if loading</p> <p>See engineering controls for additional requirements.</p> <p>Handlers performing tasks, such as cleaning equipment or spill clean-up, for which engineering controls are not feasible must wear:  Coveralls over long-sleeved shirt and long pants,  Chemical-resistant gloves,  Chemical resistant footwear plus socks, and  A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or HE prefilter.”</p>	<p>Immediately following/below  Precautionary Statements:  Hazards to Humans and  Domestic Animals</p>
<p>User Safety Requirements</p>	<p>“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.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.”</p>	<p>Precautionary Statements:  Hazards to Humans and  Domestic Animals  immediately following the  PPE requirements</p>



Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for liquid formulations (Except as specified, all mixers, loaders, applicators, and flaggers must use engineering controls to mix, load, and apply diazinon products.)</p>	<p>“Engineering Controls:  Mixer and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides that provides dermal and inhalation protection [40 CFR 170.240(d)(4)], and must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required for mixers/loaders using engineering controls;</li> <li>-- wear protective eyewear, if the system operates under pressure; and</li> <li>-- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and the respirator specified in the PPE section of this labeling for handlers not using engineering controls.</li> </ul> <p>Applicators using motorized ground equipment and flaggers supporting aerial applications to lettuce must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling for handlers using engineering controls;</li> <li>-- <i>either</i> wear the respirator specified for handlers not using engineering controls <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers not using engineering controls;</li> <li>-- be provided, and have immediately available for use in an emergency when they must exit the cab in the treated area, coveralls, chemical-resistant footwear and – if not already using one – the respirator specified for handlers not using engineering controls;</li> <li>-- take off any PPE that was worn in the treated area before reentering the cab, and</li> <li>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.</li> </ul> <p>EXCEPTION: For applications to apples and lettuce, see directions for use for a special exception to these engineering controls requirements.</p> <p>Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. When entering or leaving an aircraft contaminated with pesticide residues, pilots must wear chemical-resistant gloves and must store used gloves in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit.</p> <p>Note: aerial applications are permitted only on lettuce.”</p>	<p>Precautionary Statements:  Hazards to Humans and Domestic Animals  immediately following the User Safety Requirements.</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for wettable powder (WP) formulations in water-soluble packaging (Except as specified, all mixers, loaders, applicators, and flaggers must use engineering controls to mix, load, and apply diazinon products.)</p>	<p>“Engineering Controls</p> <p>Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required for mixers/loaders using engineering controls; and</li> <li>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and the respirator specified for handlers not using engineering controls.</li> </ul> <p>Applicators using motorized ground equipment and flaggers supporting aerial applications to lettuce must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling for handlers using engineering controls;</li> <li>-- <i>either</i> wear the respirator specified for handlers not using engineering controls <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers not using engineering controls;</li> <li>-- be provided, and have immediately available for use in an emergency when they must exit the cab in the treated area, coveralls, chemical-resistant footwear and – if not already using one – the respirator specified for handlers not using engineering controls;</li> <li>-- take off any PPE that was worn in the treated area before reentering the cab, and</li> <li>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.</li> </ul> <p>EXCEPTION: For applications to apples and lettuce, see directions for use for a special exception to these engineering controls requirements.</p> <p>Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. When entering or leaving an aircraft contaminated with pesticide residues, pilots must wear chemical-resistant gloves and must store used gloves in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit.</p> <p>Note: aerial applications are permitted only on lettuce.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the User Safety Requirements.</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for granular formulations (Except as specified, all loaders and applicators must use engineering controls to load and apply diazinon products.)</p>	<p>“Engineering Controls</p> <p>This product is formulated into a (<i>registrant to insert the trade name of the closed system in which the product is marketed</i>) system that meets the definition of a closed loading system in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Loaders using the closed loading system packaging must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required for loaders using engineering controls; and</li> <li>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and the respirator specified for handlers not using engineering controls.</li> </ul> <p>Applicators using motorized ground equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling for handlers using engineering controls;</li> <li>-- <i>either</i> wear the respirator specified for handlers not using engineering controls <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers not using engineering controls;</li> <li>-- be provided, and have immediately available for use in an emergency when they must exit the cab in the treated area, coveralls, chemical-resistant footwear and – if not already using one – the respirator specified for handlers not using engineering controls;</li> <li>-- take off any PPE that was worn in the treated area before reentering the cab, and</li> <li>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” <p>EXCEPTION: For applications to lettuce, see directions for use for a special exception to these engineering controls requirements.</p> </li></ul>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the User Safety Requirements.</p>

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>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.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards (liquid and wettable powder products)	<p><b>Environmental Hazards</b></p> <p>“This product is highly toxic to birds, fish and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed. Do not exceed maximum permitted label rates. Rates above those recommended significantly increase potential hazards to birds, especially waterfowl. Keep out of lakes, streams, ponds, tidal marshes and estuaries. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Shrimp and crab may be killed at application rates recommended on this label. Do not apply where fish, shrimp, crab, and other aquatic life are important resources. Do not contaminate water by cleaning of equipment or disposal of equipment wash water. This pesticide is highly toxic to bees exposed to direct treatment or to residues on blooming crops or weeds. Do not apply this pesticide or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”</p>	<p>Precautionary Statements immediately following the User Safety Recommendations</p>
Environmental Hazards (granular products)	<p><b>Environmental Hazards</b></p> <p>“This product is highly toxic to birds, fish and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed. Do not exceed maximum permitted label rates. Rates above those recommended significantly increase potential hazards to birds, especially waterfowl. Avoid overlapping granules. Collect or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Keep out of lakes, streams, ponds, tidal marshes and estuaries. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Shrimp and crab may be killed at application rates recommended on this label. Do not apply where fish, shrimp, crab, and other aquatic life are important resources. Do not contaminate water by cleaning of equipment or disposal of equipment wash water.”</p>	

Description	Amended Labeling Language	Placement on Label
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Directions for Use directly above the Agricultural Use Box.
Early Re-entry Personal Protective Equipment established by the RED	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>– coveralls worn over long-sleeve shirt and long pants,</li> <li>– chemical-resistant gloves made of any waterproof material,</li> <li>– chemical-resistant footwear plus socks, and</li> <li>– chemical-resistant headgear, if overhead exposures.”</li> </ul>	Directions for Use, Agricultural Use Requirements Box
Notification Requirements	“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.”	Directions for Use, Agricultural Use Application Restrictions Labels must be amended to reflect the following application restrictions which supersede, or are in addition to, Place in the Directions for Use under Application Instructions for Each Crop.

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><b>Apples:</b> Delete: all pests and directions for use except for Woolly Apple Aphid and San Jose Scale. Add: – “Maximum of two applications per year, either one dormant and one foliar application, or two foliar applications.” – “EXCEPTION for Airblast Applications to Apples: When application using enclosed-cab airblast equipment is not feasible in apple orchards, applicators are permitted to use open-cab airblast equipment, PROVIDED they are wearing chemical-resistant headgear AND the personal protective equipment specified in this labeling for handlers not using engineering controls .” – “REI is 4 days.”</p> <p><b>Apricots:</b> Delete: all references to multiple applications per season. Add: – “Maximum of one application during the growing season. Apply every other year, unless pest infestations can be controlled only with consecutive annual treatments.” – “Maximum of one application during the dormant season.” – “REI is 4 days.”</p> <p><b>Blueberries:</b> Delete: all references to multiple applications per season. Add: – “Maximum of one application per year for foliar pests.” – “Maximum of one application per year for fire ant control.” – “REI is 5 days.”</p> <p><b>Caneberries:</b> Delete: -- all pests except Raspberry Fruitworm and Raspberry Crown Borer; -- all references to multiple applications per season. Add: – “Maximum of one application per year.” – “REI is 5 days.”</p>	Place in the Directions for Use under Application Instructions for Each Crop.

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><b>Cherries:</b> Delete: Directions for a single supplemental post-harvest spray. Add: – “Maximum of one application during the growing season. Apply every other growing season, unless pest infestations can be controlled only with consecutive annual treatments.” – “Maximum of one application during the dormant season.” – “REI is 4 days.”</p> <p><b>Cranberries:</b> <i>Liquid formulations</i> Delete: any reference that allows more than three applications per growing season. Add: – “Maximum of three applications per year.” – “REI is 5 days.”</p> <p><i>Granular formulations (SLN registrations)</i> Delete: any reference that allows multiple applications per growing season. Add: – “Maximum of one application per year.” – “REI is 5 days.” – The current Section 24(c) Special Local Need (SLN) registrations in Massachusetts (MA970001), New Jersey (NJ970001), and Wisconsin (WI010001, and WI980003) will expire after December 31, 2008. Only the current registrations in Oregon (OR970002) and Washington (WA900027, and WA970001) will be allowed to continue after December 31, 2008. Registrants should contact the issuing state about changing their SLN labels to reflect the upcoming expiration and should send a copy of the letter to Product Manager 13, Insecticide Branch, Registration Division (7505C) in EPA’s Office of Pesticide Programs.</p> <p><b>Figs:</b> Delete: all references to multiple applications per season. Add: – “Maximum of one application per year.” – “REI is 4 days.”</p>	Place in the Directions for Use under Application Instructions for Each Crop.

Description	Amended Labeling Language	Placement on Label
	<p><b>Filberts (Hazelnuts):</b>  Delete: all references to multiple applications per season.  Add:  – “Maximum of one application per year.”  – “REI is 18 days.”</p> <p><b>Nectarines, Peaches:</b>  Delete: all references to multiple applications per season.  Add:  – “Maximum of one application during the growing season. Apply every other year, unless pest infestations can be controlled only with consecutive annual treatments.”  – “Maximum of one application during the dormant season.”  – “REI is 4 days.”</p> <p><b>Ornamentals:</b>  Change: maximum application rate from 2 lb ai/A to 1 lb ai/A.  Delete: all references to multiple applications per season.  Add:  – “Maximum of one foliar application per crop.”  – “REI is 7 days for flowers and other commercial ornamentals grown for cutting.”  – “REI is 2 days for all other commercial ornamentals.”  – Application is permitted only on commercial ornamentals grown outdoors in nurseries.</p> <p><b>Pears:</b>  Delete: all references to multiple applications per season.  Add:  – “Maximum of one application during the growing season. Apply every other year, unless pest infestations can be controlled only with consecutive annual treatments.”  – “Maximum of one application during the dormant season.”  – “REI is 4 days.”</p>	



Description	Amended Labeling Language	Placement on Label
	<p><b>Pineapples:</b>  Add:  – “Maximum of two applications per year.”  – “REI is 4 days.”</p> <p><b>Plums/Prunes:</b>  Delete: all references to multiple applications per season.  Add:  – “Maximum of one application during the growing season. Apply every other year, unless pest infestations can be controlled only with consecutive annual treatments.”  – “Maximum of one application during the dormant season.”  – “REI is 4 days.”</p> <p><b>Strawberries:</b>  Delete: all references to multiple applications.  Add:  – “Maximum of one foliar application per crop.”  – “Maximum of one soil application per crop.”  – “REI is 3 days.”</p>	

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><b>Beans (Succulent), Beets (Red), Broccoli, Brussels Sprouts, Cabbage, Carrots, Cauliflower, Collards, Endive, Kale, Mustard Greens, Onions, Peas (Succulent), Radishes, Rutabagas, Spinach, Tomatoes:</b></p> <p>Delete:</p> <ul style="list-style-type: none"> <li>- all foliar pests and associated directions for use, including PHIs.</li> <li>- all references to multiple applications.</li> </ul> <p>Add:</p> <ul style="list-style-type: none"> <li>- “Maximum of one soil application per year.”</li> <li>- “REI is 3 days for beans.”</li> <li>- “REI is 3 days for beets (red).”</li> <li>- “REI is 4 days for broccoli.”</li> <li>- “REI is 4 days for Brussels sprouts.”</li> <li>- “REI is 4 days for cabbage.”</li> <li>- “REI is 3 days for carrots.”</li> <li>- “REI is 4 days for cauliflower.”</li> <li>- “REI is 4 days for collards.”</li> <li>- “REI is 4 days for endive.”</li> <li>- “REI is 4 days for kale.”</li> <li>- “REI is 4 days for mustard greens.”</li> <li>- “REI is 3 days for onions.”</li> <li>- “REI is 3 days for peas.”</li> <li>- “REI is 3 days for radishes.”</li> <li>- “REI is 4 days for rutabagas.”</li> <li>- “REI is 3 days for spinach.”</li> <li>- “REI is 2 days for tomatoes.”</li> </ul>	Place in the Directions for Use under Application Instructions for Each Crop.

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><b>Ginseng</b> Delete: – all soil pests and associated directions for use. – all references to multiple applications. Add: – “Maximum of one foliar application per year.” – “REI is 3 days.”</p> <p><b>Lettuce:</b> <i>Liquid and Wettable Powder formulations:</i> Change maximum application rate from 4 lbs ai/A to 2 lbs ai/A. Add: – “Maximum of one foliar application per crop.” – “Aerial application is permitted.” – “EXCEPTION for Lettuce: applicators applying to lettuce are permitted to use open-cab equipment, PROVIDED they are wearing chemical-resistant the personal protective equipment specified in this labeling for handlers not using engineering controls.” – “REI is 3 days.”</p> <p><i>Granular Formulations (California and Arizona only)</i> Change maximum application rate from 4 lbs ai/A to 2 lbs ai/A. Add: – “Maximum of one at-plant soil application per crop.” – “EXCEPTION for Lettuce: applicators applying to lettuce are permitted to use open-cab equipment, PROVIDED they are wearing chemical-resistant the personal protective equipment specified in this labeling for handlers not using engineering controls.” – “REI is 3 days.”</p>	Place in the Directions for Use under Application Instructions for Each Crop.

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><b>Melons:</b>  <i>For melons:</i>  Add:  – “Maximum of one soil application per year.”  – “Maximum of one foliar application per year.”  – “REI is 3 days.”</p> <p><b>Watercress:</b>  Add:  “Maximum of one foliar application per season.”  – “REI is 4 days.”</p> <p><b>Trunk Wraps:</b>  On labels that contain use directions for trunk wraps, add:  – “Use limited to commercial agriculture and horticulture only. Use in residential settings is prohibited.”</p>	Place in the Directions for Use under Application Instructions for Each Crop.
Use Deletions	<p><b>Chinese Broccoli, Chinese Cabbage, Chinese Mustard, Chinese Radish, Corn, Grapes, Hops, Sugar Beets, Walnuts:</b>  Delete all of the above uses from labels for liquid or wettable powder products.</p> <p><b>Beets (red, table), Broccoli, Brussels Sprouts, Cabbage, Carrots, Cauliflower, Collards, Endive (Escarole), Ginseng, Kale, Melons, Mustard, Onions (bulb, green), Radishes, Spinach, Sugar Beets, Sweet Corn, Tomatoes:</b>  Delete all of the above uses from labels for granular products.</p> <p><b>Seed Treatment Uses:</b>  Delete all seed treatment uses, including beans (snap, lima), corn (field, sweet), and peas (green).</p>	Use Deletions

Description	Amended Labeling Language	Placement on Label
<p>Application Restrictions on Section 24 (c) – Special Local Needs labels.</p>	<p><b>SPECIAL LOCAL NEEDS LABELS:</b>  <b>Celery, Cucumbers, Parsley, Parsnips, Peppers, Irish Potatoes, Squash (winter and summer), Sweet Potatoes, Swiss Chard, Turnips (roots and tops):</b>  Delete:  – all foliar pests and associated directions for use.  – all references to multiple applications.  Add:  – “Maximum of one soil application per growing season.”  – “REI is 3 days for celery.”  – “REI is 3 days for cucumbers.”  – “REI is 3 days for parsley.”  – “REI is 2 days for peppers.”  – “REI is 3 days for Irish potatoes.”  – “REI is 3 days for sweet potatoes.”  – “REI is 3 days for Swiss chard.”  – “REI is 3 days for turnips (roots and tops).”  – “REI is 3 days for parsnips.”</p> <p>The following SLN uses/registrations will not be allowed to continue:  – Dipping of pineapple seed pieces (HI770010 and HI970005).  – Grass grown for seed (OR880001).  – All uses of granular formulations, except the cranberry uses (described under application restrictions to cranberries) in Massachusetts, New Jersey, Wisconsin, Oregon, and Washington.</p> <p>Registrants should immediately contact the issuing states about the expiration and send a copy of the letter to Product Manager 13, Insecticide Branch, Registration Division (7505C) in EPA’s Office of Pesticide Programs.</p>	<p>Place in the Directions for Use under Application Instructions for Each Crop.</p>
<p>Spray Drift Labeling</p>	<p>[Note to registrants: The Agency is currently working with stakeholders to develop appropriate generic label statements to address spray drift risk. Once this process has been completed, diazinon product labels will need to be revised to include this additional language. No labeling changes with respect to drift are needed at this time.]</p>	<p>Directions for Use in General Precautions and Restrictions</p>

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

## **VI. Related Documents and How to Access Them**

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

The docket initially contained preliminary risk assessments and related documents as of May 19, 2000. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on December 5, 2000.

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

<http://www.epa.gov/oppsrrd1/op/diazinon.htm>

## VII. APPENDICES

**Appendix A. Food/Feed Use Patterns Subject to Reregistration for Diazinon (Case 0238).**

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Food/Feed Crop Uses</b>				
<b>Almonds (only in CA)</b>				
Broadcast dormant application Ground equipment	3 lb/A	1	Not applicable (NA)	A PHI is not specified. Do not apply more than 3 lb ai/A/season. Dormant season only.
<b>Apples</b>				
Broadcast foliar application Ground equipment	2 lb/A	1	14	A 21-day PHI is specified. Do not apply more than 2 lb ai/A/season. Use only to control wooly apple aphid.
<b>Apricots</b>				
Broadcast dormant application Ground equipment	2 lb/A	1	NA	A 21-day PHI is specified. Do not apply more than 2 lb ai/A/season. Dormant season only
<b>Bananas</b>				
Broadcast foliar application Ground equipment	0.5 lb/A	6	7	A 28-day PHI is specified. Use large droplet producing nozzles to reduce spray drift. Special local needs label for Hawaii
<b>Beets, Red</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified.
<b>Blueberries</b>				
Broadcast foliar application Ground equipment	0.5 lb/A	1	NA	A 7-day PHI is specified. Do not apply more than 1 lb ai/A/year.
Fire-ant mound application Ground equipment	0.5 lb/A	1	NA	



Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Broccoli</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 7-day PHI is specified.
<b>Brussels Sprouts</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	<b>A 7-day PHI is specified.</b>
<b>Cabbage</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 21-day PHI is specified.
<b>Caneberries (Blackberries, Boysenberries, Dewberries, Loganberries, Raspberries) (only in CA, OR, and WA)</b>				
Broadcast dormant application Ground equipment	2 lb/A	1	NA	A 7-day PHI is specified.
<b>Carrots</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 21-day PHI is specified.
<b>Cauliflower</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 7-day PHI is specified.
<b>Celery</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	Special Local Needs labels

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Cherries</b>				
Broadcast dormant application Ground equipment	2 lb/A	1	NA	A 21-day PHI is specified. Do not apply more than 4 lb ai/A/year.
Broadcast foliar application Ground equipment	2 lb/A	1	NA	
<b>Collards</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 10-day PHI is specified. Do not apply more than 4 lb ai/A/season. Special Local Needs label for Texas
<b>Cranberries (Oregon and Washington)</b>				
Broadcast foliar application Ground equipment	2 or 3 lb/A	3	14	A 7-day PHI is specified. Do not apply more than 12 lb ai/A/year. Use is on Special Local Needs label for Oregon and Washington. Ground applications include chemigation using sprinkler irrigation systems; no other type of irrigation systems are permitted. For granular formulation: assure that granules fall into vines and are watered by sprinkler irrigation or rainfall.
Granular formulation Broadcast foliar application Ground equipment	3 lb/A	1	NA	
<b>Cucumbers</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 7-day PHI is specified. Special Local Needs labels
<b>Endive (Escarole)</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified.

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Figs</b>				
Broadcast foliar application Ground equipment	0.5 lb/A	1	NA	
<b>Filberts</b>				
Broadcast foliar application Ground equipment	0.5 lb/A	1	NA	
<b>Ginseng</b>				
Broadcast foliar application Ground equipment	0.5 lb/A	1	NA	A 30-day PHI is specified. Do not apply during flowering of 3 or 4 year old crops. Do not graze treated areas or feed treated forage to livestock.
<b>Kale</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 10-day PHI is specified. Special Local Needs label for Texas
<b>Lettuce</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified.
<b>Lettuce (California only)</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified. Do not apply more than 4.5 lb ai/A/season. Foliar applications are allowed in California only. The foliar use will be phased out in 2007.
Broadcast foliar application Ground equipment	0.5 lb/A	1	NA	
Granular use Broadcast pre-plant soil incorporated Ground equipment	1 lb/A	1	NA	If granular is used preplant, do not apply more than 1.5 lb ai/A/season. Granular use is allowed in California only and will be phased out in 2007.

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Melons</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 3-day PHI is specified.
<b>Honeydew Melons (California only)</b>				
Broadcast foliar application Ground equipment	0.75 lb/A	1	NA	A 3-day PHI is specified.
<b>Mustard</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 10-day PHI is specified. Special Local Needs label for Texas
<b>Nectarines and Peaches</b>				
Broadcast dormant application Ground equipment	2 lb/A	1	NA	A 21-day PHI is specified. Do not apply more than 4 lb ai/A/year.
Broadcast foliar application Ground equipment	2 lb/A	1	NA	
<b>Onions (bulb and green)</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified.
<b>Parsley</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	Special Local Needs labels

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Pears</b>				
Broadcast dormant application Ground equipment	2 lb/A	1	NA	A 21-day PHI is specified. Do not apply more than 4 lb ai/A/year.
Broadcast foliar application Ground equipment	2 lb/A	1	NA	
<b>Peas (succulent only)</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 7-day PHI is specified. Vines and hay may be fed to dairy and beef cattle and sheep; a 7-day PHI is specified if forage is to be cut for hay. Special Local Needs labels
<b>Peppers</b>				
Broadcast pre-plant soil incorporated Ground equipment	<b>4 lb/A</b>	1	NA	A 5-day PHI is specified.
<b>Pineapples</b>				
Broadcast foliar application Ground equipment	1 lb/A	2	28	A 7-day PHI is specified. Do not apply more than 2 lb ai/A/growing cycle.
<b>Plums and Prunes</b>				
Broadcast dormant or foliar application Ground equipment	2 lb/A	1	NA	A 21-day PHI is specified. Do not apply more than 4 lb ai/A/year.
Broadcast foliar application Ground equipment	2 lb/A	1	NA	
<b>Potatoes</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 35-day PHI is specified. Special Local Needs labels

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Radishes</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified. Special Local Needs label for Texas
<b>Rutabagas</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified.
<b>Spinach</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified. Special Local Needs label for Texas
<b>Squash, Summer</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 7-day PHI is specified. Special Local Needs labels
<b>Squash, Winter</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 3-day PHI is specified. Special Local Needs labels
<b>Strawberries</b>				
Broadcast pre-plant soil incorporated Ground equipment	1 lb/A	1	NA	A 5-day PHI is specified. Do not apply more than 2 lb ai/A/year.
Broadcast foliar application Ground equipment	1 lb/A	1	NA	

Site Application Type Application Timing Application Equipment	Max. Single Application Rate <sup>a,b</sup> (ai)	Max. # Apps. <sup>c</sup>	Minimum Retreatment Interval (Days)	Use Limitations <sup>d</sup>
<b>Sweet Potatoes</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	
<b>Swiss Chard</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified. Special local needs label for Texas
<b>Tomatoes</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 1-day PHI is specified.
<b>Turnips, Roots and Tops</b>				
Broadcast pre-plant soil incorporated Ground equipment	4 lb/A	1	NA	A 14-day PHI is specified. Special local needs labels

- a Available formulations are 50% Wettable Powder (EPA Reg # 100-460), 4 lb/gal EC (EPA Reg # 100-461), and 4.5 lb/gal SCI (EPA Reg # 100-784). Granular formulation 14% G [EPA Reg # 100-469] is available for use on lettuce only. Granular formulation 14% G (EPA Reg #s NJ950010, OR930006, and MA83000500) are available for use on cranberries only.
- b For use on pears and pineapples only the 50% WP [EPA Reg # 100-460] is available.
- c Maximum number of applications at the maximum single application rate.
- d Other use limitations such as the minimum amount of water used for each application and re-entry interval restrictions are not listed in this table.

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

### GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which 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 if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

**Appendix B. Data Supporting Guideline Requirements for the Reregistration of Diazinon**

New Guideline Number	Old Guideline Number	Description	Use Pattern	Citation(s)
<b>PRODUCT CHEMISTRY</b>				
830.7050	None	UV/Visible Absorption	All	<b>Data Gap</b>
830.6313	63-13	Stability	All	<b>Data Gap</b>
<b>ECOLOGICAL EFFECTS</b>				
850.2100	71-1(a) 71-1(b)	Avian Acute Oral Toxicity	ABCJO	00103959, 0020560, 0160000, 00109015, 40895303, 40895309, 40895305, 40895306, 40895307, <b>Data Gap for degradates<sup>1</sup></b>
850.2200	71-2A	Avian Dietary Toxicity - Quail	ABCJO	00034769, <b>Data Gap for degradates<sup>1</sup></b>
850.2200	71-2B	Avian Dietary Toxicity - Duck	ABCJ	0160000, 40895302, 40895301, 40895305, 40895307, 00034769, 40895308, 00103959, <b>Data Gap for degradates<sup>1</sup></b>
850.2400	71-3	Wild Mammal Toxicity	ABCJ	00238762, 00146179, 41407202, 41407210, 41332609, 41332616, 41137003, 43543901, 41580201, 41535201, 41577401, 41514701, 41511001
850.2300	71-4A	Avian Reproduction - Quail	ABCJ	41322902, <b>data reserved for degradate<sup>2</sup></b>
850.2300	71-4B	Avian Reproduction - Duck	ABCJ	41322901, 104083, <b>data reserved for degradate<sup>2</sup></b>
850.1075	72-1A	Fish Toxicity Bluegill	ABCJ	40910904, 40509802, 40509801, 00103960
850.1075	72-1C	Fish Toxicity Rainbow Trout	ABCJO	00103959
850.1010	72-2A	Invertebrate Toxicity	ABCJO	40509803, 00109022
None	72-3A	Estuarine/Marine Toxicity - Fish	ABCJ	40228401, 40914801
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk (oyster)	ABCJ	40625502
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp	ABCJ	40625501
850.1300	72-4A	Fish- Early Life Stage	ABCJ	40914801, 44244802

New Guideline Number	Old Guideline Number	Description	Use Pattern	Citation(s)
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	ABCJ	44244801
850.1400	72-4C	Early Life-Stage Freshwater Fish	ABCJ	<b>Data Gap</b>
850.1500	72-5	Fish Life Cycle Study	ABCJ	<b>Data Gap</b>
850.4100	122-1A	Terrestrial Plant Toxicity, Tier 1 (Seedling Emergence)	ABCJ	40509805
850.4150	122-1B	Terrestrial Plant Toxicity, Tier 1 (Vegetative Vigor)	ABCJ	40509804
850.4400	122-2	Aquatic Plant Growth	ABCJ	40509806
850.4225	123-1A	Seedling Germination and Seedling Emergence, Tier 2	ABCJ	40803001
850.4250	123-1B	Non-target Terrestrial Plant Phytotoxicity	ABCJ	40803002
850.4400	123-2	Aquatic Plant Growth	ABCJ	40509806
850.3020	141-1	Honey Bee Acute Contact	ABCJ	05004151
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral Toxicity-Rat	ABCJO	41407218
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	ABCJO	41407219
870.1300	81-3	Acute Inhalation Toxicity-Rat	ABCJO	41407220
870.2400	81-4	Primary Eye Irritation-Rabbit	ABCJO	41407221
870.2500	81-5	Primary Skin Irritation	ABCJO	41407222
870.2600	81-6	Dermal Sensitization	ABCJO	41407223, 00232008
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	ABCJO	44132701
870.3200	82-2	21-Day Dermal - Rabbit/Rat	ABCJO	40660807
870.3250	82-3	90-day Subchronic Dermal Toxicity Test, Rat	ABCJO	45184305, <b>Data Gap</b>
870.6200	82-7	Subchronic Neurotoxicity Study	ABCJO	43549302, 43543901
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	ABCJO	41942002
870.4100	83-1B	Chronic Feeding Toxicity -Non-Rodent	ABCJO	41942001
870.4200	83-2A	Oncogenicity - Rat	ABCJO	00073372
870.4200	83-2B	Oncogenicity - Mouse	ABCJO	00073372
870.3700	83-3A	Developmental Toxicity - Rat	ABCJO	00153017
870.3700	83-3B	Developmental Toxicity - Rabbit	ABCJO	00079017
870.3800	83-4	2-Generation Reproduction - Rat	ABCJO	41158101
870.5300	84-2	Gene Mutation Mammalian Cell	ABCJO	41557404, 40660802, 41119701
870.5375	84-2B	Structural Chromosomal Exchange	ABCJO	40660805, 41603201

New Guideline Number	Old Guideline Number	Description	Use Pattern	Citation(s)
870.5915	84-2	In Vivo Sister Chromatid Exchange	ABCJO	41577301, 43060601, 41687701, 41557405
870.6200	81-1A	Acute Neurotoxicity Screening Battery - Rat	ABCJO	43132201, 43132204, 43132203, 44219301
870.7485	85-1	General Metabolism	ABCJO	41108901
870.8700	None	Subchronic Oral Toxicity Test	ABCJO	40815004
<b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b>				
875.2100	132-1A	Foliar Residue Dissipation	ABCJ	44959101
875.2400	133-3	Dermal Passive Dosimetry Exposure	ABCJO	44348801, 44959101
875.2500	133-4	Inhalation Passive Dosimetry Exposure	ABCJO	45184305, 44959101
875.1100	231	Estimation of Dermal Exposure at Outdoor Sites	ABCJO	44972201, 44405802, <b>Data Gap</b>
875.1300	232	Estimation of Inhalation Exposure at Outdoor Sites	ABCJO	44405802, 44972201, <b>Data Gap</b>
875.1500	235	Biological Monitoring	ABCJO	<b>Data Gap</b>
<b>ENVIRONMENTAL FATE</b>				
835.2120	161-1	Hydrolysis	ABCJ	40931101
835.2240	161-2	Photodegradation - Water	ABCJ	40863401
835.2410	161-3	Photodegradation - Soil	ABCJ	00153229
835.4100	162-1	Aerobic Soil Metabolism	ABCJ	44746001
835.4200	162-2	Anaerobic Soil Metabolism	ABC	40028701
835.1230	163-1	Leaching/Adsorption/Desorption	ABCJ	00118032, 42680901, <b>Data Gap</b>
835.1410	163-2	Laboratory Volatilization (from Soil) Study	AB	<b>Data Gap</b>
835.6100	164-1	Terrestrial Field Dissipation	ABC	41320101, 41330102, 41432701, 41432702, 41320103, 41432705, 41432703, 41432704, 41320104, 41320105, 41432706, 41432707, <b>Data Gap</b> <sup>3</sup>
<b>RESIDUE CHEMISTRY</b>				
860.1500	171-4K	<b>Crop Field Trials</b>	AB	
		Blueberries		<b>Data Gap</b>
		Celery		<b>Data Gap</b>
		Spinach		<b>Data Gap</b>
		Swiss Chard		<b>Data Gap</b>

New Guideline Number	Old Guideline Number	Description	Use Pattern	Citation(s)
860.1520	171-4L	<b>Processed Food</b>	AB	
		Figs		44726801
		Watercress		44237101
		Cottonseed Meal		00032881
		Cottonseed Oil		00032881
		Grapes - Juice		41410001
		Grapes - Raisins		41410001
		Pineapples - Juice		42179501
		Pineapples - Juice Concentrate		42179501
		Plums/Prunes - Dried		43274401
		Sugar-Beet-Molasses		41336514
		Tomatoes-Catsup		41336508
		Tomatoes - Juice		41336508
		Tomatoes - Paste		41336508
		Tomatoes - Puree		41336508

## Appendix C. Technical Support Documents

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

The docket initially contained preliminary risk assessments and related documents as of May 19, 2000. EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on January 31, 2001.

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

[www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)

These documents include:

HED Documents:

1. HED's Development of Handler Risks for the Diazinon Risk Benefit Analysis. 1/15/02.
2. Revised HED Product and Residue Chemistry Chapter, 12/01/00
3. Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document
4. Diazinon Refined Anticipated Residues/Acute and Chronic Dietary Risk Assessment (including Beef Fat), 11/14/00
5. Exposure Information by Crop Group
6. Revised Report of the Hazard Identification Assessment Review Committee, 11/30/00
7. Preliminary Health Effects Risk Assessments (Released 5/19/00)
  - Product and Residue Chemistry Chapter
  - Occupational and Residential Exposure and Risk Assessment
  - Refined Anticipated Residues/Acute and Chronic Dietary Risk Assessment
  - Toxicology Chapter
  - Replacement of Human Study Used in Risk Assessments
  - Review of Diazinon Incident Reports
  - Quantitative Usage Analysis

EFED Documents:

1. Final Revised Environmental Fate and Ecological Risk Assessment Chapter for the Reregistration Eligibility Decision on Diazinon. 2-19-02.
2. Revised Science Chapter, 10/00
3. Revised Tier 2 EEC's, 11/14/00
4. Environmental Fate and Effects Water Resource Assessment

BEAD Documents:

1. Benefits Assessment for Diazinon Use in Melons: Watermelon, Honeydew and Cantaloupe, 5/29/02
2. Biological and Economic Analysis of Diazinon on Carrots, 3/6/02
3. Biological and Economic Analysis of Diazinon on Lettuce, 3/13/02
4. Biological and Economic Analysis of Diazinon on Cabbage, 5/22/02
5. Biological and Economic Analysis of Diazinon on Pears, 3/13/02
6. Biological and Economic Analysis of Diazinon on Table Beets, 5/14/02
7. Benefits Assessment for Diazinon Use in Hops: Impact of Cancellation. 7/26/02
8. Cranberry Benefits Assessment for Diazinon Considering Risks for Mixer, Loader, and Applicator. 7/18/02
9. Plum/Prune Benefits Assessment for Diazinon. 5/15/02.
10. Apricot Benefits Assessment for Diazinon. 4/10/02
11. Biological and Economic Analysis of Diazinon on Sweet Cherries: Impacts of Cancellation. 6/14/02
12. Biological and Economic Analysis of Diazinon on Cole Crops, 4/8/02
13. Benefits Assessment for Diazinon Use in Peaches and Nectarines. 4/3/02.
14. Benefits Assessment for Diazinon Use in Lowbush and Highbush Blueberries. 3/12/02.
15. Biological and Economic Analysis of Diazinon on Spinach: Impacts of Cancellation. 8-22-02
16. Benefits Assessment for Diazinon Use in Tomatoes: Impact of Cancellation. 6/7/02.
17. Biological and Economic Analysis of Diazinon on Processed Tomatoes. 6/3/02
18. Biological and Economic Analysis of Diazinon on Strawberries: Impacts of Cancellation. 7-2-02
19. Biological and Economic Analysis of Diazinon on Almonds: 7/24/02.

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

### GUIDE TO APPENDIX D

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at 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. Selection from other sources, including 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)) 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 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 EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

- b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word “received.”
  - (2) Administrative number. The next element immediately following the word “under” is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol “CDL,” which stands for “Company Data Library.” This accession number is in turn followed by an alphabetic suffix, which shows the relative position of the study within the volume.



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- 40815004 Barnes, T. (1988) Diazinon (MG-8): 90-Day Oral Toxicity Study in Dogs: Project ID 882012. Unpublished study prepared by Ciba-Geigy Corp. 647 p.
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## **Appendix E. Generic Data Call-In**

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

## **Appendix F. Product Specific Data Call-In**

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

## **Appendix G. EPA's Batching of Diazinon 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 diazinon 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. Notwithstanding 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.

One hundred and fifty five products were found which contain diazinon as the active ingredient. These products have been placed into four batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical.

- Batch 11: The representative eye studies for this batch should be conducted on EPA Reg. 572-292,9198-62, or 32802-5.
- Batch 12: The representative acute toxicity studies (except primary eye study) should be conducted on the products with the highest percentage of active ingredient. A primary eye irritation study should be conducted on each product listed in this batch.
- Batch 14: EPA Reg. Nos. 3546-27 & 19713-317 may cite data conducted on EPA Reg. No. 6218-69 or 10088-71.
- 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.	% Active Ingredient
	11678-61	92.0
	11678-62	92.0
	100-979	87.0
	100-980	87.0
	10163-263	87.0
	11678-63	87.0
	11678-64	87.0
	19713-523	87.0
	19713-524	87.0
	34822-6	87.0
	47332-4	87.0
	62366-2	87.0



Batch 2	EPA Reg. No.	% Active Ingredient
	100-784	56.0
	100-977	56.0
	10163-241	56.0

Batch 3	EPA Reg. No.	% Active Ingredient
	100-460	50.0
	655-456	50.0
	769-954	50.0
	5905-526	50.0
	10163-163	50.0
	19713-492	50.0
	34704-435	50.0
	51036-108	50.0
	66222-10	50.0

Batch 4	EPA Reg. No.	% Active Ingredient
	100-461	48.0
	655-459	48.0
	769-689	48.0
	769-841	48.0
	829-262	47.5
	1386-599	48.0
	2935-388	48.0
	5481-224	47.5
	5905-248	48.0
	9779-210	48.0
	10163-100	48.0
	19713-91	48.0
	34704-231	48.0
	37915-6	48.0
	51036-71	48.0

Batch 5	EPA Reg. No.	% Active Ingredient
	655-462	48.7
	7401-213	48.0
	66222-9	48.0

Batch 6	EPA Reg. No.	% Active Ingredient
	19713-145	Diazinon: 25.00
	42056-18	Diazinon: 25.00

Batch 7	EPA Reg. No.	% Active Ingredient
	16-157	25.0
	100-456	25.0
	239-2364	25.0
	270-282	25.0
	572-305	25.0
	1386-573	25.0
	7401-216	25.0
	8845-92	25.0
	28293-230	25.0
	33912-1	25.0
	33955-556	25.0

Batch 8	EPA Reg. No.	% Active Ingredient
	16-166	22.4
	100-770	22.4
	239-2643	22.4
	869-231	22.4
	4581-392	23.0
	7401-441	22.4
	59144-28	22.4
	61282-25	22.4

Batch 9	EPA Reg. No.	% Active Ingredient
	100-469	14.3
	655-557	14.3
	10163-104	14.3
	28293-239	14.3
	34704-230	14.0

Batch 10	EPA Reg. No.	% Active Ingredient
	2935-408	14.3
	5905-262	14.3
	19713-95	14.0
	51036-70	14.3

Batch 11	EPA Reg. No.	% Active Ingredient
	16-119	5.00
	100-528	5.00
	192-161	5.00
	228-177	5.00
	239-2479	5.00
	239-2503	5.00
	538-187	4.54
	572-292	5.00
	655-556	5.00
	829-264	5.00
	869-139	5.00
	961-358	5.00
	1386-648	5.00
	8378-32	5.00
	8750-51	5.00
	8845-95	5.00
	8845-101	5.00
	9198-62	5.00
	10163-116	5.00
	10404-23	5.00
	19713-263	5.00

Batch 11	EPA Reg. No.	% Active Ingredient
	28293-199	5.00
	32802-5	5.00
	33955-557	5.00
	34704-57	5.00
	34704-493	5.00
	34911-13	5.00
	34911-23	5.00
	40849-30	5.00
	42057-107	5.00
	51036-93	5.00
	51036-97	5.00
	53883-51	5.00
	53883-54	5.00
	59114-2	5.00

Batch 12	EPA Reg. No.	% Active Ingredient
	16-118	2.00
	100-468	2.00
	228-162	2.10
	239-2375	2.00
	538-92	2.88
	538-204	2.88
	538-254	3.67
	538-258	3.20
	1386-651	2.00
	7401-222	2.00
	8378-12	3.33
	8660-11	3.34
	8780-54	2.10
	8780-55	3.30
	9198-45	3.33
	9688-89	2.00
	10404-14	3.33
	19713-264	2.00
	51036-69	2.00
	53883-46	2.00

Batch 13	EPA Reg. No.	% Active Ingredient
	100-926	2.0
	239-2671	2.0

Batch 14	EPA Reg. No.	% Active Ingredient
	3546-27	Diazinon: 0.50
	6218-69	Diazinon: 0.50
	10088-71	Diazinon: 0.50
	19713-317	Diazinon: 0.50

Batch 15	EPA Reg. No.	% Active Ingredient
	239-2630	0.075
	67572-1	0.058

No Batch	EPA Reg. No.	% Active Ingredient
	239-2619	Diazinon: 0.50
	270-260	Diazinon: 18.00
	829-249	25.00
	769-687	47.50
	1381-165	Diazinon: 15.52
	4691-142	20.00
	4691-148	40.00
	5481-241	Diazinon: 31.60
	5905-474	77.80
	6409-14	Diazinon: 0.500
	7501-112	Diazinon: 15.00
	8780-56	Diazinon: 2.10
	13926-6	6.25
	34704-41	48.00
	39039-3	21.40
	39039-6	Diazinon: 30.00
	42056-11	Diazinon: 15.00
	42057-90	25.00
	45443-1	39.00
	53883-45	25.00

**Appendix H. List of Registrants Sent This Data Call-In**

## Appendix I. List of Available Related Document and Electronically Available Forms

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

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

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

### Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>
8570-27	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>
8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-35	Data Matrix (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>

Pesticide Registration Kit [www.epa.gov/pesticides/registrationkit/](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](http://www.epa.gov/opppmsd1/PR_Notices)



3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
  
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
  - a. Registration Division Personnel Contact List
  - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

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

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

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

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

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

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