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

MEMORANDUM **March 26, 2008**

Subject: Registration Review –Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered species and Drinking Water Assessments for Diazinon (PC Code 057801; DP Barcode D349527)

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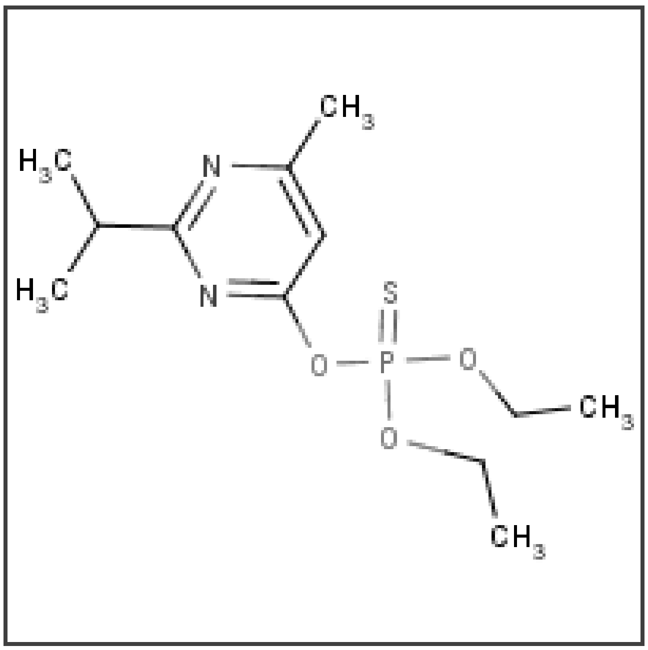
The Environmental Fate and Effects Division (EFED) has completed the preliminary problem formulation (attached) for the ecological risk, environmental fate, endangered species, and drinking water assessments to be conducted as part of the Registration Review of the organophosphate insecticide/acaricide, diazinon (DP Barcode D349527). The problem formulation draws information from both open literature and studies submitted by the technical registrants in response to data requirements. This document is intended to provide an overview of what is currently known regarding the environmental fate and ecological effects associated with diazinon and its degradates and outlines uncertainties regarding attributes of the parent compound and its transformation products. It describes the preliminary ecological risk hypothesis and the processes that will be used during the completion of drinking water and ecological risk assessments in support of registration.

Office of Prevention, Pesticides,
and Toxic Substances

Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species and Drinking Water Assessments in Support of the Registration Review of Diazinon



Diazinon (CAS 333-41-5)

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I. Purpose

The purpose of this problem formulation is to provide an understanding of the environmental fate and ecological effects of the registered uses of diazinon. Diazinon is an organophosphate used as an insecticide and acaricide on a variety of fruit, vegetable, orchard and ornamental crops. This document will provide a plan for analyzing data relevant to diazinon and for conducting environmental fate and ecological risk, endangered species and drinking water assessments for its registered uses. Additionally, this problem formulation is intended to identify data gaps, uncertainties and potential assumptions used to address those uncertainties relative to characterizing the ecological risk associated with the registered uses of diazinon.

II. Problem Formulation

A. Nature of Regulatory Action

The Food Quality Protection Act of 1996 mandated the EPA to implement a new program for assessing the risks of pesticides, *i.e.*, registration review (http://www.epa.gov/oppsrrd1/registration_review/). All pesticides distributed or sold in the United States generally must be registered by EPA. The decision to register a pesticide is based on the consideration of scientific data and other factors showing that it will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The registration review program is intended to ensure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to ensure that as change occurs, products in the marketplace can be used safely.

As part of the implementation of the new Registration Review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Agency is beginning is evaluation to determine whether diazinon continues to meet the FIFRA standard for registration. This problem formulation for the environmental fate and ecological risk assessment chapter in support of the registration review is intended for the initial docket opening the public phase of the review process.

B. Conclusions from Previous Risk Assessments

The Agency has conducted previous ecological risk assessments on diazinon that serve as a basis for this problem formulation. Each of the previous risk assessments is briefly discussed below.

1. Diazinon Interim Registration Eligibility Decision, 2002

In February 2000, the Agency completed a screening-level ecological risk assessment (USEPA 2000) in support of the Interim Reregistration Eligibility Decision (IRED) for diazinon (USEPA 2002). The IRED was finalized as part of the organophosphate cumulative assessment (USEPA 2006b), which is described below.

The IRED assessment was based on data collected in the laboratory and in the field to characterize the fate and ecotoxicological effects of diazinon. Data sources used in this assessment included: 1) registrant submissions in support of reregistration, 2) publicly available literature on ecological effects, 3) monitoring data for freshwater streams, lakes, reservoirs, and estuarine areas, 4) incident reports of adverse effects on aquatic and terrestrial organisms associated with the use of diazinon.

Primary environmental concerns were identified in the environmental fate and ecological risk assessment conducted in support of the reregistration eligibility decision for diazinon. These concerns were associated with the (now historical) uses of diazinon (USEPA 2000) and included bird kills, contamination of surface water via runoff, and impacts on aquatic species. At that time over 6 million pounds of diazinon were used annually across the United States, with 75% used for non-agricultural purposes (*e.g.*, applied outdoors by homeowners and professional lawn care companies). The assessment concluded that outdoor use of diazinon result in exposure and risk to birds and was associated with bird kills. Potential acute and chronic effects to aquatic invertebrates as well as chronic and sub-lethal effects to fish associated with use of diazinon were also identified in that assessment.

Water monitoring data reviewed in the assessment demonstrated that the use of diazinon had resulted in contamination of surface water, and concluded that impacts were likely to be particularly significant in urban settings, resulting in exposure and risk to sensitive aquatic organisms. The assessment summarized available monitoring data and reported that diazinon had been detected in drinking water reservoirs, large and smaller rivers, and in major aquifers. The assessment also included a summary of reports of detections of diazinon in effluent from wastewater treatment facilities, or publicly owned treatment works (POTWs), which have been cited as out of compliance with the Clean Water Act and the National Pollution Discharge Elimination System (NPDES). Also, the assessment indicated that diazinon had resulted in the initiation of Total Maximum Daily Loads (TMDLs) in California, where 53 water bodies were listed as impaired as a result of diazinon. TMDLs had been initiated in virtually every major urban area of the state as a result.

Diazoxon, a degradate of toxicological concern, was also found at levels approximately 2.5% of the parent in streams and rivers in California.

The 2002 IRED also noted that diazinon was one of the most frequently detected pesticides in air, rain, and fog, suggesting possible long-range atmospheric transport into regions beyond normal areas of use.

The Agency identified mitigation measures in the 2002 IRED to address unacceptable risks to agricultural workers, birds, and other wildlife that included elimination of aerial applications, reduction in the dormant season use (almonds and other orchard crops), and overall use reduction. In addition, a December 2000 agreement with the technical registrants phased out and canceled all indoor and outdoor residential uses in order to reduce risks to children and others.

2. Drinking Water Exposure Assessment, 2002

For the 2002 IRED, an assessment was completed of human exposure to diazinon through consumption of contaminated drinking water. At the time of the assessment, diazinon was detected in ground water from a variety of sources including drinking water wells, monitoring wells, and agricultural wells. Also, diazinon was one of the most frequently detected insecticides in surface water in the USGS National Water Quality Assessment (NAWQA) monitoring program. The highest concentration reported in monitoring was below the drinking water level of comparison (DWLOC), a level at which concentrations do not pose a risk to human health, and therefore did not require mitigation to address dietary risk from drinking water (USEPA 2002). Preliminary laboratory studies were summarized and suggested that chlorination of drinking water removed diazinon from treated water, transforming it to diazoxon. The assessment concluded exposure to diazoxon formed as a result of treatment could not be precluded, as preliminary evidence suggested that diazoxon could persist long enough to pass through the distribution system to the tap in some systems depending on the sequence of treatment. The Agency concluded that the elimination of residential uses and aerial applications, reduction in the dormant season use (almonds and other orchard crops), and overall use reduction through other mitigation measures would also reduce the amount of diazinon found in ground water and surface water.

3. Organophosphate Cumulative Assessment, and Diazinon Reregistration Eligibility Decision, 2006

Because the Agency had determined that diazinon shares a common mechanism of toxicity with the structurally-related organophosphates insecticides, a cumulative human health risk assessment for the organophosphate pesticides was necessary before the Agency could make a final determination of reregistration eligibility of diazinon. This cumulative assessment was finalized in 2006 (USEPA 2006b). The results of the Agency's ecological assessments for diazinon are discussed in the July 31, 2006, final Reregistration Eligibility Decision (RED) (USEPA 2006a).

4. Barton Springs Salamander Endangered Species Assessment

The Agency recently completed an endangered species risk assessment evaluating the potential effects of diazinon on the Barton Springs salamander (*Eurycea sosorum*). The assessment (USEPA 2007*a*) was a component of the settlement of the court case "*Center for Biological Diversity and Save Our Springs Alliance v. Leavitt, No. 1:04CV00126-CKK"*. The assessment concluded that diazinon use in the action area would have no direct effect on the salamander (via acute exposure) or its habitat and that it was not likely adversely affect the salamander through direct chronic effects or effects on its prey.

5. California Red-legged Frog Endangered Species Assessment

The Agency also recently completed an endangered species risk assessment of the potential effects of diazinon on the threatened California red-legged frog (*Rana aurora draytonii*; CRLF) arising from current uses of diazinon on several fruit, nuts, vegetables and outdoor ornamental crops (USEPA 2007*b*). Uses included in this 2007 assessment reflected post-RED mitigations. This endangered species risk assessment was part of the *Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 02-1580-JSW(JL)) settlement entered in the Federal District Court for the Northern District of California on October 20, 2006. The assessment resulted in a determination that the use of pesticide products containing diazinon is likely to adversely affect the CRLF. This determination is based on the potential for diazinon to both directly and indirectly affect the species and result in modification to designated critical habitat.

6. Pacific Anadromous Salmonids Endangered Species Assessment

The Agency completed an endangered species risk assessment of the potential effects of diazinon on 26 listed Evolutionarily Significant Units (ESUs) of Pacific salmon and steelhead arising from FIFRA regulatory actions regarding use of diazinon (USEPA 2002*a*). This risk assessment was part of the *Washington Toxics Coalition vs. EPA* (Case No. C01-132C) settlement entered in the Federal District Court for the Western District of Washington on July 2, 2002. The assessment concluded that diazinon is toxic to fish, but does not exhibit the extreme toxicity that would warrant concerns for direct, lethal effects on fish. Nevertheless, the high toxicity to organisms that serve as food for threatened and endangered Pacific salmon and steelhead, and the potential effects on salmon olfaction, are of significant concern, even in areas where uses were being phased out. The final conclusion was that the uses of diazinon (at that time) may affect 22 of these ESUs, and may affect but is not likely to adversely affect 4 ESUs; this assessment took mitigation, proposed by the 2002 IRED, into account.

7. Aquatic Life Criteria

The Clean Water Act requires the EPA to publish water quality criteria that accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare which might be expected from the presence of pollutants in any body of water, including ground water. An Aquatic Life Ambient Water Quality Criteria document was published for diazinon in 2005 (USEPA 2005*a*). The recommendation of the document in regards to freshwater aquatic life states the following: "Freshwater aquatic life should not be affected if the one-hour average concentration of diazinon does not exceed 0.17 micrograms per liter (µg/L) more than once every three years on the average (acute criterion) and if the four-day average concentration of diazinon does not exceed 0.17 µg/L more than once every three years on the average (chronic criterion)." While these recommended criteria do not, in themselves, impose any requirements, states and authorized tribes can use them to develop water quality standards.

8. *Final Biological Opinion on Diazinon in Response to Request for Consultation*

EPA reinitiated a formal consultation with the U. S. Fish and Wildlife Service in 1989 regarding diazinon impacts on endangered species. This consultation was on selected portions of five previous "cluster" biological opinions evaluating pesticides for certain crops (corn, cotton, soybeans, sorghum, wheat, barley, oats and rye), forestry uses pesticides, mosquito larvicides, and rangeland and pastureland pesticides. As a result, the U.S. Fish and Wildlife Service issued a formal Biological Opinion (USFWS 1989) which identified reasonable and prudent measures and alternatives to mitigate potential effects of diazinon use on endangered species. The opinion identified 6 amphibians, 77 fishes, 32 freshwater mussels, 10 arthropods, 5 birds and 2 snakes potentially affected by the use of diazinon. Of the 132 species identified, 84 were classified as in jeopardy.

III. Stressor Source and Distribution

A. Mechanism of Action

Diazinon, O,O-Diethyl O-(2-isopropyl-4-methyl-6-pyrimidinyl)phosphorothioate is an insecticide/acaricide belonging to the organophosphate class of pesticides. The pesticide acts through inhibition of acetylcholinesterase and is used to kill a broad range of insects and mites. Organophosphate toxicity is based on the inhibition of the enzyme acetylcholinesterase which cleaves the neurotransmitter acetylcholine. Inhibition of acetylcholinesterase by organophosphate insecticides, such as diazinon, interferes with proper neurotransmission in cholinergic synapses and neuromuscular junctions (USEPA 2000).

B. Overview of Pesticide Usage

Diazinon was originally registered for use in the United States in 1962. Diazinon was once one of the most widely used insecticides in the U. S. for residential as well as agricultural pest control. Based on a December 2000 agreement with the technical registrants, all indoor and outdoor residential uses of diazinon were phased-out or cancelled by 2005. All registrations for granular products have also been cancelled. Many additional risk mitigation measures identified in the 2002 IRED have been implemented, including: 1) restriction of aerial applications for all uses except lettuce, 2) cancellation of all seed treatment uses, and 3) cancellation of foliar applications to all vegetable crops.

Currently, diazinon is a liquid formulation registered for over 40 uses, including fruit and nut trees, fruits and vegetables, outdoor ornamentals and cattle ear tags. Labeled uses of diazinon include outdoor ornamentals, several fruit, nut, and vegetable crops as well as cattle ear tags. There are 13 active Section 3 labels for products containing diazinon. The EPA registration numbers for these labels are 4581-392, 5905-248, 19713-91, 19713-492, 66222-9, 66222-10, 66222-103, 11556-123, 39039-3, 39039-6, 61483-78, 61483-80, and 61483-92. A comprehensive list of currently registered diazinon uses, along with their respective methods, rates and any geographic limitations are defined in **Table 1**. Unless otherwise indicated, all uses of diazinon are permitted anywhere in the United States.

Table 1. Methods and rates of application of currently registered uses of diazinon.

Uses	Application type[1]	Number of applications / year	Maximum rate / application (lbs a.i./A)
almonds [3]	dormant or foliar	1	3
apples, apricots, cherries, nectarines, peaches, pears, plums, prunes	1 foliar + 1 dormant	2	2
blueberries	foliar	1	1
	fire ant	1	1
broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, mustard greens, spinach, endive, onions, radishes, carrots, beans, peppers (bell and chili), peas (succulent), beets (red), tomatoes, rutabagas, sweet potatoes	soil incorporation	1	4
caneberries [4] (blackberries, boysenberries, dewberries, loganberries, raspberries)	foliar	1	2
cattle ear tags	NA	NA	NA
cranberries	foliar	3	3
fig[3]	foliar	1	0.5
filberts (hazelnuts) [5]	foliar	1	0.5
Ginseng	foliar	1	0.5
Lettuce	soil incorporation	1[2]	2
	foliar	1[2]	2
melons (cantaloupes, casabas, crenshaws, honeydews, muskmelons, Persians, watermelons)	soil incorporation	1	4
	foliar	1	4
outdoor ornamentals	foliar	1[2]	1
Pineapple	foliar	2	1
strawberries	soil incorporation	1	1
	foliar	1	1
watercress [6]	foliar	1	0.5

[1]Aerial applications are permitted for uses on lettuce only. Applications to all other uses are made by ground methods.
[2]Labels indicate a maximum number of applications per crop. Therefore, if there are multiple crops per year, there is potential for more than 1 application per year.
[3]Applications only allowed in CA.
[4]Applications only allowed in CA, WA and OR.
[5]Applications only allowed in WA and OR.
[6]Applications only allowed in HI.
NA = not applicable

C. Environmental Fate and Transport

Registrant-submitted data defining the physical, chemical, fate and transport characteristics associated with diazinon are summarized in **Table 2**. In past assessments involving diazinon, values for vapor pressure, water solubility and Henry's Law Constant were obtained from USEPA 1988 (cited as 1.4 x10^{-4} torr, 40 mg/L at 20^{o}C, and 1.4 x10^{-6} atm-m^3/mol, respectively). More recent submissions for these properties are cited in **Table 2**. Diazinon is characterized as moderately persistent and mobile in the environment (USEPA 2000); the fate and transport of diazinon in the environment is briefly discussed below.

Table 2. General chemical and environmental fate properties of diazinon.

Chemical/Fate Parameter	Value(s)	Source (MRID)
Molecular weight (MW) (g/mol)	304.3	Product chemistry
Vapor pressure (VP) (torr; at 25°C)	6.6×10^{-5} 7.22×10^{-5}	402261-01 429708-09
Water solubility (mg/L; at 25°C)	59.5 65.5	402261-01 429708-08
Henry's Law Constant (atm-m^3/mol; at 25°C)	4.0 to 5.1×10^{-7}	Calculated[1]
Octanol-to-water partition coefficient (K_{OW})	6393 (Log K_{OW} = 3.8) 4904 (Log K_{OW} = 3.7)	402261-01 429708-10
Hydrolysis half-lives (23-25°C) (days)	12 (pH 5) 138 (pH 7) 77 (pH 9)	409311-01
Soil photolysis half-life (days; assuming 12 h light/day)	8.8 2.8	00153229 00153230
Aerobic soil metabolism half-life (days)	39	447460-01
Anaerobic soil metabolism half-life (days)	17	447460-01
Freundlich soil-to-water partition coefficients (K_f) for adsorption (soil texture; 1/n)	5.6 (sand; 0.63) 113.5 (unclassified; 0.70) 11.7 (loam; 0.77) 3.7 (sand; 0.60) 4.5 (loamy sand; 0.55) 23.4 (sandy clay loam; 0.93)	00118032
Organic carbon normalized partition coefficients (K_{OC})[2] (L/kg_{OC})	439 (sand) 855 (unclassified) 560 (loam) 638 (sand) 485 (loamy sand) 720 (sandy clay loam)	00118032
Fish bioconcentration	542x (edible) 583x (viscera) 542x (whole fish)	406608-08

[1] Calculated according to USEPA 2002*b* by: (VP *MW)÷(760*solubility).
[2] K_{OC} values were calculated based on K_f values for adsorption (*e.g.*, K_{OC} = K_f (adsorption) ÷ fraction organic carbon).

1. *Degradation*

Diazinon degrades by microbial metabolism as well as the abiotic processes of hydrolysis and photolysis. Aerobic and anaerobic soil metabolism half-lives are similar, with values of 39 and 17 days, respectively. Degradation due to hydrolysis varies with pH, with half-life values of 12, 138 and 77 days for pH 5, 7 and 9, respectively. Soil photolysis half-lives range 2.8 to 8.8 days.

Two degradates have been identified for diazinon; these degradates are oxypyrimidine and diazoxon. The first degradate, oxypyrimidine (2-isopropy-6-methyl-4-pyrimidinol), has been observed in laboratory (MRIDs 153229, 153230, 40931101, 44746001) and field studies as the primary degradate of diazinon. This degradate is formed by hydrolysis.

The second degradate, diazoxon (O,O-diethyl-O-(2-isopropyl-4-methyl-6-pyrimidinyl)phosphonate), is an intermediate formed by hydrolysis; it retains the organophosphate moiety of the parent compound. Diazoxon hydrolyzes more quickly than the parent, with an observed half-life in water (pH 7.4, at 30^{o}C) of 25 days, which is 7x faster than diazinon (185 d) (Gomaa *et al.* 1969). In laboratory fate studies involving diazinon, samples were not analyzed for diazoxon. Therefore, it is unknown whether diazoxon was present as a minor degradate (i.e., <10% of total residues). Although formation and degradation of diazoxon cannot be quantified from available laboratory fate studies involving diazinon, diazoxon has been detected in air, rain, fog (Majewski and Capel 1995) and surface waters in the U.S. (USGS 2008). The circumstances involving formation of diazoxon in the environment as well as its persistence are unknown. This represents major uncertainty in the Agency's understanding of the fate and persistence of diazinon and its residues of concern.

Several fate and transport studies for diazinon's degradates have been submitted to the EPA and are under review. The resulting data will be incorporated into future diazinon assessments, as appropriate.

2. *Transport*

Based on supplemental organic carbon partition coefficient data (K_{oc}), diazinon is classified moderately mobile in soil (United Nations Food and Agriculture Organization classification scheme). In leaching studies (MRIDs 132734, 118034, 40512601), oxypyrimidine and diazinon were observed in the leachate of 30 cm of soil. This indicates a potential for movement of diazinon from treatment sites to surface and ground waters.

Transport of diazinon in soil is confirmed by detections of diazinon in surface and ground waters throughout the United States. From 2004-2006, USGS analyzed 2453 samples for diazinon that were collected from surface waters throughout the United States[1] (including

[1] including locations in: AL, CA, CO, CT, FL, GA, ID, IL, IN, LA, MD, MA, MI, MN, MS, NE, NV, NJ, NY, NC, OH, OR, PA, SC,

watersheds defined as: agricultural, mixed, urban, and other). However, the USGS NAWQA monitoring program is not targeted to the use areas of diazinon or any other pesticide. In spite of this limitation, diazinon was detected in 424 samples (17%) at a maximum concentration of 0.359 µg/L. Diazinon has also been detected in non-targeted ground water samples collected throughout the US[2] (USGS 2008).

Diazoxon has also been detected in surface waters of the US, but not in ground water. From 2002-2005, USGS analyzed 1325 samples for diazoxon that were collected from surface waters throughout the US[3]. Diazoxon was detected in 27 samples (2%) at a maximum concentration of 0.0662 µg/L. Detections were in samples collected primarily in CA and also in GA. During the same time period, 687 ground water samples contained no detectable levels of diazoxon (USGS 2008).

The vapor pressure and Henry's law constants of diazinon indicate that the chemical may volatilize from soil and water. Volatilization of diazinon has been observed from soil in the laboratory (Lichtenstein and Schulz 1970; MRID 464070-03) and the field (Majewski *et al*. 1990). In addition, diazinon has been detected in air and precipitation samples throughout the United States (Majewski and Capel 1995). In California, diazinon was detected in lakes which are removed from agricultural areas. Atmospheric deposition has been proposed as the mechanism of transport to these environments (Fellers *et al.* 2004; LeNoir *et al.* 1999).

3. Terrestrial Field Dissipation

Twelve supplemental terrestrial field dissipation studies were submitted to the Agency for diazinon. These included four studies for each of the three formulations of granular, emulsifiable concentrate, and wettable powder. There appeared to be no correlation between formulation type and dissipation half-life in study results. Studies were conducted on corn, citrus, and apples in California, Illinois, Florida, and New York.

These terrestrial field dissipation studies indicated that diazinon dissipated with apparent field half-lives ranging from 5-to-20 days in the top 0- to 6-inch soil layer. These studies measured dissipation resulting from degradation, dilution and movement from the treatment site.

All of these studies were considered supplemental because frozen test samples were stored beyond the stability of diazoxon (30 days). Although diazoxon was recovered at trace amounts in four of the twelve studies, it was not possible to determine how much diazoxon was present at the time the samples were collected. All twelve studies showed that oxypyrimidine was a major degradate of diazinon, often leaching to the lowest depth sampled (48 or 72 inches).

4. Bioaccumulation

TN, TX, UT, VA, WA, WI

[2] including locations in: AR, CA, CO, CT, FL, IL, IN, KS, LA, MD, MA, MI, MN, NV, NH, NJ, NM, NY, NC, PA, SC, TX, UT, VA, WV

[3] including locations in: AL, AR, CA, CO, CT, FL, GA, ID, IL, IN, IA, LA, MD, MA, MI, MN, MS, MT, NE, NV, NJ, NY, NC, OH, OR, SC, TX, UT, VA, WA, WI

In a bioconcentration study with bluegill sunfish, diazinon residues concentrated in fish tissues at a factor of 542X for whole fish. Once fish were moved to water not containing diazinon, depuration was rapid, with 96% of diazinon residues eliminated from fish tissues within 7 days. The majority of radioactivity in fish tissues was identified as oxypyrimidine. The octanol-water partition coefficient (Log K_{OW} = 3.8) along with the submitted BCF study indicate that diazinon is not likely to bioaccumulate significantly in aquatic ecosystems.

The estimated log octanol-air partition coefficient (Log K_{OA}) of 9.1 (EPIsuite, v.3.20) suggests that bioaccumulation of diazinon in air breathing organisms is possible (Kelly *et al*. 2007); however, bioaccumulation may be limited by metabolism of diazinon to oxypyrimidine and other degradates that are not of toxicological concern. Potential bioaccumulation of diazinon in air breathing organisms will be considered in future risk assessments.

IV. Receptors

Consistent with the process described in the Overview Document (USEPA, 2004), the risk assessment for diazinon will rely on a surrogate species approach. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings.

Acute and chronic toxicity data from studies submitted by pesticide registrants along with the available open literature are used to evaluate the potential direct and indirect effects of diazinon on aquatic and terrestrial receptors. This includes toxicity data on the technical grade active ingredient, degradates, and when available, formulated products (*e.g*. “Six-Pack” studies). The open literature studies are identified using EPA’s ECOTOX database (USEPA 2007*d*), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of both sources of data can also provide insight into the direct and indirect effects of diazinon on biotic communities from loss of species that are sensitive to the chemical and from changes in structure and functional characteristics of the affected communities.

A. Effects to Aquatic Organisms

Table 3 provides a summary of the taxonomic groups and the surrogate species tested to characterize the potential acute and chronic ecological effects of diazinon. In addition, the table provides a preliminary overview of the potential acute toxicity of diazinon by providing the acute toxicity classifications. Technical grade diazinon is classified as very highly toxic to fish, aquatic-phase amphibians and aquatic invertebrates on an acute exposure basis. Chronic exposure to diazinon resulted in decreased growth in freshwater fish and decreased survival in freshwater invertebrates. Based on the available toxicity data, diazinon is orders of magnitude less toxic to aquatic plants than aquatic animals and would be classified as slightly toxic to aquatic plants based on its acute median effect concentration (EC_{50}) value.

The available information reported in the IRED (USEPA 2000) indicates that aquatic organisms are more sensitive to the technical grade active ingredient (TGAI) than the formulated products of diazinon; therefore, the focus of this assessment is on the TGAI of diazinon and its oxon degradate.

B. Effects to Terrestrial Organisms

Diazinon is very highly toxic to birds, terrestrial-phase amphibians, reptiles and mammals on an acute oral exposure basis, and it is very highly toxic to birds on a subacute dietary exposure basis. Chronic exposure to diazinon resulted in decreased reproduction in birds and decreased growth and survival in mammals. Terrestrial plant testing indicates that diazinon has roughly equivalent toxicity to both monocotyledonous and dicotyledonous plants; however, there is no acute toxicity classification scheme to characterize the toxicity of chemicals to terrestrial plants.

Table 3. Test Species Evaluated for Assessing Potential Ecological Effects of Diazinon and the Associated Acute Toxicity Classification

Taxonomic Group	Surrogate Species	Acute Toxicity -- Chronic Toxicity	Citation MRID	Acute Toxicity Classification
Birds[1]	Mallard (*Anas platyrhynchos*)	LD_{50} = 1.44 mg/kg -- NOAEC 8.3 ppm LOAEC = 16.33 ppm	408953-01 (Fletcher and Pedersen 1988) -- 431229-01 (Marselas 1989)	Very highly toxic
Mammals	Laboratory rat (*Rattus norvegicus*)	LD_{50} =882 mg/kg (females) -- NOAEC = 10 ppm LOAEC = 100 ppm	41334607 -- 41158101 (Novartis 1989)	Very highly toxic
Insects	Honey bee (*Apis mellifera L.*)	LD_{50} (contact) = 0.22 μg/bee	05004151 (Stevenson 1968)	Very highly toxic
Freshwater fish[2]	Rainbow trout (*Oncorhynchus mykiss*) -- Book Trout (*Salvelinus fontinalis*)	96-hour LC_{50} = 90 μg/L -- NOAEC <0.55 μg/L LOAEC = 0.55 μg/L	400946-02 (Johnson and Finley 1980) -- ROODI007 (Allison and Hermanutz 1977)	Very highly toxic
Freshwater invertebrates	Water flea (*Ceriodaphnia dubia*) -- Water flea (*Daphnia magna*)	48-hour EC_{50} = 0.21 μg/L -- NOAEC = 0.17 μg/L LOAEC = <0.32 μg/L	Banks *et al.* 2005 -- 407823-02 (Supernant 1988)	Very highly toxic
Estuarine/marine fish	Striped mullet (*Mugil cephalus*) -- Sheepshead minnow (*Cyprinodon variegatus*)	LC50 = 150 μg/L -- NOAEC – 0.39 μg/L LOAEC = 0.56 μg/L	402284-01 (Mayer 1986) -- RO0DO008 (Goodman *et al.* 1979)	Highly toxic
Estuarine/marine invertebrates	Mysid shrimp *(Americamysis bahia)*	EC_{50}=4.2 -- NOAEC = 0.23 μg/L LOAEC = 0.42 μg/L	406255-01 (Surprenant 1988) -- 442448-01 (Sousa 1997)	Very highly toxic
Terrestrial plants[3]	Monocots – oats / onion Dicots – carrot / cucumber	5.26 lbs a.i./A[4] -- 3.23 lbs a.i./A[5]	408030-01 (Pan-Agricultural Labs 1988) -- 408030-02 (Pan-Agricultural Labs 1988)	NA
Aquatic plants and algae	Green algae (*Pseudokirchneriella subcapitata*)	EC_{50} = 3,700 μg/L EC_{05}= 66 μg/L	405098-06	Very highly toxic

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.
[2] Freshwater fish may be surrogates for aquatic-phase amphibians.
[3] Four species of two families of monocots (one is corn); six species of at least four dicot families (one is soybeans).
[4] Based on seedling emergence study
[5] Based on vegetative vigor study.

C. Degradate toxicity

With respect to diazinon, the degradate oxypyrimidine is less toxic than the parent compound. Comparison of available toxicity information for oxypyrimidine (**Table 4**) indicates lesser aquatic toxicity than the parent for freshwater fish, invertebrates, and aquatic plants. Specifically, the available degradate toxicity data for oxypyrimadine indicate that it is practically nontoxic to freshwater fish (rainbow trout 96-hr LC_{50}>101 mg a.i./L) (MRID 463643-12; Grade 1993a) and invertebrates (48-hr EC_{50}>102 mg a.i./L) (MRID 463643-13; Grade 1993b) with no mortality at the maximum concentrations tested. In addition, available aquatic plant degradate toxicity data for oxypyrimidine indicate that oxypyrimidine is practically nontoxic to nonvascular aquatic plants (green algae) with non-definitive EC_{50} values (EC_{50}>109 mg a.i./L) (Grade 1993c; MRID 463643-14) at concentrations 29 times higher than the lowest reported aquatic plant EC_{50} value for parent diazinon.

Similarly, oxypyrimidine was practically nontoxic to birds on an acute oral and subacute dietary exposure basis (**Table 33**) and was, once again, orders of magnitude less toxic than the parent to birds. Therefore, given the lesser toxicity of oxypyrimidine to both terrestrial and aquatic animals, as compared to the parent, concentrations of this degradate are not assessed.

With respect to the intermediate degradate diazoxon, acute and subacute toxicity testing with birds indicate that the compound is minimally as toxic (LD_{50}=4.99 mg a.i./kg bw) (Rodgers 2005e ; MRID 465796-04) as the parent (LD_{50}= 5.2 mg a.i./kg bw) on an acute oral exposure basis and is more toxic (LC_{50} = 72 mg a.i./kg diet) (Rodgers 2005f; MRID 465796-02) than the parent (LC_{50}=245 mg a.i./kg diet) on a subacute dietary exposure basis (**Table 4**). Toxicity testing with aquatic-phase amphibians indicates that diazoxon (96-hr LC_{50}=0.76 mg/L) is an order of magnitude more toxic than the parent compound (96-hr LC_{50}=7.49 mg/L) (Sparling and Fellars 2007).

Table 4. Acute and subacute toxicity values for terrestrial and aquatic animals exposed to diazinon, diazoxon or oxypyrimidine.

	Diazinon		Diazoxon		Oxypyrimidine	
	Acute Oral mg/kg bw					

	5.2 (Fink 1972)					
	1.44 (Fletcher and Pederson 1988)					

	0.09 mg/L (Johnson and Finley 1980)					
	0.00021 mg/L (Banks 2005)					
	3.7 mg/L (Hughes1 988)					

*mallard ducks regurgitated the test solution therefore dosage is unknown.
NA= not applicable

D. Ecological Incidents

A preliminary review of the Ecological Incident Information System (EIIS) maintained by the Agency's Office of Pesticide Programs (OPP) indicates a total of 494 reported ecological incidents associated with the use of diazinon. These incidents were reported over the period of 1950 to 2005. These incidents resulted from the legal, registered uses of diazinon as well as misuses. In addition, in some cases it could not be determined if the incident resulted from the legal use of diazinon or misuse. Although the number of reported incidents has dropped considerably since mitigation measures were implemented following the 2002 IRED, the absence of reported incidents in 2006 should not be construed as the absence of incidents. EPA's changes in the registrant reporting requirements of incidents or other factors may account for the reduced number of reported incidents. For example, since 1998, registrants are only required to submit detailed information to EPA on 'major' incidents (for example, affecting $\geq$ 200 flocking birds). Minor incidents are aggregated and are not included in EIIS due to the lack of detail provided. In addition, there have been changes in state monitoring efforts due to lack of resources. Overall, the incident data that are available indicate that exposure pathways are complete and that exposure levels are sufficient to result in field-observable effects.

E. Ecosystems Potentially at Risk

The ecosystems potentially at risk are often extensive in scope, therefore, it may not be possible to identify specific ecosystems during the development of a nation-wide ecological risk assessment. However, in general terms, terrestrial ecosystems potentially at risk could include the treated field and immediately adjacent areas that may receive drift or runoff. Areas adjacent to the treated field could include cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats, and other uncultivated areas.

Aquatic ecosystems potentially at risk include water bodies adjacent to, or down stream from, the treated field and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers. For uses in coastal areas, aquatic habitat also includes marine ecosystems, including estuaries.

V. Assessment Endpoints

Assessment endpoints represent the actual environmental value that is to be protected, defined by an ecological entity (species, community, or other entity) and its attribute or characteristics (EPA 1998). For diazinon, the ecological entities include the following: birds, reptiles, terrestrial-phase amphibians, mammals, freshwater fish, freshwater aquatic-phase amphibians and invertebrates, estuarine/marine fish and invertebrates, terrestrial plants, insects, aquatic plants, and algae. The attributes for each of these entities include growth, reproduction, and survival.

VI. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

The conceptual model for diazinon provides a written description and visual representation of the predicted relationships between diazinon, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (USEPA 1998).

As discussed previously, several ecological and endangered species risk assessments have been conducted by EFED for diazinon, including a national level risk assessment supporting the IRED (USEPA 2000), an assessment of the risks of diazinon to the Federally-listed endangered Barton Springs salamander (USEPA 2007*a*), and an assessment of the risks of diazinon to the California red-legged frog, a Federally-listed threatened species (USEPA 2007*b*). An endangered species assessment has also been conducted by the Agency's Field and External Affairs Division (FEAD) for exposures of diazinon to the Pacific Anadromous Salmonids (USEPA 2002). Also, the Agency's Office of Water (OW) recently completed an Aquatic Life Criteria for diazinon (USEPA 2005). The U. S. Fish and Wildlife Service also issued a final biological opinion on specific uses of diazinon in 1989 (USFWS 1989). These previous assessments and more recent data serve as a basis for the risk hypothesis and conceptual model developed for current registered uses of diazinon.

A. Risk Hypothesis

A risk hypothesis describes the predicted relationship among the stressor, exposure, and assessment endpoint response along with the rationale for their selection. For diazinon, the following ecological risk hypothesis is being employed for this national-level ecological risk assessment:

> *Diazinon, when used in accordance with current labels, can result in off-site movement of the compound and its oxon transformation product via runoff, spray-drift, and atmospheric transport leading to exposure of nontarget plants and animals. Although a number of diazinon uses have either been cancelled or*

phased-out, monitoring data indicate frequent detections of diazinon in surface waters and at sites distant from use areas presumably due to current uses. Applications to foliar surfaces may serve as a major source of diazinon exposure to wildlife as soil applications are intended to be incorporated. This potential exposure pathway may result in adverse effects upon the survival, growth, and reproduction of non-target terrestrial and aquatic organisms. These nontarget organisms include Federally-listed threatened and endangered species.

B. Conceptual Diagram

The environmental fate properties of diazinon along with monitoring data identifying its presence in surface waters, air and precipitation, indicate that runoff, spray drift, volatilization and atmospheric transport and deposition represent potential transport mechanisms of diazinon to aquatic and terrestrial organisms. These transport mechanisms (*e.g*. sources) are depicted in the conceptual models below (**Figures 1** and **2**) and result in the movement of diazinon into aquatic (water) and terrestrial (soil and foliage) habitats. The movement away from the site of application in turn represents exposure pathways for a broad range of biological receptors of concern (nontarget animals) and the potential attribute changes, *i.e*., effects such as reduced survival, growth and reproduction, in the receptors due to diazinon and diazoxon exposure.

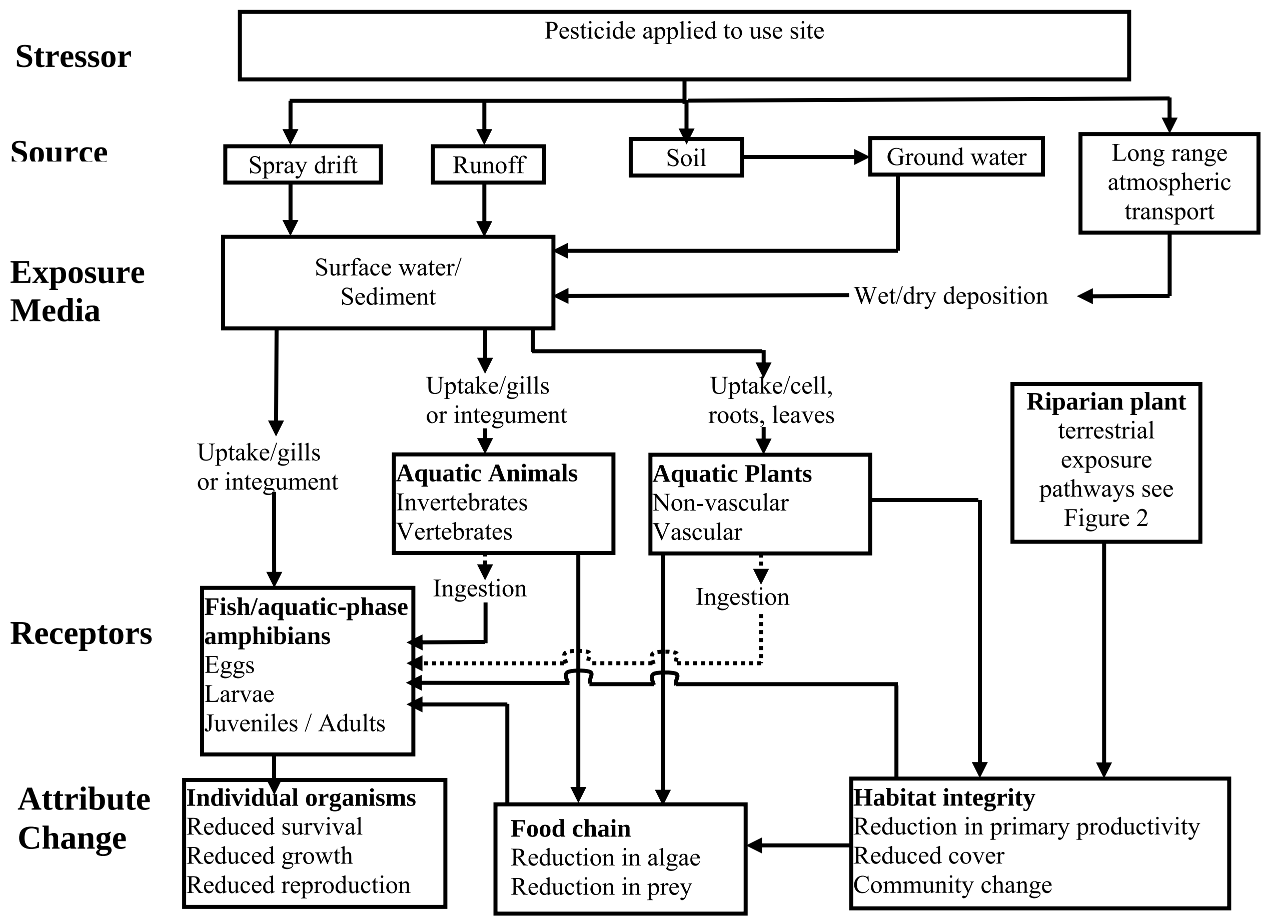

Figure 1. Conceptual model for diazinon effects on aquatic organisms. Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk.

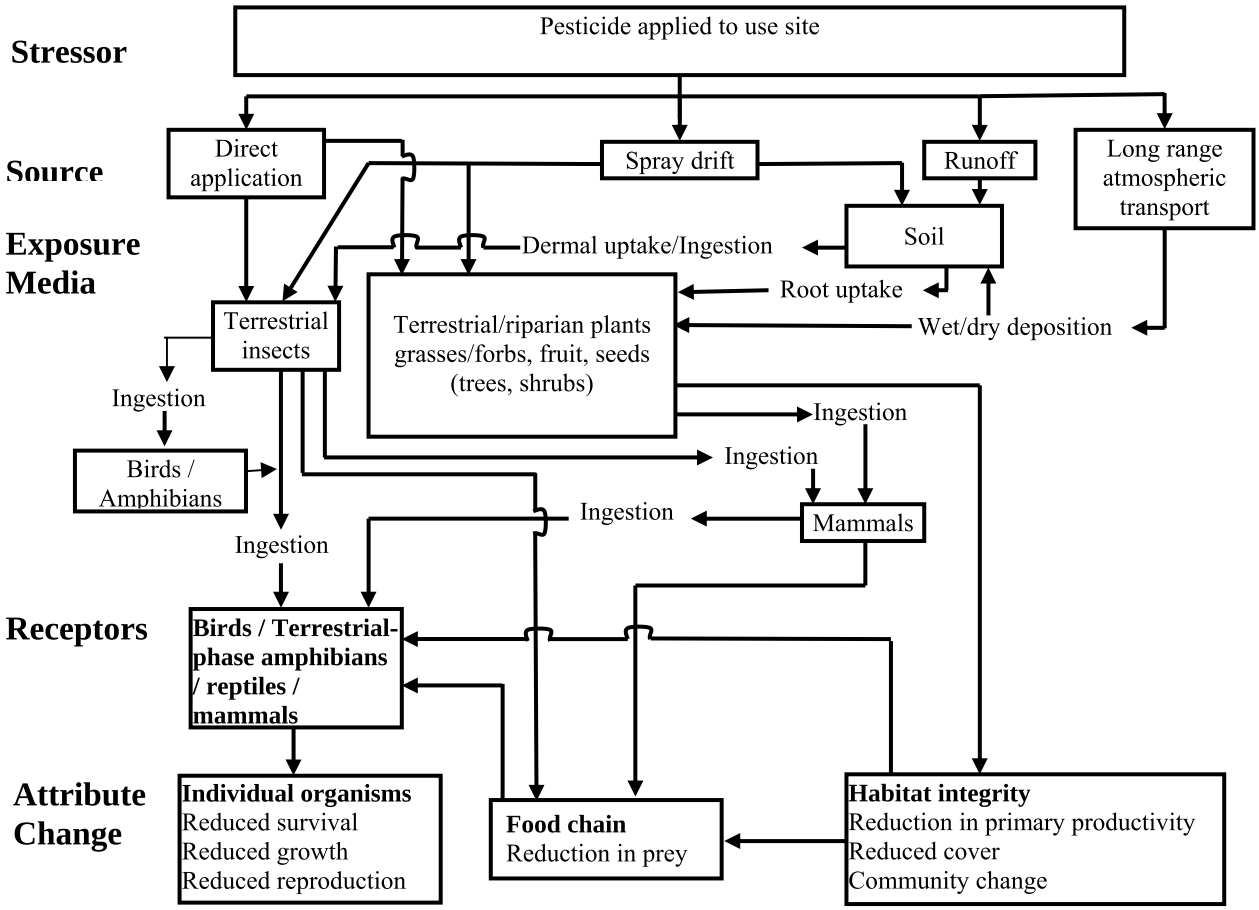

Figure 2. Conceptual model for diazinon effects on terrestrial organisms.

VII. Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment is estimated. The use, environmental fate, and ecological effects of diazinon are characterized and integrated to assess the risks. This is accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA 2004), the likelihood of effects to individual organisms from particular uses of diazinon is estimated using the probit dose-response slope and either the level of concern (discussed below) or actual calculated risk quotient value.

This analysis plan will be revisited and may be revised depending upon the information submitted by the public in response to the opening of the Registration Review docket for diazinon.

A. Stressors of Concern

As discussed above, the primary degradate of diazinon is oxypyrimidine. Comparison of available toxicity information for oxypyrimidine indicates that it is less toxic than the parent for freshwater and estuarine/marine fish, invertebrates, aquatic plants and birds. Because oxypyrimidine is less toxic than diazinon, exposure to this transformation product will not be included in this assessment.

Diazinon also degrades to diazoxon. Available data indicate that diazoxon is more toxic to amphibians than the parent compound (Sparling and Fellars 2007). Also, diazoxon is at least as toxic as the parent to birds. Submitted environmental fate studies for diazinon do not identify diazoxon, as it does not form >10% of residues, indicating that it is not expected to be a major degradate of diazinon in aquatic and terrestrial environments. However, diazoxon has been detected in air, precipitation and surface water samples, indicating that it is present in the environment. No laboratory data are available to estimate the formation and decline of diazoxon; therefore, it is not possible to estimate aquatic exposures using PRZM/EXAMS.

The stressors of concern for this assessment include diazinon and diazoxon. Exposures in aquatic habitats will be quantified considering diazinon only; however, available monitoring data for diazoxon will be used to bracket potential exposure of aquatic organisms to the oxon degradate. Exposures in terrestrial habitats will consider diazinon and, if possible, will also include diazoxon.

Evaluation of pesticide mixtures is beyond the scope of this assessment because of the myriad factors that cannot be quantified based on the available data. Those factors include identification of other possible co-contaminants and their concentrations, differences in the pattern and duration of exposure among contaminants, and the differential effects of other physical/chemical characteristics of the receiving waters (*e.g.* organic matter present in sediment and suspended water). Evaluation of factors that could influence additivity/synergism is beyond the scope of this assessment and is beyond the capabilities of the available data to allow for an evaluation. However, it is acknowledged that not considering mixtures could over- or under-estimate risks depending on the type of interaction and factors discussed above. The assessment will however, analyze the toxicity of formulated products (including formulations involving more than one active ingredient) and will determine whether formulated products are more toxic than the technical grade active ingredient data used for assessing both direct and indirect risks.

B. Measures of Exposure

In order to estimate risks of diazinon exposures in aquatic and terrestrial environments, all exposure modeling and resulting risk conclusions will be based on maximum application rates and methods cited in **Table 1** and will be estimated for each use of diazinon. Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) of diazinon. The models used to predict aquatic EECs are the Pesticide Root Zone Model coupled with the Exposure Analysis

Model System (PRZM/EXAMS). The model used to predict terrestrial EECs on food items is T-REX. The model used to derive EECs relevant to terrestrial and wetland plants is TerrPlant. These models are parameterized using relevant reviewed environmental fate data from registrant submissions and the literature; model input values will be consistent with the most recent version of the input parameter guidance (Version 2; EFED 2000)

PRZM (v3.12.2, May 2005) and EXAMS (v2.98.4.6, April 2005) are simulation models coupled with the input shell pe5.pl (Aug 2007). The models generate daily exposures and calculated 1-in-10 year EECs of diazinon that may occur in surface water bodies adjacent to application sites receiving diazinon through runoff and spray drift. PRZM simulates pesticide application, movement, and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion and spray drift. EXAMS simulates the fate of the pesticide in the water body and estimates resulting concentrations. The standard scenarios used for ecological pesticide assessments assume application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body that is 2 meters deep (20,000 m^3 volume) with no outlet. PRZM/EXAMS is used to estimate screening-level exposure of aquatic organisms to diazinon. The measure of exposure for aquatic species is the 1-in-10 year return peak or rolling mean concentration. The 1-in-10 year peak is used for estimating acute exposures of direct effects to aquatic organisms. The 1-in-10-year 60-day mean is used for assessing chronic exposure to fish and aquatic-phase amphibians. The 1-in-10-year 21-day mean is used for assessing chronic exposure to aquatic invertebrates.

Exposure estimates for terrestrial animals assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX model (version 1.3.1, 12/07/2006). This model incorporates the Kenega nomograph, as modified by Fletcher *et al.* (1994), which is based on a large set of field residue data. The upper limit values from the nomograph represent the 95th percentile of residue values from actual field measurements (Hoerger and Kenega 1972). The Fletcher *et al.* (1994) modifications to the Kenega nomograph are based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. EECs for terrestrial plants inhabiting dry and wetland areas are derived using TerrPlant (version 1.2.2, 12/26/2006). This model uses estimates of pesticides in runoff and in spray drift to calculate EECs. EECs are based upon solubility, application rate and minimum incorporation depth.

Available monitoring data will be used to qualitatively characterize exposure and compare with modeling results. The Agency is aware of monitoring conducted by storm water management agencies and this route of exposure will be considered in the assessment.

Two spray drift models, AGDisp and AgDRIFT are used to assess exposures of terrestrial plants to diazinon deposited in terrestrial habitats by spray drift. AGDisp (version 8.13; dated 12/14/2004) (Teske and Curbishley 2003) is used to simulate aerial and ground applications using the Gaussian far-field extension. AgDrift (version 2.01; dated 5/24/2001) is used to simulate spray blast applications to orchard crops.

At this time, the Agency does not have an approved model for estimating atmospheric transport of pesticides and resulting exposure to organisms in areas receiving pesticide deposition from the atmosphere. Methods to describe the contributions of atmospheric transport and deposition of diazinon and diazoxon to exposures to non-target organisms will be explored and incorporated into this risk assessment as part of registration review of diazinon.

C. Measures of Effect

Ecological effect data are used as measures of direct and indirect effects to biological receptors. Data were obtained from registrant-submitted studies or from literature studies identified by ECOTOX. The ECOTOXicology database (ECOTOX) was searched in order to provide more ecological effects data to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data and potential chemical mixture toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division (USEPA 2007*d*).

Information on the potential effects of diazinon on non-target animals is also collected from the Ecological Incident Information System (EIIS; USEPA 2007*c*). The EIIS is a database containing adverse effect (typically mortality) reports on non-target organisms where such effects have been associated with the use of pesticides.

Where available, sublethal effects observed in both registrant-submitted and open literature studies will be evaluated qualitatively. Such effects have included behavioral changes (*e.g.*, lethargy, changes in coloration and effects olfaction). Quantitative assessments of risks, though, are limited to those endpoints that can be directly linked to the Agency's assessment endpoints of impaired survival, growth and reproduction.

The assessment of risk for direct effects to non-target organisms makes the assumption that toxicity of diazinon to birds is similar to terrestrial-phase amphibians and reptiles. The same assumption is made for fish and aquatic-phase amphibians.

The acute measures of effect used for animals in this screening-level assessment are the LD_{50}, LC_{50} and EC_{50}. LD stands for "Lethal Dose", and LD_{50} is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for "Lethal Concentration" and LC_{50} is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for "Effective Concentration" and the EC_{50} is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC and NOEC. NOAEL stands for "No Observed-Adverse-Effect-Level" and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (*i.e.*, "No-Observed-Adverse-Effect-Concentration") is the highest test concentration at which none of the observed effects were statistically different from the control. The NOEC is the No-Observed-Effects-Concentration. For non-listed plants, only acute exposures are assessed (*i.e.*, EC_{25} for terrestrial plants and EC_{50} for aquatic plants); for listed plants, either the NOAEC or EC_{05} is used.

In the absence of data for either acute or chronic effects, the conservative assumption will be to presume that diazinon is toxic.

D. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of diazinon on fruits, nuts, vegetables and ornamentals, and the likelihood of direct and indirect effects to non-target organisms in aquatic and terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of diazinon risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA 2004). These criteria are used to indicate when diazinon's uses, as directed on the label, have the potential to cause adverse direct or indirect effects to non-target organisms. As noted previously, where data are lacking on the toxicity of diazinon, risk will be presumed.

1. Deterministic and Probabilistic Assessment Methods

The quantitative assessment of risk will primarily depend on the deterministic point-estimate based approach described in the risk assessment. An effort will be made to further qualitatively describe risk using probabilistic tools that the Agency has developed. These tools have been reviewed by FIFRA Scientific Advisory Panels and have been deemed as appropriate means of refining assessments where deterministic approaches have identified risks.

E. Endangered Species Assessments

Consistent with the Agency's responsibility under the Endangered Species Act (ESA), EPA will evaluate risks to Federally-listed threatened and/or endangered (listed) species from registered uses of diazinon. This assessment will be conducted in accordance with the Overview Document (USEPA 2004), provisions of the ESA, and the Services' *Endangered Species Consultation Handbook* (USFWS/NMFS 1998).

The assessment of effects associated with registrations of diazinon is based on an action area. The action area is considered to be the area directly or indirectly affected by the federal action, as indicated by the exceedance of Agency Levels of Concern (LOCs) used to evaluate direct or indirect effects. The Agency's approach to defining the action area under the provisions of the Overview Document (USEPA 2004) considers the results of the risk assessment process to establish boundaries for that action area with the understanding that exposures below the Agency's defined LOCs constitute a no-effect threshold. For the purposes of this assessment, attention will be focused on the footprint of the action (*i.e.*, the area where diazinon application occurs), plus all areas where offsite transport (*i.e.*, spray drift, runoff, long-range atmospheric transport, etc.) may result in potential exposure that exceeds the Agency's LOCs. Specific measures of ecological effect that define the action area for listed species include any direct and indirect effects and/or potential modification of its critical habitat, including reduction in survival, growth, and reproduction as well as the full suite of sublethal effects available in the effects literature. Therefore, the action area extends to a point where environmental exposures are below any measured lethal or sublethal effect threshold for any biological entity at the whole organism, organ, tissue, and cellular level of organization. In situations where it is not possible to determine the threshold for an observed effect, the action area is not spatially limited and is assumed to be the entire United States.

F. Drinking Water Assessment

A drinking water assessment will be conducted to support future human health risk assessments of diazinon. The drinking water assessment will incorporate model estimates of diazinon in surface and ground waters. Concentrations of diazinon in surface waters will be estimated using PRZM/EXAMS (see description above). Ground water estimates of diazinon concentrations will be established using SCI-GROW (v.2.3, July 2003). The drinking water assessment will also include available surface and ground water monitoring data, with consideration of changes in use patterns since mitigations have been imposed. States are encouraged to submit monitoring data for review.

Preliminary laboratory evidence suggests chlorination of drinking water removes diazinon from treated water, transforming it to diazoxon. As discussed above, the toxicity of diazoxon is of concern. Although diazoxon persistence has not been conclusively established, it may persist long enough to pass through the distribution system to the tap in some systems depending on the sequence of treatment. Therefore, in future drinking water assessments of diazinon, formation of diazoxon will be considered.

G. Preliminary Identification of Data Gaps

1. Fate

Although many submissions have been made to provide data on the environmental fate of diazinon and its degradates, several data gaps exist (**Table 5**). The data gaps are discussed below. A data call in (DCI) was issued June 2, 2004 to obtain data to fulfill some of these data gaps for diazinon and its degradates. The specific components of the DCI are also discussed below.

One of the major areas of uncertainty associated with the fate of diazinon in the environment involves the formation and persistence of its oxygen analog, diazoxon. As discussed above, diazoxon was not reported as a major degradate of diazinon, *i.e.*, did not constitute greater than 10% of total residues, in any of the available laboratory fate studies; however, diazoxon has been detected in surface waters, air and precipitation and is also known to form during water treatment. The conditions necessary for the formation of diazoxon and its persistence in the environment are unknown. Since data indicate that diazoxon has the potential to be as toxic as or more toxic than diazinon, this represents a gap in the overall understanding of potential risks associated with uses of diazinon. Future assessments of diazinon will involve exploration of degradation pathways leading to formation and transport of diazoxon in the environment.

Submission of any available information relevant to the circumstances resulting in the formation, persistence and transport of diazoxon in the environment would greatly reduce the uncertainties associated with the environmental fate of diazinon and its degradate of toxicological concern, *i.e.* diazoxon. Of particular interest would be the identification of pathways of formation for diazoxon in the environment. In cases where data are unavailable for the formation of diazoxon in the environment, conservative assumptions will be made to estimate exposure concentrations for diazoxon.

Table 5. Available environmental fate data for diazinon and remaining data gaps.

158 Guideline (OPPTS)	Description	MRID	Classification	Data Gap?	comments
161-1 (835.2120)	Hydrolysis	118021	Supplemental	**Yes**	
		40931101	Acceptable		
161-2 (835.2240)	Photodegradation in water	None[1]	Not applicable	**Yes**	[1]MRID 40863401 was originally considered useful for fulfilling this guideline requirement. Reevaluation of this study indicates that it is invalid due to insufficient material balances.
161-3 (835.2410)	Photodegradation in soil	153229	Supplemental	**Yes**	
		153230	Supplemental		
161-4 (835.2370)	Photodegradation in air	None	Not applicable	**Yes**	
162-1 (835.4100)	Aerobic soil metabolism	73059	Supplemental	**Pending[2]**	[2]A DCI was issued to fulfill this guideline by providing data for the parent and degradates. Several submissions have been made in response to this DCI. EFED will review these submissions.
		118025	Supplemental		
		118031	Supplemental		
		44746001	Supplemental		
162-2 835.4200	Anaerobic soil metabolism	44746001	Supplemental	**Yes**	
162-4 (835.4300)	Aerobic Aquatic Metabolism	None	Not applicable	**Pending[3]**	[3]MRID 46386604 was submitted to fulfill this guideline. This study will be reviewed by EFED.
162-3 (835.4400)	Anaerobic Aquatic Metabolism	None	Not applicable	**Pending[4]**	[4]MRID 46386602 was submitted to fulfill this guideline. This study will be reviewed by EFED.
163-1 (835.1230) (835.1240)	Leaching and adsorption/ desorption	118023	Supplemental	**Pending[5]**	[5]A DCI was issued to fulfill this guideline by providing adsorption/desorption data for the parent and degradates. Studies submitted to describe the leaching of two degradates (MRIDs 46407101 and 46407103) will be reviewed by EFED.
		118032	Supplemental		
		118034	Supplemental		
		132734	Supplemental		
		132735	Supplemental		
		40512601	Acceptable		
		42680901	Acceptable		
163-2 (835.1410)	Laboratory Volatility	90826	Supplemental	**Yes[6]**	[6]A DCI was issued to fulfill this guideline by providing volatility data for the parent. This DCI has not been fulfilled.
		46407003	Supplemental		
164-1 (835.6100)	Terrestrial Field Dissipation	118024	Supplemental	**Pending[7]**	[7]A DCI was issued to fulfill this guideline requirement. Several submissions have been made in response to this DCI, including MRID 46847006. EFED will review these submissions.
		118025	Supplemental		
		41320101	Supplemental		
		41320102	Supplemental		
		41320103	Supplemental		
		41320104	Supplemental		
		41320105	Supplemental		
		41432701	Supplemental		
		41432702	Supplemental		
		41432703	Supplemental		
		41432704	Supplemental		
		41432705	Supplemental		
		41432706	Supplemental		
		41432707	Supplemental		
164-2 (835.6200)	Aquatic Field Dissipation	None	Not applicable	**Yes**	
165-4	Bioaccumulation in Fish	40660808	Acceptable	No	
		41194401	Acceptable		

a. Hydrolysis

Although an acceptable hydrolysis study is available to quantify the hydrolysis half-lives of diazinon at different pH values, no studies are available which quantify the amount of diazoxon formed during a hydrolysis study involving diazinon. This represents a significant data gap (Guideline 161-1) because 1) diazoxon represents a degradate of toxicological concern, which has the potential to be as toxic as or more toxic than the parent; 2) diazoxon has been detected in surface water samples collected in the United States, indicating that it could potentially form in aquatic environments; and 3) diazoxon is formed by oxidation of diazinon, so it is possible that diazoxon could form in water under abiotic conditions, such as those present in hydrolysis studies.

EFED suggests that the Agency request a hydrolysis study consistent with OPPTS Guideline 835.2120. This study should include quantification of: 1) residues of diazinon, 2) residues of diazoxon, 3) residues of any degradates composing >10% of the overall residues, 4) the half-life of diazinon, and 5) if diazoxon is formed, the rate of formation and degradation of diazoxon. These data are necessary to allow the Agency to quantify diazoxon exposure concentrations for future environmental fate, ecological risk, endangered species and drinking water assessments.

In the acceptable hydrolysis study (MRID 40931101), the amounts of diazinon and oxypyrimidine were quantified. In addition, an unidentified degradate was quantified. The concentration of this unidentified degradate increased over time in the pH 7 treatment, reaching 7.5% of the applied radioactivity at day 30. If no additional data are available to quantify the formation of diazoxon, future risk assessments of diazinon will quantify the presence of diazoxon formed under abiotic aquatic conditions by assuming that the unidentified diazinon degradate observed in MRID 40931101 was diazoxon.

b. Photolysis in Water

Acceptable data are not available to quantify the degradation of diazinon in water due to photolysis. MRID 40863401 was originally considered useful for fulfilling this guideline requirement (Guideline 161-2). Reevaluation of this study indicates that it is invalid due to insufficient material balances. The lack of aqueous photolysis data represents a significant data gap because: 1) the potential influence of photolysis on the persistence of diazinon in the aqueous environment cannot be quantified; 2) available soil photolysis studies suggest that diazinon is susceptible to photolysis; and 3) some literature studies (Schomburg *et al*. 1991; Glotfelty *et al.* 1990) suggest that diazinon is photo-oxidized in air to diazoxon, therefore, diazoxon could form in water due to photo-oxidation as well.

EFED suggests that the Agency request an aqueous photolysis study to fulfill Guideline 835.2240. This study should include quantification of: 1) residues of diazinon, 2) residues of diazoxon, 3) residues of any degradates composing >10% of the overall residues, 4) the half-life of diazinon, and 5) if diazoxon is formed, the rate of formation and degradation of diazoxon. These data are necessary to allow the Agency to quantify diazinon and diazoxon exposure concentrations for future environmental fate, ecological risk, endangered species and drinking water assessments.

If no additional data are available to quantify the degradation of diazinon in aqueous environments, EFED will assume that diazinon is stable to aqueous photolysis. EFED will also explore possible influences of photo-oxidation of diazinon to diazoxon in the aqueous environment.

c. Photolysis on Soil

Supplemental data are available to describe the degradation of diazinon on soil due to photolysis; however, no studies are available which quantify the amount of diazoxon formed during a soil photolysis study involving diazinon. Although this represents a data gap; EFED does not recommend that the Agency request these data at this time, if the aqueous photolysis and photodegradation in air studies are requested. Since no acceptable studies have been submitted, the guideline requirement for photolysis on soil is not met.

d. Photodegradation in Air

Acceptable data are not available to quantify the degradation of diazinon in air due to photolysis. The lack of air photolysis data represents a significant data gap because 1) literature data suggest that diazinon has the potential to volatilize from treatment sites and therefore has the potential to be present in the air; 2) available air and precipitation data confirm that diazinon has been detected in the air; 3) available soil photolysis studies suggest that diazinon is susceptible to photolysis; 4) the potential influence of photolysis on the persistence of diazinon cannot be quantified; 5) some literature studies (Schomburg *et al*. 1991; Glotfelty *et al*. 1990) suggest that diazinon is photo-oxidized in air to diazoxon; and 6) diazoxon has been detected in precipitation.

EFED suggests that the Agency request a photodegradation in air study with diazinon to fulfill Guideline 161-4. This study should include quantification of: 1) residues of diazinon, 2) residues of diazoxon, 3) residues of any degradates composing >10% of the overall residues, 4) the half-life of diazinon, and 5) if diazoxon is formed, the rate of formation and degradation of diazoxon. EFED suggests the Agency request submission of a protocol for review by the Agency prior to initiation of this study. These data will assist the Agency in quantifying diazinon and diazoxon exposure concentrations for future environmental fate, ecological risk, endangered species and drinking water assessments.

If no additional data are available to quantify the degradation of diazinon due to photolysis in air, EFED will also explore possible influences of photo-oxidation of diazinon to diazoxon in the air.

e. Soil Metabolism

At this time, several aerobic and anaerobic soil metabolism studies have been reviewed by EFED. These studies provide supplemental information to describe the degradation of diazinon on soil due to metabolism. Several aerobic soil metabolism studies have been submitted by the registrant (MRIDs 46386605, 46867004 and 46407102) to provide additional information to fulfill this guideline (Guideline 162-1). These studies will be reviewed by EFED during registration review of diazinon.

No additional anaerobic soil metabolism studies have been submitted. Since no acceptable anaerobic soil metabolism studies have been submitted, the guideline (Guideline 162-2) for anaerobic soil metabolism is not met. At this time, these data are not necessary to conduct future environmental fate, ecological risk, endangered species and drinking water assessments for diazinon. Therefore, EFED does not suggest that the Agency request additional studies to fulfill the anaerobic soil metabolism guideline.

f. Aquatic Metabolism

At this time, aerobic and anaerobic aquatic metabolism studies (MRIDs 4636604 and 4636602, respectively) have been submitted by the registrant. These studies will be reviewed by EFED during registration review of diazinon.

g. Leaching and Adsorption/Desorption

Several studies (MRIDs 464071-01, -02, -03 and 46479601) have been submitted to fulfill the DCI requesting adsorption/desorption data. These studies will be reviewed by EFED during the registration review of diazinon. The resulting data will be incorporated into future diazinon assessments as appropriate. The fulfillment of the DCI will be evaluated after the submissions have been fully reviewed.

h. Laboratory Volatility

At this time, there are no acceptable studies to quantify the volatility of diazinon. Two submitted supplemental studies (MRIDs 46407003 and 00090826) were insufficient to quantify volatilization of diazinon or its degradates, but did demonstrate that diazinon volatilizes from soil. The lack of volatility data represents a significant data gap because available air and precipitation data confirm that diazinon has been detected in the air. Therefore, in order to understand the exposure of non-target organisms to diazinon it is necessary for the Agency to understand the extent to which diazinon can be expected to volatilize from treated areas.

In order to quantify the potential for volatilization of diazinon, a DCI was issued for a laboratory study involving volatilization of diazinon from soil (Guideline 163-2). Although several submissions have been made relevant to this DCI, insufficient data have been provided to quantify the volatility of diazinon. Therefore, the DCI from the diazinon RED is still outstanding for this guideline study requirement.

Without these data, EFED will characterize the volatility of diazinon by 1) utilizing available literature data describing the volatility of diazinon; and 2) estimating the potential volatility of diazinon using the Henry's Law constant of diazinon.

i. Terrestrial Field Dissipation

Several submissions (MRIDs 468670-03, -04 and -06) have been made to fulfill the DCI requesting terrestrial field dissipation (Guideline 164-1) data for diazinon. These studies will be reviewed by EFED during the registration review of diazinon. The resulting data will be incorporated into future diazinon assessments as appropriate. The fulfillment of the DCI will be evaluated after the submissions have been fully reviewed.

j. Aquatic Field Dissipation

Acceptable data have not been provided to fulfill the guideline for aquatic field dissipation (Guideline 164-2). According to Subpart D of Part 158 data requirements for pesticides, aquatic field dissipation data are required for aquatic uses. Since registered uses of diazinon include watercress, an aquatic use, the lack of aquatic field dissipation data for diazinon represents a data gap. At this time, these data are not necessary to conduct future environmental fate, ecological risk, endangered species and drinking water assessments for diazinon. Therefore, EFED does not suggest that the Agency request additional studies during registration review in order to fulfill this guideline requirement.

k. Other Data Gaps

Because of the presence of diazinon in air and precipitation and its model-calculated K_{OA} there is uncertainty regarding the extent to which diazinon will accumulate in terrestrial organisms. Submission of measured K_{OA} data for diazinon would reduce uncertainty associated with characterizing the partitioning of diazinon between the air and octanol and allow for characterization of the bioaccumulation potential of diazinon in air breathing organisms.

l. Summary of Fate Studies that EFED recommends the Agency request

The following components of the June 2, 2004 DCI are still outstanding:

- Laboratory volatility (163-2; OPPTS Guideline 835. 1410)

In addition, EFED recommends that the Agency request the studies listed below in order to increase its understanding of the fate of diazinon in the environment, as well as the formation of diazoxon, a degradate of toxicological concern.

- Hydrolysis (161-1; OPPTS Guideline 835.2120)
- Aqueous Photolysis (161-2; OPPTS Guideline 835.2240)
- Photodegredation in air (161-4; OPPTS Guideline 835.2370)

2. Effects

Although many submissions have been made to provide data on the effects of diazinon to aquatic and terrestrial organisms, data gaps still exist (**Tables 6-8**). These include: effects of diazoxon on avian reproduction. These data gaps are discussed below. A data call in (DCI) was issued June 2, 2004 to obtain data to fulfill some of these data gaps for diazinon and its degradates. Some submissions resulting from the DCI were sufficient to fulfill two of the data gaps. The outstanding components of the DCI are discussed below.

Table 6. Available ecological effects data for terrestrial animals exposed to technical diazinon and remaining data gaps.

158 Guideline (OPPTS)	Description	MRID/ Accession	Classification	Data Gap?	comments
71-1 (850.2100)	Avian oral toxicity	FEODIA02	Supplemental	No*	*Acceptable acute oral toxicity data were submitted for exposures of bobwhite quail to diazoxon and oxypyrimidine. Therefore, the DCI issued for these studies is considered fulfilled.
		FEODIA04	Acceptable		
		FEODIA06	Acceptable		
		FEODIA07	Supplemental		
		FEODIA08	Supplemental		
		20560	Acceptable		
		109015	Supplemental		
		160000	Acceptable		
		40895301	Acceptable		
		40895303	Supplemental		
		40895304	Supplemental		
		40895305	Acceptable		
		46579604*	Acceptable		
		46579608*	Supplemental		
		46579609*	Supplemental		
		46579605*	Acceptable		
71-2 (850.2200)	Avian dietary toxicity	FEODIA10	Supplemental	No**	**Acceptable subacute dietary toxicity data were submitted for exposures of bobwhite quail and mallard ducks to diazoxon and oxypyrimidine. Therefore, the DCI issued for these studies is considered fulfilled.
		FEODIA11	Supplemental		
		34769	Acceptable		
		40910905	Supplemental		
		40895302	Acceptable		
		46579602**	Acceptable		
		46579606**	Acceptable		
		46579603**	Acceptable		
		46593301**	Acceptable		
71-4 (850.2300)	Avian reproduction	104083	Supplemental	**Yes*****	***A DCI was issued to fulfill this guideline by providing data for diazoxon and oxypyrimidine. This DCI has not been fulfilled.
		41322901	Acceptable		
		41322902	Acceptable		
141-1 (850.3020)	Honeybee acute contact toxicity	36935	Supplemental	No	
		5004151	Acceptable		

Table 7. Available ecological effects data for aquatic animals exposed to technical diazinon and remaining data gaps.

Guideline	Description	MRID/ Accession	Classification	Data Gap?	comments
72-1 (850.1075)	Freshwater fish – Acute toxicity	RO0DI007	Acceptable	No	
		40094602	Supplemental		
		40910904	Acceptable		
		46364312*	Supplemental		*Exposure involved oxypyrimidine.
72-3 (850.1075)	Saltwater fish – Acute toxicity	RO0DI007	Acceptable		
		40228401	Supplemental		
72-2 (850.1010)	Freshwater invertebrates – Acute toxicity	109022	Acceptable	No	
		40094602	Supplemental		
		46364313*	Supplemental		
72-3 (850.1025) (850.1035) (850.1045) (850.1055)	Saltwater invertebrates – Acute toxicity	40228401	Supplemental	No	
		40625501	Acceptable		
		40625502	Acceptable		
72-4 (850.1300)	Freshwater invertebrate – life cycle test	40782302	Supplemental	No	
72-4 (850.1350)	Saltwater invertebrates – life cycle test	44244801	Acceptable	No	
72-4 (850.1400)	Freshwater fish – early life stage test	40782301	Supplemental	**Yes****	**A DCI was issued to fulfill this guideline by providing data for the parent. This DCI has not been fulfilled.
72-4 (850.1400)	Saltwater fish – early life stage test	RO0DO008	Acceptable	No	
		44244802	Acceptable		
72-5 (850.1500)	Fish – life cycle test	None	Not applicable	**Yes*****	***A DCI was issued to fulfill this guideline by providing data for the parent. This DCI has not been fulfilled.

Table 8. Available ecological effects data for plants exposed to diazinon and remaining data gaps.

Guideline	Description	MRID	Classification	Data Gap?	comments
122-1 (850.4100)	Terrestrial Plant toxicity: Tier I seedling emergence	40509805	Acceptable	No	None
123-1 (850.4225)	Terrestrial Plant toxicity: Tier 2 seedling emergence	40803001	Acceptable	No	
122-1 (850.4150)	Terrestrial Plant toxicity: Tier I vegetative vigor	40509804	Acceptable	No	
123-1 (850.4150)	Terrestrial Plant toxicity: Tier 2 vegetative vigor	40803002	Acceptable	No	
123-2 (850.4400)	Aquatic Plant Growth: algae	40509806	Acceptable	No	
		46364314	Supplemental		
123-2 (850.4400)	Aquatic Plant Growth: vascular plants	None	Not applicable	**Yes**	

a. Acute, Subacute and Chronic Effects to Birds

A DCI was also issued for toxicity data for birds exposed to diazinon. Requested studies included: 1) two avian acute oral toxicity tests (Guideline 71-1), preferably with the redwing blackbird and either the mallard or the bobwhite quail; and 2) an avian dietary toxicity test (Guideline 71-2), preferably with either the mallard or the bobwhite quail. A review of avian toxicity data for diazinon indicates that sufficient data are available to characterize the acute and subacute toxicity of diazinon to several species of birds.

In addition, the DCI included a reproduction test (Guideline 71-4) involving exposures of birds to diazinon's degradates. No data have been submitted to characterize the reproductive toxicity of diazinon's degradates to birds. Therefore, the DCI from the diazinon RED is still outstanding for Guideline 71-4. Submission of two separate acceptable avian reproduction tests involving separate exposures to diazoxon and oxypyrimidine would be necessary to fulfill this guideline requirement.

b. Chronic studies with freshwater fish

No definitive chronic toxicity data are available for freshwater fish. Although the registrant submitted a partial life cycle test using fathead minnow (*Pimephales promelas*; MRID 468670-01), the study did not fulfill guideline test requirements. Based on acute toxicity data, fathead minnows, a warm water fish, are one of the least sensitive species tested with diazinon while salmonids, a coldwater fish, are considerably more sensitive. Chronic toxicity data are preferred on the more sensitive test species; however, if acceptable chronic toxicity data are provided on fathead minnow, the Agency will rely on an adjustment factor to account for the apparent difference in sensitivity between warm water and coldwater fish.

A DCI was issued (June 2, 2004) for toxicity data for fish exposed to diazinon. Requested studies included: 1) a fish early-life stage toxicity test (guideline 850.1400); and 2) a fish life cycle toxicity test (Guideline 72-5). Although the registrant submitted preliminary data and a waiver request for additional chronic toxicity data, acceptable studies have not been submitted to fulfill these requirements. Therefore, the DCI from the diazinon RED is still outstanding for guidelines 72-4 and 72-5. If an acceptable fish life cycle toxicity test involving exposures to diazinon were submitted, EFED would concur with an earlier request by the registrant to waive the early life stage test (USEPA 2005*b*).

c. Aquatic plant studies

No data are available for assessing the effects of exposures of diazinon to freshwater, vascular plants. Generally, data for duckweed (*Lemna gibba*) are used to assess these effects. Given the mode of action of diazinon in combination with the anatomy of plants, as well as the relatively low toxicity of diazinon to non-vascular, aquatic plants (green algae) and to terrestrial plants, this data gap is not of particular concern for this risk assessment. However, this data gap represents an uncertainty in the assessment of potential risk to non-target organisms.

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