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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date: 07-03-2008
Chemical: Difenoconazole
PC Code: 128847
DP Barcode: D353502-(IN)

MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Risk Assessment for the Section 18 Emergency Exemption of Difenoconazole in Indiana

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I. Environmental Risk Conclusions

The Environmental Fate and Effects Division (EFED) has completed its review of the Section 18 Emergency Exemption request (DP Barcode D353502) for the aerial and/or ground spray application of difenoconazole (Inspire/Vanguard) on watermelons grown in the state of Indiana to control an outbreak of gummy stem blight. The maximum proposed single application rate is 0.114 lb a.i./A with 2 applications for an annual maximum rate of 0.228 lb a.i./A. The Inspire Super™ MP multipack, consisting of Inspire Super™ MP fungicide and Vangard® WG fungicide, from Syngenta Crop Protection contains the active ingredients difenoconazole and cyprodinil. This assessment only pertains to risks due to difenoconazole.

Assuming that all Indiana water-melon acreage is susceptible in 2008, an estimated total of 7,000 acres may be sprayed.

Based on the previous Section 18 for this chemical, the application rate was equal to the current application rate petitioned in this Section 18 Emergency Exemption Request for difenoconazole use on Indiana Water-melons. The application number for the previous Section 18 Emergency Request (4 applications for the use of Difenoconazole on cucurbits grown in Georgia and California, **DP Barcodes:** D351238 {GA}, D351716 {CA}) is twice of the present number of applications for this Section 18 Emergency Exemption Request (2 applications for the use of difenoconazole on watermelons grown in Indiana **DP Barcode: D353502-{IN}**).

The proposed emergency label results in exposure exceedences at dose-based chronic level for the following: mammals consuming difenoconazole treated food-items:

- 15-1000 gram mammals consuming short grass, tall grass, and broadleaf plants/small insects ;
- 15-gram mammals consuming fruits/pods/large insects;

Also, the proposed emergency label results in exposure exceedences at the dietary-based chronic level for mammals and birds consuming the following difenoconazole treated-food-items:

- Mammals consuming short grass-food-items;
- Mammals consuming broadleaf plants/small insects;
- short grass; and
- broadleaf plants/small insects

Although the chronic Level of concern for estuarine/marine invertebrates (using the mysid shrimp) were exceeded, the non-existence of estuarine/marine environments in the state of Indiana and the less than inequality sign in the original NOAEC toxicity value makes the resulting chronic risk quotient non-definite.

II. Background

The Indiana Department of Agriculture and Consumer Services requested a Section 18 Emergency Exemption for the aerial and/or ground spray application of difenoconazole on Indiana Water-melons to impede the outbreak of gummy stem blight. Gummy stem blight is a fungus caused by the fungi known as *Didymella bryoniae.*

Difenoconazole is a broad spectrum, preventive fungicide with systemic and curative properties recommended for the control of many important plant diseases. The mode of action is demethylation inhibititor of sterol biosynthesis which disrupts membrane synthesis by blocking demethylation.

Because all growth stages of the water-melon plant are susceptible to attack from gummy stem blight, this Section 18 is requesting access to difenoconazole throughout all production seasons. For the purposes of this Section 18, it is assumed that there is one growing season per year.

Based on the proposed label, difenoconazole may be applied by aerial or ground spray application to water-melons grown in Indiana.

III. Environmental Fate and Transport Summary

In soil environment, difenoconazole is persistent and slightly mobile. Difenoconazole has low potential to reach ground water, except in soils of high sand and low organic matter content. During a runoff event, difenoconazole will potentially runoff into adjacent bodies of surface water. In aquatic environment, difenoconazole main route of dissipation is partitioning into the bottom sediment as shown in an aerobic aquatic metabolism study (MRID 42245134), in which the distribution ratio of sediment and water phases was 8:1 at 1 day post treatment and 40:1 at 30 days post treatment. Difenoconazole undergoes potentially relatively fast to slow aqueous photolysis in clear water conditions.

Difenoconazole was stable to hydrolysis at pH 5, 7, and 9 in aqueous buffered solutions maintained at 25 °C over the course of a 30 day incubation period (MRID 42245128). Based on the registrant-submitted laboratory studies, difenoconazole may potentially undergo relatively fast photolysis in natural aquatic environment. The photolytic degradation may be attributable to absorption by organic components present in the natural water. Aqueous photolysis of difenoconazole in sterile buffer solutions proceeded with the half-lives of 6 and 228 days (MRIDs: 42245128 and 46950105). The half-life of 228 days was extrapolated from a 15-day study in which difenoconazole slowly photolyzed from 100% to 91% under artificial light conditions (supplemental study; MRID 46950105). Difenoconazole was stable to soil photolysis.

Difenoconazole is relatively stable to aerobic soil metabolism, stable to anaerobic soil metabolism, and aerobic and anaerobic aquatic metabolism. When applied at 0.1-0.23 ppm to an aerobic soil, difenoconazole appear to degrade with half-lives ranging from 84.5 to 533 days based on laboratory studies conducted on variety of soils, European and domestic origin. At concentrations of 10 ppm, difenoconazole degraded with the half-lives of 1059-1600 days in aerobic, and 947 days anaerobic loam soil, respectively. The longer half-life values obtained for those higher concentration rates may imply that the rate of difenoconazole microbially mediated degradation may be concentration dependent.

In aquatic environment under aerobic conditions, difenoconazole microbially degraded with half-lives ranging from 315 to 565 days at concentrations up to 0.17 mg ai/L, and 860 days in concentration of 10 mg ai/L. Under anaerobic conditions, difenoconazole degraded with 370 days at concentration of 0.04 mg ai/L, and 1245 days at concentrations of 10 mg ai/L.

During aqueous photolysis, difenoconazole breaks down to triazolyl acetic acid (CGA-142856) and is further degraded to triazole methanol (CGA-107069) and triazole (CGA-71019). Minimal carbon dioxide is also produced (MRID 46950104). In aerobic soil (MRID 46950109-12), difenoconazole degrades slowly to CGA 205374, which in turn degrades to CGA 205375, CGA 189138 and other minor compounds, and these are mineralized to CO_2 (formed up to 23%, MRID 46950111) and converted to bound residues (up to 48.9% of the applied at 293 days, MRID 46950110).

According to the Food and Agriculture Organization of the United Nations classification system (UN FAO, 2000), difenoconazole appears to be slightly mobile in soils. Freundlich K_{ads} values were 12.8 for sand soil, 63.0 for sandy loam soil, 54.8 for silt loam soil, and 47.2 for silty clay loam soil. The corresponding Koc values were 3867, 3518, 3471, and 7734 mL/g. (MRID 42245135). In another study, registrant-calculated Freundlich adsorption K values were 11.6, 22.9, 182, and 201 for the Madera loamy sand, Visalia sandy loam, North Dakota clay loam, and Florida sand soils, respectively; corresponding Freundlich Koc values were 3870, 4587, 4799, and 11202.

Difenoconazole major degradate, CGA205375 (1-[2-Chloro-4-(4-chlorophenoxy)-phenyl]-2-[1,2,4]triazol-1-yl-ethanol), has potential to be slightly more mobile in the soil than its parent fungicide. Freundlich adsorption K values for CGA205375 are 9.6, 12.3, 145, and 116 for the Madera loamy sand, Visalia sandy loam, North Dakota clay loam, and Florida sand soils, respectively; corresponding Freundlich Koc values are 3214, 2470, 3824, and 6432 (MRID 46950123). According to the UN FAO classification, CGA205375 appears to be slightly mobile. In addition, the K_{ads} values are directly proportional to soil organic carbon content.

Submitted terrestrial field dissipation studies showed that difenoconazole and its degradates did not leach below 30 cm of soil depth except in one study that it leached up to 60 cm of the cropped plot soil (under potato production conditions in ND; MRID 46950129). Difenoconazole degraded with half-lives ranging from 136 to 462 days in the terrestrial field dissipation studies.

Based on difenoconazole low vapor pressure of 2.5×10^{-10} mm Hg and solubility in water of 15 mg/L, difenoconazole has a low propensity to volatilize and generate vapors after application. At the study termination in the laboratory studies, the residues detected in the organic volatiles trap totaled 0.7% or less, most instances less than 0.1%, of the applied difenoconazole. The concentrations of the applied defenoconazole lost through volatilization were not measured in the terrestrial field dissipation studies.

Difenoconazole accumulated rapidly in edible and non-edible bluegill sunfish tissues with bioconcentration factors of 170x for edible tissues, 570x for nonedible tissues, and 330x for whole body. Depuration was also rapid with a depuration half-life of approximately 1 day and 96-98% clearance after 14 days of depuration. From both edible and non-edible tissues, one metabolite was recovered, CGA-205375, and accounted for 51-64% of the applied.

Table 1 summarizes the environmental fate data of the parent difenoconazole:

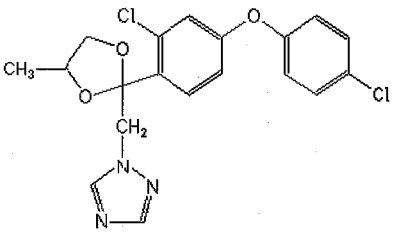
Table 1. Summary of the physical and chemical properties of difenoconazole.		
Property	**Value**	**Source**
Name	Difenoconazole	
SMILES notation	O1CC(C)OC1(Cn2ncnc2)c3c(Cl)cc(Oc4ccc(Cl)cc4)cc3	EPI Suite, v3.12 SMILES
Structure		
CAS number	119446-68-3	
Molecular weight	406.27	MRID 46950104
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$	
Water solubility	15 mg/L (25 °C)	MRID 46515901
log K_{ow}	4.4 (25 °C)	MRID 46950105
Vapor pressure	2.5×10^{-10} mm Hg (25 °C)	MRID 46515901
Henry's Law constant	8.9×10^{-12} atm x m^3/mol	MRID 46515901
Soil adsorption coefficient K_{oc} (L/kg)	3867, 3518, 3471, and 7734 3870, 4587, 4799, and 11202	MRID 42245135[A] MRID 46950121
Hydrolysis half-life pH = 5 pH = 7 pH = 9	 Stable Stable Stable	 MRID 42245127
Photolysis half-life in water	6 days – ca. 1 ppm in sterile buffer solution (30-day study) ca. 9.2 days – 1mg ai/L in natural water 228 days – 1.52 ml ai/L in sterile buffer solution (15-day study)	MRID 42245128 MRID 46950104 MRID 46950105[B]
Photolysis half-life in soil	349 - 823 days	MRID 46950106[C]
Aerobic soil metabolism half-life	84.5 days – at 0.1 ppm concentration 1600 days – at 10 ppm in loam 1059 days – at 10 ppm in sandy loam 120 days – at 0.13 ppm; Swiss loam 104 days – at 0.13 ppm; Swiss loam 165 (158) days – at 0.23 ppm; Swiss sandy loam 204 (187) days – at 0.23 ppm; Swiss sandy loam/loamy sand 204 (198) days – at 0.23 ppm; French silty clay loam 433 (408) days – at ca. 0.1 ppm in CA loamy sand at 25 °C 533 days – at ca. 0.1 ppm in CA loamy sand at 25 °C	MRID 42245131 MRID 42245132[D] MRID 42245133[D] MRID 46950109 MRID 46950110 MRID 46950111 MRID 46950112 MRID 46950114
Anaerobic soil metabolism half-life	947 days – at 10 ppm in loam	MRID 42245132
Aerobic aquatic metabolism half-life	860 days (10mg a.i./L) 315 (330) days (nominal 0.1 kg a.i./ha (=0.17 mg a.i./L); Swiss pond water-silty clay loam sediment) 335 (301) days (0.17 mg a.i./L; Swiss river water-sandy loam sediment) 565 days (0.04 mg a.i./L)	MRID 42245134[E] MRID 46950116 MRID 46950117
Anaerobic aquatic metabolism half-life	1245 days (10mg a.i./L) 370 days (433) (0.04 mg a.i./L)	MRID 42245134[E] MRID 46950119

Table 1. Summary of the physical and chemical properties of difenoconazole.		
Property	**Value**	**Source**
Terrestrial field dissipation half-life	252 days - determined in the 0- to 3-inch depth – CA bare loamy sand 231 days – GA bare loamy sand (four applications of 0.13 lb ai/A) 139 days – CA bare plot of loam soil (four applications of 0.13 lb ai/A) 462 days – ND bare sandy clay loam	MRID 42245140 MRID 46950126 MRID 46950127 MRID 46950129
Laboratory accumulation in fish bioaccumulation factor (*Lepomis macrochirus*) a depuration half-life	170x in edible tissues 570x nonedible tissues 330x for whole body 1 day	MRID 42245142

[A] There was another adsorption/desorption study (MRID 42245136) reviewed in which the test soils were autoclaved prior to conducting the study which could distort the mobility characteristic of difenoconazole, thus, the study results were not used for calculation of modeling input parameters.
[B] For the modeling purposes the longest half-life was used as it represents the most conservative scenario.
[C] The soil photolysis half-life under xenon light condition was recalculated to represent the conditions under natural sunlight intensity during 30-day periods between June and September (104.7-246.9 W·min/cm^2), as a result, a range of half-lives was obtained.
[D] In those aerobic soil metabolism studies (MRID 42245132 and MRID 42245133) the test application rate was significantly higher than expected under registrant-proposed use condition for difenoconazole.
[E] In those aquatic metabolism studies, the test application rates were significantly higher than expected under registrant-proposed use condition for difenoconazole.

The proposed application rate of difenconazole for emergency exemption use on watermelons in the state of Indiana is same or lower than the application rates for already registered uses. Difenconazole was first registered in Aug 4, 1994; the existing difenoconazole uses include wheat, triticale, and canola seed treatment. The recently registered uses include pome fruits, sugar beets, fruiting vegetables, vegetables, tuberous and corm, subgroup, and ornamentals (Sec 3, July 2007; D333319).

Among all the registered uses, the highest estimated drinking water concentrations (EDWCs) from surface water sources were derived for aerial applications of difenoconazole to California ornamental nurseries at the maximum annual application rate of 0.60 kg ai/ha. The second highest EDWC were derived for Maine potatoes at the maximum annual application rate of 0.48 kg ai/ha. These concentrations are recommended to be used for the human health risk assessment purpose. The highest predicted drinking water concentrations of difenoconazole from surface water sources, from agricultural and non-agricultural uses, are presented in **Table 2**.

Table 2. Tier II PCA Corrected Difenoconazole EDWCs from Surface Water Sources				
Scenario	Application Type/Annual Fungicide Application Rate (kg ai/ha))	Estimated Drinking Water Concentrations (µg/L)		
		1 in 10 year annual peak	1 in 10 year annual mean	36 year annual mean
CA Ornamental Nursery	aerially applied 0.15 x 4 = 0.60	13.3	9.43	7.18
ME Potato [a]	aerially applied 0.12 x 4 = 0.48	12.5	8.14	6.63

[a] EXAMS EECs multiplied by 0.87, a default PCA factor. No PCA was applied to the EDWCs from the Ornamental scenario.

For same difenconazole registered uses on nurseries and potato, the SCI-GROW model estimated the concentration of difenoconazole in drinking water from shallow ground water sources to be 1.08 x 10^{-2} µg/L for agricultural uses (nurseries), and 1.28 x 10^{-2} µg/L for non-agricultural uses (potato). These concentrations can be considered as both the

acute and chronic values.

For detail information regarding drinking water assessment refer to document untitled, Amended Difenoconazole (Parent Only) Drinking Water Assessment in Support of New Use Registration Action for Fruiting Vegetables, Tuberous, Corn, Vegetables Subgroup, Pome Fruit, Ornamentals, and Sugar beets, from June 19, 2007 (D333319 and D340041).

In clear natural water, difenoconazole may break down by photolysis to triazolyl acetic acid and further to triazole methanol and triazole. 1,2,4-Triazole and its conjugates (triazole alanine and triazole acetic acid) are common metabolites to the class of compounds known as the triazole-derivative fungicides (T-D fungicides, conazoles). A separate cumulative risk assessment was conducted on 1,2,4-trizole degradates. The Office of Pesticide Program's Health Effects Division (HED) has conducted aggregate human health risk assessments for 1,2,4-triazole and triazole conjugates which was completed on Feb 7, 2006 (D320683). A Tier II drinking water assessment for 1,2,4-triazole was completed in Feb 28, 2006 (D320682).

IV. Terrestrial Exposure Assessment

Estimated exposure concentrations for terrestrial receptors were determined using the standard screening-level exposure model, TREX (v.1.3.1.) (EPA, December 7, 2006). Essentially, for a single application, there is a linear relationship between the amount of pesticide applied and the amount of pesticide residue present on a given food item. These relationships for the various food items are determined from the Kenaga nomogram as modified by Fletcher (Hoerger and Kenaga, 1972; Fletcher et al., 1994). TREX (v.1.3.1) is a terrestrial exposure model that, in addition to incorporating the nomogram relationship, also includes pesticide degradation in the estimate of EECs.

If foliar dissipation half-life data is available, this value is incorporated into the TREX model. Since the foliar dissipation half-life value was not available, half-life default of 35 days was used to provide an upper-bound difenoconazole residue concentration on foliage. Maximum Kenaga EECs for two applications to water-melons are shown in **Table 3** and additional information on TREX modeling is in **Appendix A**

Table 3. Estimates of dietary based-maximum Kenaga EECs for foliar residues of difenoconazole on water-melons with a foliar dissipation $t_{1/2}$ =35 days half-life value and a 7-day application interval.

Use/App. Method	Application Rate lbs. a.i./A (# app / interval, days)	Food Items	Maximum EEC (mg/kg)
Water-melons (aerial/ground-spray)	0.114 7-days 2 applications per year	Short grass	**51.18**
		Tall grass	**23.46**
		Broadleaf plants/small insects	**28.79**
		Fruits, pods, seeds, and large insects	**3.20**

Summary of Terrestrial Hazard Toxicity:

Table 4. Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms Exposed to Difenoconazole.

Species	Acute Toxicity				Chronic Toxicity	
	LD_{50}	Acute Oral Toxicity (MRID)	5-day LC_{50}	Subacute Dietary Toxicity (MRID)	NOAEC / LOAEC	Affected Endpoints (MRID)
Bobwhite quail			4579 mg ai/kg-diet	Slightly toxic (42245103)	NOAEC = 21.9 mg ai/kg-diet LOAEC = 108 mg ai/kg-diet	significant reduction in hatchling body weight observed at 108 mg ai/kg-diet significant reduction is eggs laid occurred at 539 mg ai/kg-diet; (46950202)
Mallard duck	>2150 mg ai/ kg-bwt	practically non toxic (42245105)				
Laboratory rat	1453 mg ai/kg-bwt	slightly toxic (42090006)				
Laboratory rat					NOAEC = 25 mg ai/kg-diet LOAEC = 250 mg ai/kg-diet	decreased maternal body weight gain, decreased pup weights at day 21 (42090018)
Honey bee	>100 µg ai/bee	practically non toxic (42245124)				
Earthworm	> 610 mg/kg dw	42245125				
Terrestrial Plants	No phytotoxic effects were observed in any species at the five treatments tested following pre- or post-emergence application (NOAEC > 0.44 lb a.i./A)					469502-03

Summary of Terrestrial Risk Conclusions:

Using the label-proposed application rate in this Section 18 Exemption Request, terrestrial risk conclusions for this Section 18 are as follows:

Chronic-dietary based avian levels of concern were exceeded for birds feeding on:

- short grass (RQ=1.76); and
- broadleaf plants/small insects (RQ=1.00)

Chronic-dietary based levels of concern for mammals were exceeded for mammals feeding on the following difenoconazole-treated food-items:

- Mammals consuming short grass-food-items (RQ=2.05)

- Mammals consuming broadleaf plants/small insects (RQ=1.15)

Chronic-dose-based levels of concern for mammals were exceeded for mammals consuming the following difenoconazole-treated food items:

- 15-1000 gram mammals consuming short grass, tall grass, and broadleaf plants/small insects (chronic risk quotients ranged from 4.60-17.8)

- 15-gram mammals consuming fruits/pods/large insects (RQ=1.11)

A summary of terrestrial LOC exceedence values is found in **Appendix B** of this document.

V. Aquatic Exposure Assessment

EECs were estimated using EFED's aquatic models PRZM (Pesticide Root Zone Model) version 3.12 beta (dated 5/24/01) and EXAMS (EXposure Analysis Modeling System) version 3.12.2 (dated 7/18/01). PRZM is used to simulate pesticide transport as a result of runoff, erosion, and spray drift from a 10-ha agricultural field, and EXAMS considers environmental fate and transport of pesticides in surface water and predicts EECs in a standard farm pond (10,000-m^2 pond, 2-m deep), with the assumption that the small field is cropped at 100%. Simulations are carried out with the linkage program shell – PE5V01.pl which is incorporated the Florida crop scenario developed by EFED. Additional information on these models can be found at: http://www.epa.gov/oppefed1/ models/ water/index.htm. **Table 5** shows the PRZM/EXAMS environmental fate input parameter values and justification.

Table 5. PRZM/EXAMS Chemical Specific Input Parameters for Difenoconazole		
Parameter	**Input Value and Unit**	**Source**
Maximum application rate	0.128 kg ai/ha	Product Label Inspire®
Maximum number of applications	2- Water-melons	Product Label Inspire®
Method of application (CAM = 2)	Aerial and ground spray	Product Label Inspire®
Minimum interval between applications	7	Product Label Inspire®
Application efficiency	0.95 (aerial spray) 0.99 (ground spray)	EFED Model Input Guidance, Version II (2002)
Spray drift	0.05 (aerial), and 0.01 (ground)	EFED Model Input Guidance, Version II (2002)[a]
Partition coefficient K_{oc}[b]	5381 mL/g	MRIDs: 42245135 and 46950121
Application date	5-27	Application timing was selected based on the registrant data and based on the USDA Crop Profile website
Henry's Law constant	8.9×10^{-12} atm x m^3/mol	MRID 46515901
Hydrolysis	Stable	MRID 42245127
Aerobic soil metabolism ($t_{1/2}$)[c]	313 days	MRIDs.: 42245131, 46950109-12, and 46950114
Aerobic aquatic metabolism ($t_{1/2}$)[d]	556 days	MRIDs.: 46950116 & 46950117
Anaerobic aquatic metabolism ($t_{1/2}$)[e]	1110 days	MRID 46950119
Aquatic photolysis $t_{1/2}$ (days)[f]	228 days	MRID 46950105
Vapor pressure	2.5×10^{-10} mm Hg (25 °C)	MRID 46515901
Solubility in water[g]	150 mg/L (25 °C)	MRID 46515901
Molecular Weight	406	MRID 46950104
Foliar dissipation	Default value	

[a] *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version II"* dated February 28, 2002.
[b] There was a positive correlation between the K_F values *vs.* organic matter content; therefore, the average K_{oc} was used as an parameter.
[c] The 90% of the UCL of the mean metabolism half-life.
[d] The 90% of the UCL of the mean metabolism half-life of all available half-lives but those obtained for high test rate.
[e] At proposed application rate only one half-life was available, the half-life was multiplied by three (i.e., 3 x 370 days).
[f] The maximum value available.
[g] Solubility 15 mg/L x 10.

The maximum application rate, maximum number of applications minimum interval, and modeled application date are listed **Table 6**. The estimated 4-day peak average, 21- day average, and 60 day average concentrations of pyraclostrobin in surface water predicted by PRZM/EXAMS are presented in **Table 7**. The PRZM/EXAMS model runs for difenoconazole is in **Appendix C**.

Table 6. Standard EFED aquatic modeling scenarios for proposed difenoconazole uses				
PRZM Crop Scenario	**First Application Date dd-mm**	**Max Number of Applications**	**Minimum Application Interval (days)**	**Maximum Single Application Rate (lb ai/A)**
Indiana Water-melons	05-25	2	7	0.114

Table 7. Estimated concentrations of difenoconazole in based on aerial and ground applications to Indiana Water-melon scenario			
Spray Application	**Peak Conc. (µg/L)**	**21day Conc. (µg/L)**	**60 day Conc. (µg/L)**
Indiana (0.114 lbs ai/acre x 2 applications with 7-day interval)			
Aerial	2.2897	1.9885	1.8421
Ground	1.7741	1.5793	1.4627

Summary of Aquatic Hazard Profile:

Based on the aquatic toxicity studies, the toxicity endpoints used for the aquatic risk assessment of difenoconazole are characterized as follows in Table 8:

Table 8. Summary of Acute and Chronic Aquatic Toxicity Data Using Difenoconazole

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC_{50} (µg ai/L)	48-hr EC_{50} (µg ai/L)	Acute Toxicity Classification (MRID)	NOAEC / LOAEC (µg ai/L)	Affected Endpoints (MRID)
Rainbow Trout *Oncorhynchus mykiss*	810	--	highly toxic (42245107)	--	--
Fathead minnow *Pimephales promelas*	--	--	--	NOAEC = 8.7 LOAEC = 19.0	larval length at 30 days post hatch (42245115)
Water flea *Daphnia magna*	--	770	highly toxic (42245110)	NOAEC = 5.6 LOAEC =13.0	number of young/adult/ reproduction day and adult length (42245114)
Sheepshead minnow *Cyprinodon variegatus*	819	--	highly toxic (42245112)	NOAEC = 8.8*	--
Eastern oyster *Crassostrea virginica*	--	96hr EC_{50} = 424	highly toxic (42906701)	--	--
Mysid shrimp *Americamysis bahia*	150	--	highly toxic (42245111)	NOAEC < 0.115	number of young/adult/ reproduction day (46950133)
Duckweed (*Lemna gibba*)	EC_{50} = 1900		469205-04	--	--
FW Diatom (*Navicula pelliculosa*)	EC_{50} = 98		469205-08	--	--

Aquatic Risk Conclusions

Based on the aquatic EECs for sugarcane generated by PRZM/EXAMs, the proposed application rate (0.114 lbs ai/A), application interval (7-days between applications) and the number of applications (2 per growing season), no acute or chronic levels of concern are exceeded for aquatic organisms (freshwater and estuarine/marine) at this time.

While chronic levels of concern were exceeded for estuarine/marine invertebrates (using the estuarine/marine shrimp NOAEC value of <0.115 µg ai/L), the resulting risk quotient value is indefinite because of the presence of the inequality sign in the original toxicity value and the fact that there are no existing estuarine/marine environments in the state of Indiana.

Endangered Species

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated critical habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species."[1]

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2), the Environmental Protection Agency Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's baseline risk assessment is conducted, if any of the Agency's listed species LOCs are exceeded for either direct or indirect effects, an analysis is conducted to determine if any listed or candidate species may co-occur in the area of the proposed pesticide use or areas downstream or downwind that could be contaminated from drift or runoff/erosion. If determined that listed or candidate species may be present in the proposed action areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act. The federal action addressed herein is the use of difenoconazole on water-melons in Indiana where the maximum application rate is 0.114 lbs a.i./A applied aerially two times per year.

Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are collocated with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located adjacent to the treated site and aquatic organisms are assumed to be located in surface water that is the treated site. The assessment also assumes that the listed species are located within an assumed area which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area. The use characterization section

[1] 50 C.F.R. § 402.02

of this risk assessment presents the pesticide use sites that are used to establish initial collocation of species with treatment areas.

Taxonomic Groups Potentially at Risk

If the assumptions associated with the screening-level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects upon listed species that depend upon the taxonomic group covered by the RQ as a resource. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites could be considered to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps could consider how this information would impact the action area for a particular listed organism and may potentially include areas of exposure that are downwind and downstream of the pesticide use site.

Assessment endpoints, exposure pathways, the conceptual model addressing the proposed difenoconazole use, and the associated exposure and effects analyses conducted for the difenoconazole screening-level risk assessment have been discussed previously. The assessment endpoints used in the screening-level risk assessment include those defined operationally as reduced survival, reproduction, and growth for both aquatic and terrestrial animal species from direct acute and direct chronic exposures. These assessment endpoints address the standard set forth in the Endangered Species Act requiring federal agencies to ensure that any action they authorize does not reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species. Risk estimates (*i.e.*, RQs integrating exposure and effects) are calculated for broad-based taxa groups for the screening-level risk assessment and presented in risk estimation section of this document.

Appendix A: T-REX Input Data and RUNS

Avian Results

[redacted]

[redacted]

[redacted]

58.29	33.24	14.88
26.71	15.23	6.82
32.79	18.70	8.37
3.64	2.08	0.93

[redacted]

0.05	0.02	0.01
0.02	0.01	0.00
0.03	0.01	0.00
0.00	0.00	0.00

[redacted]

Acute	Chronic
0.01	1.76
0.01	0.81
0.01	0.99
0.00	0.11

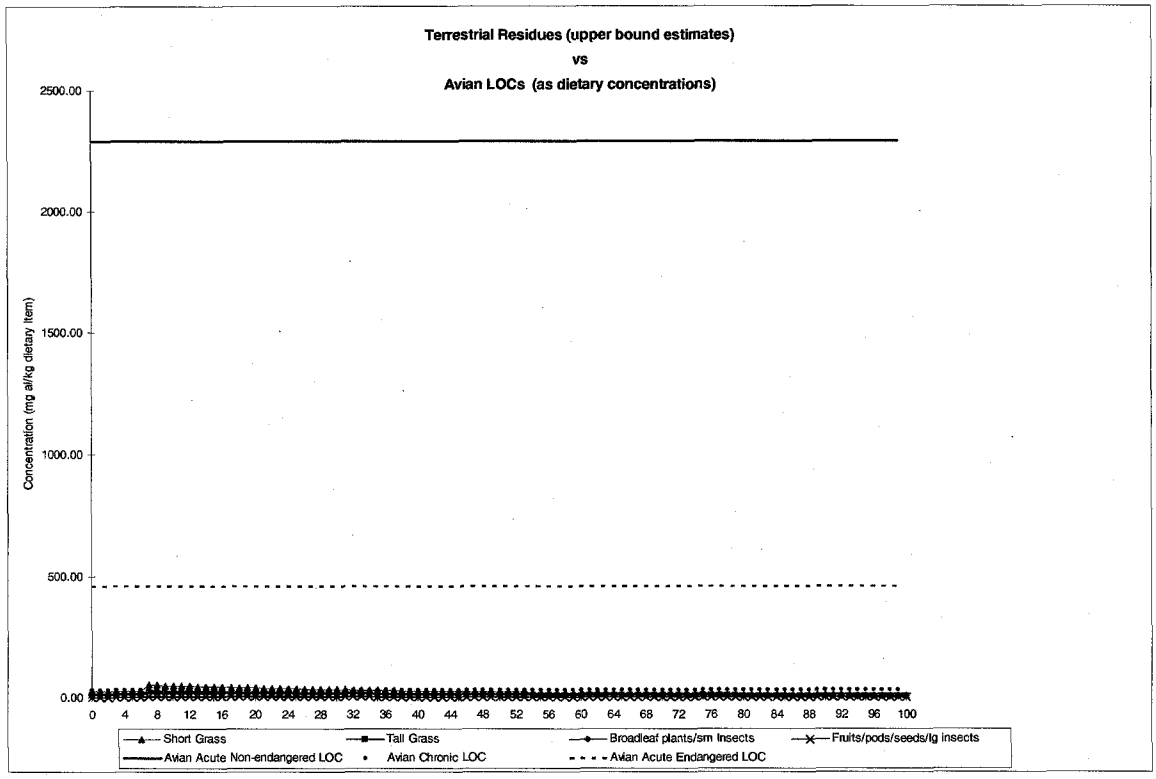
Note: To provide risk management with the maximum possible information, it is recommended that both the dose-based and concentration-based RQs be calculated when data are available

Difenoconazole **Watermelons** **Upper bound Kenaga Residues**

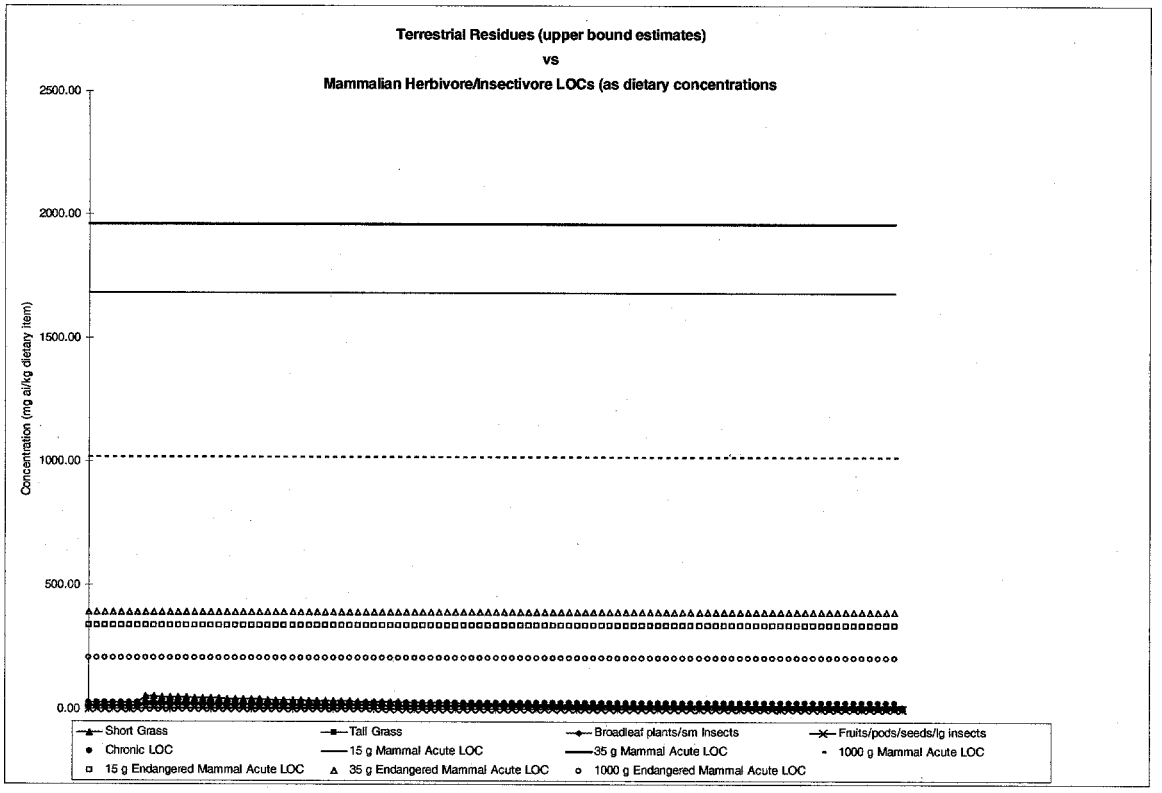
Mammalian Results

[redacted]

[redacted]



Graph 1: Avian LOCs (as dietary concentrations)



Graph 2: Mammalian Granivore LOCs (as dietary concentrations)

Species Listing by State with Use Criteria

No species were excluded
Minimum of 1 Acre.
All Medium Types Reported
Mammal, Marine mml, Bird, Amphibian, Reptile, Fish, Crustacean, Bivalve, Gastropod, Arachnid, Insect, Dicot, Monocot, Ferns, Conf/cycds, Coral, Lichen
watermelons, watermelons harvested for sale (PR)

Indiana (12) species:

Habitat		Taxa	Critical
Plover, Piping *(Charadrius melodus)*	Endangered	Bird Terrestrial	Yes
Tern, Interior (population) Least *(Sterna antillarum)*	Endangered	Bird Terrestrial	No
Clover, Running Buffalo *(Trifolium stoloniferum)*	Endangered	Dicot Terrestrial	No
Goldenrod, Short's *(Solidago shortii)*	Endangered	Dicot Terrestrial	No
Milkweed, Mead's *(Asclepias meadii)*	Threatened	Dicot Terrestrial	No
Thistle, Pitcher's *(Cirsium pitcheri)*	Threatened	Dicot Terrestrial	No
Butterfly, Karner Blue *(Lycaeides melissa samuelis)*	Endangered	Insect Terrestrial	No
Butterfly, Mitchell's Satyr *(Neonympha mitchellii mitchellii)*	Endangered	Insect Terrestrial	No
Bat, Gray *(Myotis grisescens)*	Endangered	Mammal Subterraneous, Terrestrial	No
Bat, Indiana *(Myotis sodalis)*	Endangered	Mammal Subterraneous, Terrestrial	Yes
Wolf, Gray *(Canis lupus)*	Endangered	Mammal Terrestrial	Yes
Snake, Northern Copperbelly Water *(Nerodia erythrogaster neglecta)*	Threatened	Reptile Freshwater, Terrestrial	No

Species Counts by State for Indicated Crops

No species were excluded.
Minimum of 1 Acre.
All Medium Types Reported

watermelons, watermelons harvested for sale (PR)
Indiana

Indiana

The taxa Bird has 2 species co-occurring with indicated crops.

The taxa Dicot has 4 species co-occurring with indicated crops.

The taxa Insect has 2 species co-occurring with indicated crops.

The taxa Mammal has 3 species co-occurring with indicated crops.

The taxa Reptile has 1 species co-occurring with indicated crops.

Appendix B: Terrestrial Risk Quotients and LOC Levels

Table B-1. Risk presumptions for terrestrial animals (birds and wild mammals).		
Risk Presumption	**RQ**	**LOC**
Acute	EEC[1]/LC50 or LD50/ft^2 or LD50/day3	0.5
Acute Restricted Use	EEC/LC50 or LD50/ft^2 or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/ft^2 or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{\text{mg/ft}^2}{LD_{50} * \text{wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{LD_{50} * \text{wt. of bird}}$

Table B-2. Risk presumptions for aquatic animals.		
Risk Presumption	**RQ**	**LOC**
Acute	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOAEC	1

[1]EEC = (ppm or ppb) in water

Table B-3. Risk presumptions for aquatic plants.		
Risk Presumption	**RQ**	**LOC**
Acute Risk	EEC[1]/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOAEC/EC_{05} or NOAEC	1

Table B-4. Risk presumptions for terrestrial and semi-aquatic plants.		
Risk Presumption	**RQ**	**LOC**
Acute Risk	EEC[1]/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOAEC	1

Appendix C: PRZM/EXAM EECs for Water-melons in Indiana:

stored as difenMOg.out
Chemical: difenoconazole
PRZM environment: MOmelonRegionalStd.txt modified Wedday, 11 June 2008 at 09:01:56
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.3179	0.2817	0.23	0.1823	0.1365	0.05083
1962	0.3888	0.3542	0.33	0.2824	0.2679	0.2042
1963	0.6739	0.6172	0.4675	0.4251	0.3995	0.3279
1964	0.7152	0.6647	0.5797	0.4882	0.4674	0.4239
1965	1.213	1.107	0.8454	0.6956	0.6779	0.6061
1966	0.7965	0.768	0.7317	0.6971	0.6796	0.6599
1967	0.9126	0.8768	0.8052	0.7519	0.7475	0.7162
1968	1.249	1.167	0.9936	0.9121	0.9015	0.832
1969	1.494	1.398	1.16	0.9996	0.9619	0.8991
1970	1.119	1.088	1.042	1.009	1.003	0.9696
1971	1.356	1.287	1.135	1.042	1.022	0.9793
1972	1.278	1.221	1.134	1.079	1.063	0.9979
1973	1.243	1.202	1.13	1.086	1.07	1.059
1974	1.706	1.605	1.485	1.335	1.302	1.176
1975	1.389	1.351	1.301	1.253	1.242	1.181
1976	1.597	1.512	1.322	1.228	1.209	1.164
1977	1.243	1.212	1.172	1.155	1.156	1.121
1978	1.621	1.533	1.409	1.284	1.246	1.191
1979	1.757	1.678	1.519	1.433	1.39	1.323
1980	2.05	1.919	1.625	1.535	1.477	1.373
1981	1.543	1.493	1.439	1.394	1.377	1.332
1982	1.505	1.476	1.38	1.33	1.322	1.298
1983	1.886	1.79	1.63	1.473	1.43	1.343
1984	1.742	1.688	1.586	1.466	1.428	1.367
1985	1.416	1.395	1.38	1.342	1.336	1.297
1986	1.623	1.57	1.389	1.317	1.263	1.227
1987	1.684	1.646	1.363	1.322	1.265	1.228
1988	1.776	1.675	1.507	1.35	1.322	1.282
1989	1.633	1.583	1.468	1.4	1.381	1.352
1990	1.593	1.537	1.402	1.357	1.342	1.319

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	2.05	1.919	1.63	1.535	1.477	1.373
0.0645161290322581	1.886	1.79	1.625	1.473	1.43	1.367
0.0967741935483871	1.776	1.688	1.586	1.466	1.428	1.352

0.129032258064516	1.757	1.678	1.519	1.433	1.39	1.343
0.161290322580645	1.742	1.675	1.507	1.4	1.381	1.332
0.193548387096774	1.706	1.646	1.485	1.394	1.377	1.323
0.225806451612903	1.684	1.605	1.468	1.357	1.342	1.319
0.258064516129032	1.633	1.583	1.439	1.35	1.336	1.298
0.290322580645161	1.623	1.57	1.409	1.342	1.322	1.297
0.32258064516129	1.621	1.537	1.402	1.335	1.322	1.282
0.354838709677419	1.597	1.533	1.389	1.33	1.302	1.228
0.387096774193548	1.593	1.512	1.38	1.322	1.265	1.227
0.419354838709677	1.543	1.493	1.38	1.317	1.263	1.191
0.451612903225806	1.505	1.476	1.363	1.284	1.246	1.181
0.483870967741936	1.494	1.398	1.322	1.253	1.242	1.176
0.516129032258065	1.416	1.395	1.301	1.228	1.209	1.164
0.548387096774194	1.389	1.351	1.172	1.155	1.156	1.121
0.580645161290323	1.356	1.287	1.16	1.086	1.07	1.059
0.612903225806452	1.278	1.221	1.135	1.079	1.063	0.9979
0.645161290322581	1.249	1.212	1.134	1.042	1.022	0.9793
0.67741935483871	1.243	1.202	1.13	1.009	1.003	0.9696
0.709677419354839	1.243	1.167	1.042	0.9996	0.9619	0.8991
0.741935483870968	1.213	1.107	0.9936	0.9121	0.9015	0.832
0.774193548387097	1.119	1.088	0.8454	0.7519	0.7475	0.7162
0.806451612903226	0.9126	0.8768	0.8052	0.6971	0.6796	0.6599
0.838709677419355	0.7965	0.768	0.7317	0.6956	0.6779	0.6061
0.870967741935484	0.7152	0.6647	0.5797	0.4882	0.4674	0.4239
0.903225806451613	0.6739	0.6172	0.4675	0.4251	0.3995	0.3279
0.935483870967742	0.3888	0.3542	0.33	0.2824	0.2679	0.2042
0.967741935483871	0.3179	0.2817	0.23	0.1823	0.1365	0.05083

0.1	1.7741	1.687	1.5793	1.4627	1.4242	1.3511

Average of yearly averages: 1.00999766666667

Inputs generated by pe5.pl - Novemeber 2006

Data used for this run:
Output File: difenMOg
Metfile: w13893.dvf
PRZM scenario: MOmelonRegionalStd.txt
EXAMS environment file: pond298.exv
Chemical Name: difenoconazole

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	406	g/mol	
Henry's Law Const.	henry	8.9e-12	atm-m^3/mol	
Vapor Pressure	vapr	2.5e-10	torr	
Solubility	sol	150	mg/L	
Kd	Kd		mg/L	
Koc	Koc	5381	mg/L	

Photolysis half-life kdp 228 days Half-life
Aerobic Aquatic Metabolism kbacw 556 days Halfife
Anaerobic Aquatic Metabolism kbacs 1110 days Halfife
Aerobic Soil Metabolism asm 313 days Halfife
Hydrolysis: pH 7 0 days Half-life
Method: CAM 2 integerSee PRZM manual
Incorporation Depth: DEPI 0 cm
Application Rate: TAPP 0.1277 kg/ha
Application Efficiency: APPEFF 0.99 fraction
Spray Drift DRFT 0.01 fraction of application rate applied to pond
Application Date Date 01-05 dd/mm or dd/mmm or dd-mm or dd-mmm
Interval 1 interval 7 days Set to 0 or delete line for single app.
app. rate 1 apprate kg/ha
Record 17: FILTRA
IPSCND 1
UPTKF
Record 18: PLVKRT
PLDKRT 0.0198
FEXTRC 0.5
Flag for Index Res. Run IR EPA Pond
Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)

stored as difenMOa.out
Chemical: difenoconazole
PRZM environment: MOmelonRegionalStd.txt modified Wedday, 11 June 2008 at 09:01:56
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.5476	0.4598	0.2931	0.2323	0.1885	0.09939
1962	0.6824	0.6036	0.4654	0.3782	0.3637	0.2987
1963	0.8533	0.7903	0.6272	0.6072	0.5745	0.4613
1964	1.004	0.924	0.7855	0.6611	0.6471	0.5905
1965	1.436	1.327	1.058	0.9359	0.8884	0.7969
1966	1.309	1.228	1.111	0.9922	0.9514	0.8759
1967	1.423	1.329	1.163	1.065	1.04	0.9543
1968	1.502	1.422	1.276	1.187	1.172	1.086
1969	1.737	1.644	1.415	1.257	1.219	1.166
1970	1.717	1.63	1.492	1.368	1.336	1.247
1971	1.863	1.756	1.561	1.412	1.361	1.268
1972	1.697	1.614	1.48	1.366	1.368	1.295
1973	1.852	1.761	1.608	1.465	1.43	1.362
1974	2.034	1.932	1.804	1.687	1.643	1.48
1975	1.949	1.887	1.754	1.644	1.592	1.491
1976	1.889	1.807	1.659	1.603	1.558	1.48
1977	1.887	1.807	1.668	1.549	1.512	1.44
1978	2.169	2.036	1.77	1.612	1.566	1.507
1979	2.291	2.172	1.994	1.825	1.759	1.636
1980	2.352	2.225	1.939	1.844	1.809	1.684
1981	2.069	1.99	1.864	1.785	1.732	1.641
1982	2.026	1.947	1.807	1.723	1.69	1.61
1983	2.278	2.171	2.033	1.86	1.797	1.655
1984	2.389	2.261	2.064	1.86	1.798	1.68
1985	2.08	1.997	1.859	1.731	1.69	1.614
1986	1.968	1.891	1.752	1.662	1.616	1.545
1987	1.969	1.925	1.749	1.64	1.603	1.545
1988	2.053	1.956	1.796	1.672	1.652	1.597
1989	2.066	1.987	1.848	1.759	1.754	1.667
1990	2.063	1.983	1.855	1.743	1.701	1.637

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	2.389	2.261	2.064	1.86	1.809	1.684
0.0645161290322581	2.352	2.225	2.033	1.86	1.798	1.68
0.0967741935483871	2.291	2.172	1.994	1.844	1.797	1.667

0.129032258064516	2.278	2.171	1.939	1.825	1.759	1.655
0.161290322580645	2.169	2.036	1.864	1.785	1.754	1.641
0.193548387096774	2.08	1.997	1.859	1.759	1.732	1.637
0.225806451612903	2.069	1.99	1.855	1.743	1.701	1.636
0.258064516129032	2.066	1.987	1.848	1.731	1.69	1.614
0.290322580645161	2.063	1.983	1.807	1.723	1.69	1.61
0.32258064516129	2.053	1.956	1.804	1.687	1.652	1.597
0.354838709677419	2.034	1.947	1.796	1.672	1.643	1.545
0.387096774193548	2.026	1.932	1.77	1.662	1.616	1.545
0.419354838709677	1.969	1.925	1.754	1.644	1.603	1.507
0.451612903225806	1.968	1.891	1.752	1.64	1.592	1.491
0.483870967741936	1.949	1.887	1.749	1.612	1.566	1.48
0.516129032258065	1.889	1.807	1.668	1.603	1.558	1.48
0.548387096774194	1.887	1.807	1.659	1.549	1.512	1.44
0.580645161290323	1.863	1.761	1.608	1.465	1.43	1.362
0.612903225806452	1.852	1.756	1.561	1.412	1.368	1.295
0.645161290322581	1.737	1.644	1.492	1.368	1.361	1.268
0.67741935483871	1.717	1.63	1.48	1.366	1.336	1.247
0.709677419354839	1.697	1.614	1.415	1.257	1.219	1.166
0.741935483870968	1.502	1.422	1.276	1.187	1.172	1.086
0.774193548387097	1.436	1.329	1.163	1.065	1.04	0.9543
0.806451612903226	1.423	1.327	1.111	0.9922	0.9514	0.8759
0.838709677419355	1.309	1.228	1.058	0.9359	0.8884	0.7969
0.870967741935484	1.004	0.924	0.7855	0.6611	0.6471	0.5905
0.903225806451613	0.8533	0.7903	0.6272	0.6072	0.5745	0.4613
0.935483870967742	0.6824	0.6036	0.4654	0.3782	0.3637	0.2987
0.967741935483871	0.5476	0.4598	0.2931	0.2323	0.1885	0.09939

0.1	2.2897	2.1719	1.9885	1.8421	1.7932	1.6658

Average of yearly averages: 1.280333

Inputs generated by pe5.pl - Novemeber 2006

Data used for this run:
Output File: difenMOa
Metfile: w13893.dvf
PRZM scenario: MOmelonRegionalStd.txt
EXAMS environment file: pond298.exv
Chemical Name: difenoconazole

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	406	g/mol	
Henry's Law Const.	henry	8.9e-12	atm-m^3/mol	
Vapor Pressure	vapr	2.5e-10	torr	
Solubility	sol	150	mg/L	
Kd	Kd		mg/L	
Koc	Koc	5381	mg/L	

Photolysis half-life kdp 228 days Half-life
Aerobic Aquatic Metabolism kbacw 556 days Halfife
Anaerobic Aquatic Metabolism kbacs 1110 days Halfife
Aerobic Soil Metabolism asm 313 days Halfife
Hydrolysis: pH 7 0 days Half-life
Method: CAM 2 integerSee PRZM manual
Incorporation Depth: DEPI 0 cm
Application Rate: TAPP 0.1277 kg/ha
Application Efficiency: APPEFF 0.95 fraction
Spray Drift DRFT 0.05 fraction of application rate applied to pond
Application Date Date 01-05 dd/mm or dd/mmm or dd-mm or dd-mmm
Interval 1 interval 7 days Set to 0 or delete line for single app.
app. rate 1 apprate kg/ha
Record 17: FILTRA
IPSCND 1
UPTKF
Record 18: PLVKRT
PLDKRT 0.0198
FEXTRC 0.5
Flag for Index Res. Run IR EPA Pond
Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)