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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Transmittal of EFED List A Summary Report for Diflubenzuron
(Dimilin) Chemical #108201; Case #0144

FROM: Linda Kutney *Linda C. Kutney*
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

THRU: *Kathy S. Monk*
Kathy S. Monk, Acting Chief
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Environmental Fate and Effects Division

TO: Walter Waldrop, Acting Chief
Reregistration Branch
Special Review & Reregistration Division

Attached please find the following documents for the completed EFED summary report of
Diflubenzuron (Dimilin).

1. SACS Reregistration Summary Report
2. EEB Science Chapter
3. EFGWB Science Chapter

Several data requirements are outstanding, however, a risk assessment was done using
available information. Levels of concern were exceeded for aquatic invertebrates. If you
have any questions concerning this case, please contact Linda Kutney on 305-6155.

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6-30-95
EFED



2018708

CC:\ (with SACS Reregistration Summary Report attached)

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SACS RED Summary Report: DIFLUBENZURON

FROM: Linda Kutney
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

THRU: *Kathy S. Monk*
Kathy S. Monk, Acting Chief
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TO: Walter Waldrop, Acting Chief
Reregistration Branch
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Case number: 0144

Chemical number: 108201

Active ingredient: N-[[[4-Chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide

Common name: Diflubenzuron

Trade names: Dimilin, Micomite

List: A

I. Exceedance of Levels of Concern (LOCs)

The major environmental risk of diflubenzuron is to aquatic invertebrates. Its unique mode of action disrupts the molting process of insects and aquatic invertebrates by interfering with the deposition of chitin and formation of a new exoskeleton.

Acute and chronic levels of concern (LOCs) were exceeded for freshwater aquatic invertebrates, for the use of diflubenzuron on cotton, citrus, forest trees and forest plantings. Acute and chronic risk quotients for these crops ranged as follows, 1 to 31 for cotton, 2 to 38 for citrus, and 3 to 1529 for forest trees and forest plantings, at application rates of 0.0156 to 0.6666 lb ai/A diflubenzuron.

Acute and chronic levels of concern (LOCs) were exceeded for estuarine and marine aquatic invertebrates for the use of diflubenzuron on cotton, citrus, forest trees and forest plantings. Acute and chronic risk quotients for these crops ranged as follows, 2 to 25 for cotton, 4 to 31 for citrus, and 5 to 1223 for forest trees and forest plantings, at application rates of 0.0156 to 0.6666 lb ai/A diflubenzuron.

One RQ for marine fish exceeded the chronic LOC for the forestry use. The RQ was 2 for the 0.125 lb ai/A application rate.

Estimated environmental concentrations (EECs) for forest trees and forest plantings were calculated assuming direct application of diflubenzuron to water. This estimate was used because the available models do not apply to the forestry scenario.

II. Data Gaps

A. ECOLOGICAL EFFECTS

The outstanding data requirements are:

- 1) A 96-hour mummichog estuarine/marine study using technical diflubenzuron.

There is a moderately low value of information associated with this data requirement. It would allow a basis of comparison of diflubenzuron's marine fish toxicity to that of other pesticides.

- 2) Aquatic invertebrate lifecycle studies for freshwater and estuarine/marine species using technical diflubenzuron.

There is a moderately high value of information associated with this data requirement. The submitted life-cycle tests with the technical grade failed to meet guideline requirements because the test concentrations were too high to provide a NOEL, which is needed to calculate chronic risk. Although existing data clearly show a high risk to aquatic invertebrates, the risk may be an underestimate because the acute test results indicate that technical diflubenzuron is more toxic than the 25% WP formulation. Therefore, using chronic test data for the 25% WP may underestimate the level of chronic risk to which freshwater invertebrates are exposed.

- 3) A marine/estuarine fish life-cycle study.

There is a moderate value of information associated with this data requirement. The submitted life-cycle study did not adequately test the effects on reproduction, a major objective of this test. The study was poorly designed

since there were no dose-response reactions. The magnitude or types of chronic risk cannot be determined with the present study. Therefore a well-designed life-cycle study conducted with an estuarine fish will provide additional information.

B. ENVIRONMENTAL FATE

The outstanding data requirements are:

- 1) An acceptable field spray drift study (202-1). These data are necessary to estimate spray drift. The Registrants may elect to satisfy this requirement through the Spray Drift Task Force. In that case, the study may be reserved.
- 2) Storage stability data for diflubenzuron and its degradates using the same type of soil, litter, and leaves that were used in the forestry dissipation study (164-3). These data are necessary for the validation of the submitted forestry dissipation study.
- 3) There are 24c (Special Local Need/State) registrations in Florida, California, Hawaii, Nevada and Alabama, for aquatic uses to control mosquitoes and/or midges in non-potable water, irrigation ditches, tailings, livestock wastewater lagoons, man-made ponds, noncrop lakes, ponds, channels, ditches, percolation basins, wastewater biological filter beds, storm water drains, street gutters, stock piled rubber tires, sewage effluent, grassy swales, temporary rainwater groundpools, junkyards, refuse dumps, etc). If a more comprehensive environmental fate assessment is needed to support aquatic uses, aerobic aquatic metabolism (162-4), aquatic (sediment) dissipation (164-2), accumulation in irrigation crops (165-3), and accumulation in aquatic non-target organisms (165-5) may be required. These studies will furnish data needed to more accurately predict the environmental impact in States where aquatic uses are permitted.
- 4) Adsorption/desorption data on CPU (not diflubenzuron) and bare ground data from typical use area(s) in the North. P-chlorophenyl urea (CPU) and P-chloro-aniline (PCA) are toxicologically significant degradates of diflubenzuron. PCA is carcinogenic. Metabolites of diflubenzuron which are chemically related to PCA should be evaluated as PCA unless there is evidence that they are not carcinogenic.

In the bare ground plot studies, due to the volume of water (rainfall plus irrigation) to the plots in Louisiana and Arizona, there is concern that CPU was below the detection limits in the 6-30 inch soil depth segments. To better understand the environmental fate of CPU, adsorption/desorption data on CPU (not diflubenzuron) and bare ground field dissipation data from a typical use

area(s) further north with less rainfall and irrigation are needed. These data should provide a better understanding of the mobility and persistence of CPU in the environment to determine its potential as a ground water contaminant.

III. Endangered Species

Acute and chronic LOCs for endangered species are exceeded for freshwater and estuarine/marine aquatic invertebrates for the citrus, cotton and forestry uses. A chronic LOC was exceeded for estuarine/marine fish for the highest forestry use rate (0.125 lb ai/A). The acute LOC for estuarine/marine mollusks was exceeded for the three highest forestry use rates.

IV. Labeling

a) Manufacturing Use

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b) Non-granular End-Use Products

"This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wastewater or rinsate."

c) Aquatic Use Sites (mosquito larvicides)

"This pesticide is toxic to aquatic invertebrates. Fish and aquatic invertebrates may be killed where this pesticide is used. Do not contaminate water when disposing of equipment or rinsate. Consult with State agency in charge of fish and game before applying to public waters to determine if a permit is required."

V. Risk Reduction Measures/Mitigation

The major environmental risk of diflubenzuron is to aquatic invertebrates. Its unique mode of action disrupts the molting process of insects and aquatic invertebrates by interfering with the deposition of chitin and formation of a new exoskeleton.

In addition to seeking rate reduction to the lowest efficacious level, the following mitigation is recommended:

Citrus Use:

Risk mitigation should follow the mitigation currently on the label for Florida citrus. This includes specific protection of unique or valuable aquatic resources (for example, in Florida, the commercial shrimp industry).

Row Crop and Orchard Use:

Risk mitigation should include a 150' buffer zone for aerial applications, a 25' vegetative buffer zone for ground application and a 25' vegetative filter strip to decrease runoff. The standard spray drift mitigation language should apply for all aerial uses.

Mosquito Use:

Although the risk to aquatic invertebrates is substantial, no mitigation is currently proposed due to direct application near waterbodies. A task force is currently addressing this problem on a generic basis.

C. ENVIRONMENTAL ASSESSMENT

1. ECOLOGICAL TOXICITY DATA

EFED has adequate data to assess the hazard of diflubenzuron to nontarget terrestrial organisms.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of diflubenzuron to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). The following tables summarize the available data.

Avian Acute Oral Toxicity Findings					
Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	99.4	> 5000 mg/kg	00073935 Roberts / 1976	practically non-toxic	Yes
Mallard Duck ¹	Technical	> 5000 mg/kg	00073936 Roberts / 1976	practically non-toxic	Yes
Red-winged Blackbirds ¹	Technical	> 3763 mg/kg	00038614 Alsager / 1975	practically non-toxic	Supplemental

Avian Subacute Dietary Toxicity Findings					
Species	% A.I.	LC_{50} ppm	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	Technical	> 4640 ppm	00039080 / 1976 R. Fink	Slightly Toxic	Yes
Mallard Duck	Technical (100%)	> 4640 ppm	00038613 / 1973 R. Fink	Slightly Toxic	Yes
Bobwhite Quail Mallard Duck	1% Granular	> 20,000 ppm	00060381 / 1976 Roberts	NA	Supplemental

These results indicate that diflubenzuron is **practically non-toxic** to avian species on an acute oral dietary basis and **slightly toxic** on an subacute dietary basis. The guideline requirements for avian acute and subacute toxicity are

fulfilled. (MRID #s: 00039080; 00038613; 00073935; 00073936; 00038614; 00039085; 00060381)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously due to pesticide persistence, bioaccumulation, multiple applications, or when mammalian reproduction tests indicate a reproductive hazard. Avian reproduction studies are required because repeat applications are allowed on all uses and potential reproductive impairment is suggested by the available reproductive data. The following table summarized the available data.

Avian Reproduction Findings						
Species	% A.I.	NOEL ppm	LOEL ppm	Endpoints affected	MRID No. Author/Year	Fulfills Guideline Requirement
Northern Bobwhite	97.6	500 ppm a.i.	1000 ppm a.i.	egg production	416680-02 Beavers / 1990	Yes
Mallard Duck	97.6	500 ppm a.i.	1000 ppm a.i.	eggshell thickness	416680-01 Beavers / 1990	Yes
Bobwhite Quail		No effects up to 250 ppm	NA	NA	00099719 Booth / 1977	Supplemental
Bobwhite Quail		Repro. parameters significantly affected @ 10 ppm (eggs embryonated) and 40 ppm (eggs laid)	NA	NA	00099862 Reinert / 1975	Supplemental
Mallard		No effects up to 40 ppm				
Bobwhite Quail		No effects up to 250 ppm	NA	NA	00099730 Roberts / 1977	Supplemental

The avian reproductive studies indicate that diflubenzuron affects egg production in bobwhite quail and eggshell thickness in the mallard duck at concentrations of over 500 ppm ai. The guideline requirements are fulfilled. (MRIDS: 41668002, 41668001, 00099719, 00099862, 00099730)

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies intended use pattern, and pertinent environmental fate characteristics. In most cases, an acute oral LD₅₀ from the

Agency's Health Effects Division is used to determine toxicity to mammals. This LD₅₀ is reported below.

Mammalian Acute Oral Toxicity Findings			
Species	LD ₅₀ mg/kg	MRID #	Toxicity Category
Acute Oral LD ₅₀ Mice	> 4640 mg/kg	00070024	Practically Non-toxic
Acute Oral LD ₅₀ Rat	> 4640 mg/kg	00070024	Practically Non-toxic

Available mammalian data indicate that diflubenzuron is **practically non-toxic** to small mammals on an acute oral basis. (MRID #: 00070024)

(4) Insects

A honey bee acute contact LD₅₀ study is required when pesticide use will result in honey bee exposure. The available data are summarized in the following table.

Nontarget Insect Acute Contact Toxicity Findings					
Species	% AI	LD ₅₀ µg a.i./bee	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	Technical	Contact LD50 >30 Oral LD50 >30	05001991 Stevenson/1978	Non-toxic	Yes
Honey Bee	Technical	Contact LD50 =114.8	00099890 Atkins/1974	Non-toxic	Yes

These results indicate that diflubenzuron is **non-toxic** to bees. The guideline requirement for honey bee acute toxicity is fulfilled. (MRID #s: 05001991; 00099890)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). The available data are summarized in the following table.

Freshwater Fish Acute Toxicity Findings					
Species	% A.I.	LC ₅₀ ppm a.i.	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	Technical	140 ppm	00056150	Practically Non-toxic	Yes
Bluegill sunfish	Technical	135 ppm	00056150	Practically Non-toxic	Yes
Rainbow trout	Technical	> 100 ppm	00003503	Practically Non-toxic	Yes
Brook trout	Technical	> 50 ppm		Slightly Toxic	Supplemental
Channel catfish	Technical	> 100 ppm		Practically Non-toxic	Yes
Bluegill sunfish	Technical	> 100 ppm		Practically Non-toxic	Yes
Yellow perch	Technical	> 25 ppm		Slightly Toxic	Supplemental
Bluegill Sunfish	Technical	> 100 ppm	00056035	Practically Non-toxic	Supplemental
Fathead Minnow	Technical	> 500 ppm	00060376	Practically Non-toxic	Supplemental
Cutthroat trout	25 % Wettable Powder	57 ppm	00003503	Slightly Toxic	Supplemental
Rainbow trout	25 % Wettable Powder	240 ppm		Practically Non-toxic	Yes
Fathead Minnow	25 % Wettable Powder	> 100 ppm		Practically Non-toxic	Supplemental
Channel Catfish	25 % Wettable Powder	> 100 ppm		Practically Non-toxic	Supplemental
Bluegill Sunfish	25 % Wettable Powder	> 100 ppm		Practically Non-toxic	Yes
Bluegill Sunfish	25 % Wettable Powder	230 ppm	00056150	Practically Non-toxic	Yes
Rainbow trout	25 % Wettable Powder	195 ppm		Practically Non-toxic	Yes
Common Carp	25 % Wettable Powder	389.5 ppm	00060384	Practically Non-toxic	Supplemental
Rainbow trout	25 % Wettable Powder	341.75 ppm		Practically Non-toxic	Yes
Bluegill Sunfish	1% Granular	> 1000 ppm	00060380	Practically Non-toxic	Supplemental
Rainbow trout	1% Granular	> 1000 ppm		Practically Non-toxic	Supplemental

The 96-hour acute toxicity studies indicate that diflubenzuron is **practically non-toxic** to freshwater fish.

The guideline requirements for 96-hour acute toxicity studies in freshwater fish are fulfilled for the technical grade and the 25% WP (wetable powder). (MRID #'s: 00056150; 00003503; 00056035; 00060376; 00060384; 00060380)

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. The available data are summarized in the following table.

Freshwater Invertebrate Toxicity Findings					
Species	% A.I.	EC ₅₀	MRID NO. Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Daphnia magna</i>	Technical	48 hr LC50 = 3.7 ppb	436658-01	Very Highly Toxic	Yes
<i>Gammarus pseudolimnaeus</i>	95 %	96hr LC50 = 45 ppb	400980-01 Mayer & Ellersieck/1986	Very Highly Toxic	Supplemental
<i>Gammarus pseudolimnaeus</i> (mature)	95 %	96hr LC50 = 30 ppb	00003503 Johnson and Finley/1980	Very Highly Toxic	Supplemental
<i>Daphnia magna</i>	25 % Wet. Pwdr.	48hr EC50 = 7.1 ppb	408405-02	Very Highly Toxic	Yes
<i>Daphnia magna</i>	25 % Wet. Pwdr.	48hr EC50 = 15 ppb	400980-01 Mayer & Ellersieck/1986	Very Highly Toxic	Supplemental
<i>Daphnia magna</i>	25 % Wet. Pwdr.	48hr EC50 = 16 ppb	00003503 Johnson and Finley/1980	Very Highly Toxic	Supplemental
<i>G. pseudolimnaeus</i>	25 % Wet. Pwdr.	96hr LC50 = 25 ppb	00003503 Johnson and Finley/1980	Very Highly Toxic	Supplemental

The results indicate that diflubenzuron is **very highly toxic** to freshwater aquatic invertebrates. The guideline requirements for freshwater invertebrate toxicity for the technical grade and the 25 % WP formulation are fulfilled. (MRID 40098001; 43665801; 00003503; 40840502)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial non-food use of diflubenzuron may result in exposure to the estuarine environment.

Required studies under this category include a 96-hour LC₅₀ for an estuarine fish, a 96-hour LC₅₀ for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study using oysters. The available data are summarized in the following table.

Estuarine/Marine Acute Toxicity Findings					
Species	% A.I.	LC ₅₀ /EC ₅₀ (ppb, ppm)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Mysidopsis bahia</i>	99	1.97 ppb	436620-01 Nimmo/1977	Very Highly Toxic	Yes
<i>Mysidopsis bahia</i>	95	2.06 ppb	402284-01 Mayer/1986	Very Highly Toxic	Yes
Quahogs (<i>Mercenaria mercenaria</i>)	97.6	>0.320 ppm	413920-01 Suprenant/1989	Highly Toxic	Yes
Grass Shrimp (<i>Palaemonetes pugio</i>)	100	0.64 ppm	00038612 EG&G Inc./1975	Highly Toxic	Supplemental
Mummichog (<i>Fundulus heteroclitus</i>)	25% Wet. Pwdr.	255 ppm	00056150	Practically non-toxic	Yes
Eastern Oyster (<i>Crassostrea virginica</i>)	25% Wet. Pwdr.	130 ppm	00038611 Marine Research Inst./1973	Practically Non-toxic	Supplemental
Quahogs (<i>Mercenaria mercenaria</i>); <i>Anodonta sp.</i> ; <i>Uca pugilator</i> ; <i>Carcinus maenas</i>	25 Wet. Pwdr.	> 1000ppm	00039088 Union Carbide/1976	Practically Non-toxic	Supplemental

The study results indicate that diflubenzuron is **very highly toxic** to marine/estuarine crustacea and **highly toxic** to marine/estuarine mollusks. The guideline requirements are fulfilled for an acute marine/estuarine mollusk study, and for an acute marine/estuarine crustacea study. Testing of an estuarine crustacean species with the 25% WP formulation is waived.

Results of the 96-hour acute toxicity study indicate that diflubenzuron is **practically non-toxic** to marine/estuarine fish. The guideline requirement for the 96-hour acute toxicity study with an estuarine/marine fish is fulfilled for the 25% wettable powder formulation, but is still outstanding for the technical grade diflubenzuron. (MRID: 43662001; 40228401; 41392001; 00038612; 00038611; 00039088; 00060377; 60228401; 00056150)

There is a moderately low value of information associated with this data requirement. It would allow a basis for comparison of diflubenzuron's marine fish toxicity to that of other pesticides.

(4) Freshwater and Estuarine/Marine Chronic Results

Aquatic Invertebrates

Early life-stage tests or life-cycle tests are required if the product is applied directly to water or expected to be transported to water from the intended use site, and if the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days).

Aquatic invertebrate chronic testing is required due to repeated applications of diflubenzuron, an aquatic invertebrate acute LC_{50} of less than 1 mg/L, and the pesticide's direct application to water as a mosquito larvicide. Additionally, available information indicates the potential for chronic hazard to aquatic invertebrates.

Finfish chronic testing is required due to repeated applications of diflubenzuron, and the pesticide's direct application to water as a mosquito larvicide.

The following table summarizes the available data.

Aquatic Invertebrate Life-Cycle Toxicity Findings							
Species	% A.I.	NOEL	LOEL	MATC	MRID No. Author/ Year	Endpoints Affected	Fulfills Guideline Rqmts.
<i>Daphnia magna</i>	99%	< 0.06 ppb	0.06 ppb		Test#2424 ABL- Beltsville Lab/Tomp kins/ 1979	Repro. & Surv.	Supplemental
<i>Daphnia magna</i>	Formul ation not ID'd	<0.09 ppb (Repro.)	0.09 ppb (Repro.)	<0.61 ppb (Surv.)	00010865 Leblanc/19 75	Repro. & Surv.	Supplemental
Brine Shrimp (<i>Artemia salina</i>)	100	> 10 ppb	> 10 ppb		00073933 Cunningha m/1975	Repro.	Supplemental
<i>Mysidopsis bahia</i>	99	No NOEL	0.075 ppb		436620-01 Nimmo/19 77	Repro.	Supplemental
<i>Daphnia magna</i>	25	40 pptr	93 pptr		408405-01	Surv. Growth Repro.	Core

The results indicate that diflubenzuron affects reproduction, growth and survival in freshwater invertebrates, and reproduction in marine/estuarine invertebrates. The guideline requirement is fulfilled for the 25% WP formulation with a freshwater invertebrate. (MRID: 2424, 00010865, 40130601, 00073933, 40840501)

The guideline requirements are not fulfilled for aquatic invertebrate life-cycle toxicity studies with freshwater and estuarine species using the technical grade active ingredient. There is a moderately high value of information associated with this data requirement. The submitted life-cycle tests with the technical grade failed to meet guideline requirements because the test concentrations were too high to provide a NOEL, which is needed to calculate chronic risk. Although existing data clearly show a high risk to aquatic invertebrates, the risk may be an underestimate because the acute test results indicate that technical diflubenzuron is more toxic than the 25% WP formulation. Therefore, using chronic test data for the 25% WP may underestimate the level of chronic risk to which freshwater invertebrates are exposed.

Fish

The fish life-cycle test is required when an end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site, when any of the following conditions apply: the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test; or if studies of other organisms indicate the reproductive physiology of fish may be affected.

The following table summarizes the available data.

Fish Life-Cycle Toxicity Findings							
Species	% A.I.	NOEL	LOEL	MATC	MRID No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement
Fathead minnow (<i>Pimephales promelas</i>)	99.4	0.10 ppm	>0.10 ppm	>0.10 ppm	00099755 Krize/1976	None	Yes
Mummichog ¹ (<i>Fundulus heteroclitus</i>)	Technical	50 ppb	NA	NA	00099722 Livingston/197 7	None	Supplemental

1) In the first generation 4 to 10 percent juveniles (test and control) developed abnormally. Several different statistical analyses showed no dose-dependent reactions with respect to abnormalities or mortalities. There was no significant difference in growth (wet weight) and number of eggs per female. Second generation showed no dose-dependent relationship for any observed relationship. This study did not provide an adequate test of the effects of diflubenzuron on reproductive success.

The results indicate that diflubenzuron does not affect reproduction in freshwater fish. However, the data for the estuarine species was supplemental. The guideline requirement is fulfilled for a fish life-cycle toxicity study with a freshwater species. (MRID: 00099755, 00099722)

A repeated estuarine/marine test is required. There is a moderate value of information associated with this data requirement. The submitted life-cycle study did not adequately test the effects on reproduction, a major objective of this test. The footnote above indicates the study was poorly designed since there were no dose-response reactions. The magnitude or types of chronic risk cannot be determined with the present study. Therefore a well-designed life-cycle study conducted with an estuarine fish will provide additional needed information. (MRID: 00099755, 00099722)

(5) Aquatic Field Testing (Data excerpted from the Diflubenzuron Registration Standard)

Twelve freshwater invertebrate field studies were reviewed. The table below summarizes these field studies.

Freshwater Invertebrate Field Testing		
Reference	Description	Result
Ali and Mulla (1978) 05000841	1% active granular product @ 0.1 and 0.2 lb. a.i./A was applied to finger areas on residential-recreational lakes in California. Observations were for 9 weeks post-treatment.	Reductions to cladocerans, copepods and amphipods.
Apperson et al. (1977) 00099897	25% active wettable powder @ 2.5, 5, and 10 ppb a.i. was applied to a farm pond and a small lake.	Crustacean zooplankton suppressed at all rates for up to 6 weeks, with recovery noted thereafter.
Booth (1975) 00038213	25% active wettable powder @ 0.4 lb. a.i./A were applied to small ponds in Utah, post-treatment samples were taken 30 and 80 days later.	Immature aquatic insect populations were reduced 30 days post-treatment.
Birdsong (1975) 00099791	25% active wettable powder @ 0.03 and 0.12 lb. a.i./A were applied 4 times at 2 week intervals to small ponds in Virginia. Samples were taken once pre-treatment and once post-treatment.	Cladocerans were reduced at both treatment levels.
Buckner et al. (1975) 00071210	25% active wettable powder @ 0.18 lb. a.i./A applied to forest in Canada for control of spruce budworm. Samples taken pre-treatment and 3 days post-treatment.	Amphipod and aquatic beetle larvae populations were removed, and copepods and ostracods may also have been impacted.
Jackson (1976) 00099891	25% active wettable powder @ 0.03 lb. a.i./A was applied 4 times at 2 week intervals to man-made ponds stocked with representative fauna. Samples were taken pre-treatment and 10 days after final treatment.	Invertebrate populations were susceptible with cladocerans particularly depressed.
Mulla et al. (1975) 00099839	1% active granular and 25% active wettable powder @ 0.025 and 0.05 lb. a.i./A were applied to replicated ponds. Observations were up to 13 days post-treatment.	Non-target organisms were reduced, cladocerans were affected more than the target species.
Steelman et al. (1975) 00038212	25% active wettable powder @ 0.01 to 0.25 lb. a.i./A were applied to flooded rice fields. One sample was taken 80 days post-treatment.	Certain non-target aquatic insects were reduced and others increased (due to reduction in predators).
Union Carbide Corp. (1976) 00039090	25% wettable powder @ 0.03 and 0.12 lb. a.i./A were applied to ponds 4 times at 2 week intervals in Texas. Samples were taken pre-treatment and 10 days after last treatment.	Certain benthic and zooplankton organisms were reduced or eliminated at both treatment levels.
Union Carbide Corp. (1976) 00039091	25% wettable powder @ 0.03 and 0.12 lb. a.i./A were applied 4 times at 2 week intervals to ponds in Arkansas. Samples were taken pre-treatment and 10 days post-treatment.	Copepods were reduced but generally a minimal impact when applied in December.
Union Carbide Corp. (1976) 00039092	25% wettable powder @ 0.03 and 0.12 lb. a.i./A were applied 4 times at 2 week intervals to ponds in North Carolina. Samples were taken pre-treatment and 9 days post-treatment.	May have eliminated certain sensitive and reduced other species.
Wan and Wilson (1977) 00095416	1% active granular @ 0.02 and 0.04 lb. a.i./A were applied to marsh habitat on the Fraser River, BC, Canada. Samples were taken up to 71 days post-treatment.	Reduced zooplankton and non-target insects.

All twelve freshwater invertebrate field studies demonstrated similar effects attributed to diflubenzuron when directly applied to an aquatic environment. Generally, aquatic invertebrate fauna (especially cladocerans) were markedly reduced with some recovery noted.

Three estuarine invertebrate field studies were reviewed and are summarized below:

Estuarine Invertebrate Field Testing		
Reference	Description	Result
Farlow (1976) 00099678	25% active wettable powder @0.025 lb. a.i./A was applied six times to a Louisiana coastal marsh over an 18 month period.	5 invertebrate taxa were reduced and 15 taxa were increased.
McAlonan (1975) 00099895	25% active wettable powder @ 0.04, 0.1 and 0.2 lb. a.i./A were applied up to 3 times to replicated semi-natural pools. Observations were taken from 2 to 4 weeks from initial treatment.	Grass shrimp and fiddler crabs exhibited high mortality from just 1 treatment. Killifish showed no discernable effects.
Union Carbide Corp. (1976)	25% active wettable powder @0.03 and 0.12 lb. a.i./A were applied 4 times at 2 week intervals to open water canals in Louisiana during the winter. Samples were taken 3 day pre-treatment and 7 days post-treatment.	No apparent effects.

Two of the studies demonstrated similar effects attributed to diflubenzuron when directly applied to an aquatic environment. One study showed no effects.

c. Toxicity to Plants

(1) Terrestrial

No terrestrial plant studies were submitted or are currently required for diflubenzuron. However, Agency proposed revisions to CFR 40, Part 158 would require Tier 1 plant phytotoxicity tests for all insecticides, including diflubenzuron. The new requirements are expected to be implemented in 1995.

(2) Aquatic

All insecticides require Tier I aquatic plant testing, except those intended only for indoor uses and outdoor domestic homeowner uses. Tier I test results showing effects of greater than 50% for aquatic plants trigger Tier II data requirements. Tier I testing should include *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

The following table summarizes the available data.

Nontarget Aquatic Plant Toxicity Findings				
Species	% A.I.	EC ₅₀	MRID No. Author/Year	Fulfills Guideline Requirement
<i>Selenastrum capricornutum</i>	Not Rept'd	0.20 mg/L	42487101 Berends/1992	Supplemental

The guideline requirements for aquatic plant testing are not fulfilled. (MRID: 42487101)

2. ENVIRONMENTAL FATE

a. Environmental Fate Assessment

Based on acceptable laboratory and supplemental and acceptable field data, diflufenzuron appears to be relatively non-persistent and relatively immobile under normal use conditions. The major route of dissipation for diflufenzuron appears to be biotically mediated processes (half-life of approximately 2 days for aerobic soil metabolism). Binding to soil organic matter ($K(n=1)$ values for sand clay, silty clay loam, silt loam, sand loam, sandy clay loam, clay, clay hydrosol, and peat hydrosol were 40, 40, 20, 25, 130, 110, 150, 3500, respectively). Binding to soil organic matter appears to contribute to the dissipation of diflufenzuron. Anaerobic aquatic metabolism was reported to be slower (half-life of approximately 34 days). Other laboratory data indicate that diflufenzuron is stable to hydrolysis (half-life of approximately 30-80 days for pHs 5-9) and photolysis (half-life of approximately 80 days for aquatic; the half-life for control < light exposed for soil) and is relatively immobile in soil (R_f values=0.01, 0.07, 0.14, and 0.34 for silty clay loam, clay loam, and two sand loam soils, respectively).

Supplemental and acceptable field data (including forestry dissipation data) confirm the laboratory data with reported half-lives of 5.8 to 60 days. Diflufenzuron was discernible only in the 0-15 cm soil depth segments. However, calculated half-lives for California and Oregon orchard applications were higher (half-life of approximately 68.2-78 days). Diflufenzuron has not been detected in well monitoring (National Summary-Pesticides in Ground Water Database-A Compilation of Monitoring Studies: 1971-1991 compiled by the Environmental Fate and Ground Water Branch). In addition, based on chemical and physical properties and LOC's, diflufenzuron does not trigger ground water concerns, meet the triggers for ground water restricted use chemicals, or exceed the ground water levels of concern.

Under aerobic conditions diflufenzuron appears to degrade to 4-chlorophenyl urea (CPU) which reached a maximum concentration of 30.8% of applied at 7 days posttreatment. The other major degradate, CO_2 , was reported to reach a maximum concentration of 26.8% of applied by day 21 post-treatment. Three minor degradates, 2,6-difluorobenzoic acid, 2,6-difluorobenzamide, and p-chloroaniline, each reaching a maximum concentration of < 10% of applied, were identified in the aerobic study. These metabolites were discernible in an anaerobic metabolism study, as well. Due to the stability of diflufenzuron to abiotic processes, limited data are available on the persistence and mobility of diflufenzuron metabolites. However, CPU was reported in leachate of a column leaching study (approximately 15 to 30% of applied). Even though CPU appears to be mobile under laboratory conditions, it has not been reported below the 0 to 15 cm soil depth segment in the field.

Diflubenuron does appear to accumulate at low levels and depurate rapidly in fish tissue. The reported bioconcentration factors ranged from 34 to 200X for fillet, 78 to 360X for whole fish, and 100 to 500X for viscera. In addition, the depuration rate indicates a rapid decrease (99%) of accumulated residues in tissue during the 14 day depuration period.

b. Environmental Fate and Transport

i. Degradation

Hydrolysis

The data requirement for hydrolysis (161-1) is satisfied.

Diflubenuron appears to be stable to hydrolysis at pH 5 and pH 7 (90% unchanged after 4 weeks). At pH 9, a 32 day hydrolytic half-life was reported. (MRID 40859801 and 41087801)

Photodegradation in water

The data requirement for photodegradation in water (161-2) is satisfied.

Diflubenuron appears stable to unsensitized aqueous photolysis at pH 7. An extrapolated natural light half-life of 80 days was reported in the data. (MRID 40816301 and 41087802)

Photodegradation on soil

The data requirement for photodegradation on soil (161-3) is satisfied.

Diflubenuron had a reported half-life of 11.3 and 3.7 days for light exposed and control samples, respectively. Five degradates, p-chlorophenyl urea (CPU), 2,6-difluorobenzoic acid (DFBA), two unidentified degradates (labeled SP1 and PK1), and $^{14}\text{CO}_2$, were discernible in the light exposed and control samples. The maximum concentration reported for DFBA, CPU, SP1, and PK1 in the light exposed samples were 3.0% (Day 7), 12.9% (Day 10), 0.6% (Day 10), and 0.1% (Day 16) of applied radioactivity, respectively. The maximum concentration for DFBA, CPU, SP1, and PK1 (2.1% at Day 2, 21.1% at Day 7, 3.5% at Day 10, and 0.2% at Day 10 & 16, respectively) in the control samples were similar. (MRID 42251201)

Aerobic soil metabolism

Three guideline aerobic soil metabolism studies were submitted to fulfill the data requirement for aerobic soil metabolism (162-1).

Diiflubenzuron, applied to sandy loam soil, was calculated to have a half-life of 2-14 days (depending on soil texture) when incubated at $24 \pm 1^\circ\text{C}$ and maintained at 77% of 0.33 bar moisture capacity. The major degradate, 4-chlorophenyl urea, reached a maximum concentration of 30.8% to 37% of the applied radioactivity at 7 to 14 days post-treatment. The other major degradate, CO_2 , reached a maximum concentration of 26.3% of applied radioactivity by day 21 post-treatment. Three minor degradates, 2,6-difluorobenzoic acid, 2,6, difluorobenzamide, and 4-chloroaniline, which each had a maximum concentration of < 10% of applied radioactivity were identified, as well. (MRIDs 00039473, 00039474, and 41722801)

Anaerobic soil metabolism

A guideline anaerobic soil metabolism study together with an anaerobic aquatic metabolism study fulfill the anaerobic data requirements (162-2 & 162-3).

Diiflubenzuron degraded with a half-life of 2 to 14 days when applied to sandy loam soil and incubated at 14°C and 24°C . The major degradate, 4-chlorophenyl urea, reached a maximum concentration of 37% of the applied radioactivity at days 2 to 14 (depending on temperature). The other major degradate, 2,6-difluorobenzoic acid, increased to a maximum concentration of 23% of the applied radioactivity. However, bound residues increased to 37% of the applied radioactivity as extractable residues decreased during the testing period. (MRID 00040782 and MRID 41837601)

Anaerobic aquatic metabolism

One guideline anaerobic aquatic metabolism study fulfilled the data requirement for anaerobic aquatic metabolism (162-3).

A half-life of 34 days was reported for diiflubenzuron when applied to silt loam soil and incubated at 24°C under anaerobic conditions. Three degradates (2,6-difluorobenzoic acid, 4-chlorophenyl urea, and 4-chloroaniline) were identified at maximum concentrations of 0.42 ug/g, 0.33 ug/g, and 0.004 ug/g in floodwater and maximum concentrations of 0.38 ug/g, 1.15 ug/g, and 0.02 ug/g in soils, respectively. (MRID 41837601)

ii. Mobility

Leaching, adsorption/desorption

The data requirement for leaching, adsorption/desorption (163-1) is satisfied.

Four mobility studies were submitted. One contained thin layer chromatography (TLC) data which is no longer acceptable for a guideline study. Two mobility studies contained column leaching data and one adsorption/desorption data. The column leaching and adsorption/desorption data combined fulfilled the requirement for leaching, adsorption/desorption (163-1). Adsorption values (40, 40, 20, 25, 130, 110, 150, and 3500 for a sand clay, a silty clay loam, a silt loam, a sand loam, a sandy clay loam, a clay, a clay hydrosoil, and a peat hydro-soil, respectively) reported for diflubenuron indicate that diflubenuron is relative immobile and adsorbs preferentially to soil organic matter over remaining in solution. There did appear to be some desorption, but desorption was not quantified as percent of adsorption.

¹⁴C-Diflubenuron residues (mainly p-chlorophenyl urea) were mobile in sandy loam-loamy sand, sandy loam, silt loam, and clay loam-clay soils treated with ¹⁴C-diflubenuron at ≈ 2.2 lb ai/A and leached with 30 inches of water over a 20 day period. Of the applied radioactivity (residues not identified in top areas), 36.4-56.9% remained within 1 inch of the treated surface, 78.2-102.9% remained in the soil, and 18.9-34.3% leached from the 24 inch columns. More than 90% of the radioactivity in the each leachate was in the form of p-chlorophenyl urea.

¹⁴C-Diflubenuron was immobile in clay loam and silty clay loam soils (R_f s = 0.01 - 0.07) and had a low mobility in sandy loam soils (R_f s = 0.14 - 0.34), as well, based on TLC test. (MRID 00039476, 00039477, 00040777, and 00157842)

iii. Accumulation

One guideline fish study was submitted which fulfills the data requirement for accumulation in fish (165-4).

Diflubenuron appears to accumulate and to depurate from all fish tissues. Bluegill sunfish exposed to 0.0093 (± 0.0021) ppm for 28 days were reported to have bioconcentration factors of 34 to 200X for fillet, 78 to 360X for whole fish, and 100 to 550X for viscera. By day 3 to 7 of the uptake phase, the accumulation of ¹⁴C-residues appeared to have reached their maximum and leveled to a steady state concentration in all tissues. The maximum uptake tissue concentrations of ¹⁴C-diflubenuron were 1.7 mg/kg for fillet, 3.3 mg/kg for whole fish, and 4.7 mg/kg for viscera. A depuration of 99% of accumulated ¹⁴C-residues from all sampled tissue was reported for the 14 day

depuration period. During the depuration period, ^{14}C -residues dropped to <0.06 mg/kg in fish tissues. (MRID 42258401)

iv. Field Dissipation

Terrestrial field dissipation

The bare soil and orchard data terrestrial field dissipation requirement (164-1) is satisfied.

Eight guideline terrestrial field dissipation studies were submitted. The field dissipation studies included three performed in California (one orchard and two field dissipation studies), two in Oregon (one on orchard and on bare ground), one on a Louisiana soil, one on an Arkansas soil, one on a Florida citrus orchard, and one on a New York apple orchard. The combined studies fulfill the bare soil and orchard terrestrial field dissipation requirement.

The orchard and bare ground data had similar reported and/or observed half-lives (half-life of approximately 5.8 to 13.2 days). However, the calculated half-lives for the California citrus and the Oregon apple orchards (half-life of approximately 68.2 to 78 days) were higher.

P-Chloro-phenyl urea appears to be the major degradate in field dissipation data with maximum concentrations ranging from <0.02 to 0.06 ppm. Another discernible degradate, 2,6-difluorobenzoic acid, had reported concentrations ranging from not detected (ND) to 0.01 ppm. Diflubenzuron and its degradates were not detected below the top 30 cm soil depth.

Forestry dissipation

One guideline forestry dissipation study furnished supplemental data but did not fulfill the data requirement for forestry dissipation (164-3). Addenda to this study partially addressed concerns in the original review and analytical methodology; however, the storage stability data could not address the storage stability of diflubenzuron and its degradates when applied to soil, litter, and leaves. Further storage stability data are needed for diflubenzuron and its degradates using the same type of soil, litter, and leaves that were used in the forestry dissipation study.

Residues of diflubenzuron either did not occur or did not persist in flowing water or ponds, sediment, or soil. In addition, the degradate, 4-chlorophenyl urea, was not detected in exposed soil samples. Residues in leaf litter increased for 60 days posttreatment to a peak of 1.5 ppm, and then declined slowly with an apparent calculated half-life of 70 days. Residues in laurel

leaves reached a maximum concentration of 1.3 ppm at 14 days posttreatment, and then declined steadily with an apparent calculated half-life of 30 days. Conifer and hardwood leaf residues declined steadily with an apparent calculated half-life of 30 to 35 days, respectively. (MRID 00163853, 41922201-41922210, 00163853)

v. Spray Drift

Droplet size spectrum (201-1)

An adequate study was submitted fulfilling the data requirement for droplet size spectrum (201-1).

The droplet size spectrum data indicated that smaller droplets are more likely to move off target. Droplets 122 um and smaller are readily airborne and transported in the atmosphere as drift loss. (MRID 42151701-addendum)

Drift field evaluation

Two field spray studies have been submitted. These studies furnish supplemental data, but do not fulfill the data requirement for drift field evaluation (202-1).

The spray drift data indicate that approximately 4% of applied diflubenzuron drifted 110 feet from the edge of a citrus orchard sprayed with DIMILIN 25W at a rate of 1.25 lb ai/250 gallon (4X max label rate) by air blast orchard sprayers. At a distance of 300 feet, drift was only 0.5% of applied. The concentration of diflubenzuron collected by high volume air samplers during the course of the event at 300, 600, and 1200 ft. was 0.22 ug/ft³, and 0.02 ug/ft³, respectively. (MRID 42151701 and 42151702)

c. Water Resources

i. Ground Water

Diflubenzuron exceeded the Ground Water Leaching Criteria for Field dissipation half-life, Hydrolysis half-life and Henry's law Constant. Exceeding only these three criteria is not sufficient to trigger concerns based on chemical and physical properties. Diflubenzuron also does not exceed the proposed triggers for classification as a candidate for restricted use based on ground water concerns. Diflubenzuron did not exceed any Ground Water Levels Of Concern (LOC's).

No detections of diflubenzuron have been reported in EPA's Pesticide in Ground Water Data Base and no incidents were found in OPP's Ecological Incident Information System.

Potential diflubenzuron contamination of ground water using the Patriot model on sandy citrus soils in Highlands County, Florida was simulated as an example of a highly vulnerable use area located in the Central Ridge of Florida. Twelve sandy Highland County soils with orange production were modeled, only one scenario resulted in any mass leaching to ground water. The model predicted the mass leached to the top of a water table to be 0.025 % kg/HA of applied diflubenzuron. This is not considered significant.

P-chlorophenyl urea (CPU) and P-chloro-aniline (PCA) are toxicologically significant degradates of diflubenzuron. PCA is carcinogenic. Metabolites of diflubenzuron which are chemically related to PCA should be evaluated as PCA unless there is evidence that they are not carcinogenic.

In the bare ground plot studies, due to the volume of water (rainfall plus irrigation) to the plots in Louisiana and Arizona, there is concern that CPU was below the detection limits in the 6-30 inch soil depth segments. To better understand the environmental fate of CPU, adsorption/desorption data on CPU (not diflubenzuron) and bare ground field dissipation data from a typical use area(s) further north with less rainfall and irrigation are needed. These data should provide a better understanding of the mobility and persistence of CPU in the environment to determine its potential as a ground water contaminant.

ii. Surface Water

Substantial amounts of diflubenzuron could be available for runoff to surface waters for several days to weeks post-application (aerobic soil metabolism half-lives of 2 days to 2 weeks, terrestrial field dissipation half-lives of 5.8, 13, 68, and 78 days, anaerobic soil metabolism half-lives of 2-14 days). The intermediate to high soil/water partitioning of diflubenzuron (K_d values of 20, 25, 40, 40, 120, 130, and 150, SCS/ARS database K_{oc} of 9000) indicates that diflubenzuron runoff will often be primarily via adsorption to eroding soil. However, in cases where the runoff volume is much greater than the sediment yield, runoff via dissolution in runoff water could also contribute significantly to the total pesticide runoff.

Diflubenzuron is not susceptible to direct aqueous photolysis, to abiotic hydrolysis at pH 5 or 7, or to volatilization from water (estimated Henry's Law constant = 1.8×10^{-9} atm*m³/mol). It has only moderate susceptibility to abiotic hydrolysis at pH 9 (half-life of 32 days). The stability of diflubenzuron to abiotic processes (except at highly alkaline pHs) and low volatility indicate

that the dissipation of diflubenzuron in aquatic systems will depend primarily upon biodegradation and non-volatile transport.

The susceptibility of diflubenzuron to biodegradation under both aerobic and anaerobic conditions varies substantially as evidenced by terrestrial laboratory and field half-lives varying from 2 to 78 days. There may be similar variations in the rates of biodegradation in aquatic systems further complicated by possibly significant differences in biodegradation rates in terrestrial and aquatic systems. Consequently, the persistence of diflubenzuron in aquatic systems with long hydrological residence times is uncertain, but may vary substantially from low to somewhat intermediate. The persistence of diflubenzuron in aquatic systems with shorter hydrological residence times should be lower due to removal by flow of diflubenzuron dissolved and adsorbed to suspended sediment. However, the intermediate to high soil/water partition coefficient of diflubenzuron indicates that much of the diflubenzuron in aquatic systems will be adsorbed to bottom sediment.

A major degradate of diflubenzuron in soil under both aerobic and anaerobic conditions is 4-chlorophenyl urea. Another major degradate under anaerobic conditions is 2,6-difluorobenzoic acid. The data are inadequate to assess the fate and mobility of those degradates.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

The following explains Risk Quotients (RQs) and Levels of Concern (LOC). The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. To determine if an LOC has been exceeded, a risk quotient is derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, such as the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, such as the LC_{50} .

Typical acute effect levels are:

- EC_{25} for terrestrial plants,
- EC_{50} for aquatic plants and invertebrates,
- LC_{50} for fish and birds, and

- LD₅₀ for birds and mammals.

Typical chronic test results are:

- for avian and mammalian reproduction studies, the no observed effect level (NOEL), sometimes referred to as the no observed effect concentration (NOEC); and
- for chronic aquatic studies, either the NOEL or the maximum allowable toxicant concentration. The MATC is the geometric mean of the NOEL and the lowest observable effect level (LOEL), sometimes referred to as the lowest observable effect concentration (LOEC).

When the risk quotient exceeds the LOC for a particular category, potential risk to that category is assumed. Risk presumptions and the corresponding LOCs are shown below.

Levels of Concern (LOC) and Associated Risk Presumption

Mammals and Birds

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ >	0.5	High acute risk
acute RQ >	0.2	Risk that may be mitigated through restricted use
acute RQ >	0.1	Endangered species may be acutely affected
chronic RQ >	1	Chronic risk Endangered species may be chronically affected

Fish and Aquatic invertebrates

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ >	0.5	High acute risk
acute RQ >	0.1	Risk that may be mitigated through restricted use
acute RQ >	0.05	Endangered species may be acutely affected
chronic RQ >	1	Chronic risk Endangered species may be chronically affected

Plants

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
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RQ>

1

High risk

Endangered plants may be affected

Currently, no separate criteria exist for restricted use or chronic effects on plants.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Residues found on dietary food items following Diflubenzuron application may be compared to LC_{50} values to predict hazard. The maximum concentration of residues of Diflubenzuron which may be expected to occur on selected avian or mammalian dietary food items following a single foliar application are provided in the following table.

This table includes EECs for avian and mammalian species, but gives acute and chronic RQs for avian species only.

Avian/Mammal Dietary EECs and Avian Acute and Chronic Risk Quotients					
Crop	App. Rate (lbs a.i./A)	Food items: AVIAN & MAMMAL	EEC (PPM) on Food	AVIAN Acute Risk Quotient (EEC/LC50)	AVIAN Chronic Risk Quotient (EEC/NOEL)
Citrus	0.6666	Range Grasses (short)	160	0.0345	0.3200
		Long Grass	73	0.0158	0.1467
		Broad Leaf Plants	83	0.0180	0.1667
		Forage, Small Insects	39	0.0083	0.0773
		Seed Containing Pods	8	0.0017	0.0160
		Fruit	5	0.0010	0.0093
Cotton	0.125	Range Grasses (short)	30	0.0065	0.1800
		Long Grass	14	0.0030	0.0825
		Broad Leaf Plants	16	0.0034	0.0938
		Forage, Small Insects	7	0.0016	0.0435
		Seed Containing Pods	1.5	0.0003	0.0090
		Fruit	0.9	0.0002	0.0053
Forest Trees and Forest Plantings	0.125	Range Grass (short)	30	0.0065	0.0600
		Long Grass	14	0.0030	0.0275
		Broad Leaf Plants	16	0.0034	0.0313

	Forage, Small Insects	7	0.0016	0.0145
	Seed Containing Pods	1.5	0.0003	0.0030
	Fruits	0.9	0.0002	0.0018

Diflubenzuron does not exceed LOC's for citrus, forest trees, forest plantings, and cotton uses of diflubenzuron, based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive avian species tested.

(b) Mammals

Small mammal exposure is addressed using acute oral LD₅₀ values converted to estimate a LC₅₀ value for dietary exposure. The estimated LC₅₀ is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

The estimated LC₅₀ values are shown in the following table.

Small Mammal Food Consumption in PPMs (Based on an LD ₅₀ = mg/kg)				
Small Mammal	Body Weight in Grams	% of Weight Eaten Per Day	Food Consumed Per Day in Grams	Estimated LC ₅₀ Per Day in PPMs
Meadow vole	46 gms	61 %	28.1 gms	7596 ppm
Adult field mouse	13 gms	16 %	2.1 gms	28724 ppm
Least shrew	5 gms	110 %	5.5 gms	4218 ppm

The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golley, published by Reinhold Corporation, 1963.

The estimated LC₅₀ values are then compared to the EEC's listed above in the table entitled, "Avian/Mammalian Dietary EECs and Avian Acute and Chronic Risk Quotients."

The table below shows the risk quotients for mammalian species.

Mammalian Dietary Risk Quotients (based on Dietary RQ = EEC/Lowest LC ₅₀)			
Small Mammal	Application Rates in lbs. a.i./A		
	Citrus 0.6666	Cotton 0.125	Forest 0.125
Meadow vole consuming range grasses	0.0211	0.0039	0.0197
Adult field mouse consuming seeds	0.0003	0.0001	0.0003
Least shrew consuming forage and insects	0.0092	0.0017	0.0017

Diflubenzuron does not exceed the mammalian levels of concern for uses on citrus, cotton, forest trees, and forest plantings.

(c) Insects

Based on acute honey bee studies, diflubenzuron is characterized as practically non-toxic to the honey bee. Its use is not a risk to honey bees.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: There are no available monitoring data concerning the concentrations of diflubenzuron in surface water. However, refined EEC's were calculated for the citrus and cotton uses. Computer modeling was used to generate Tier 2 (single site over multiple years) EECs for diflubenzuron in a 1 hectare (ha) surface area, 2 meters deep pond draining a 10 ha citrus grove and a 10 ha cotton field.

Adamsville Sand in Florida was modelled for citrus and a Loring Silt Loam in Mississippi for cotton. Each was simulated over 36 years. For citrus, one application/year at 0.667 lbs ai/acre was simulated with an assumed air blast drift of 3%. For cotton, 6 applications/year each at 0.063 lbs ai/acre were simulated with an assumed aerial spray drift of 5%. Distributions of annual maximum initial, 96 hour, 21 day, 60 day, and 90 day EECs over the 36 years simulated for the citrus and cotton scenarios were calculated.

The standard models do not apply to the forest scenario. Water resources in forests generally consist of streams and rivers. Habitats of this type typically contain cool and cold water fisheries. Such fisheries are almost wholly dependent on invertebrate forage. Large scale impact on invertebrae resources may negatively affect these fisheries resources. The direct application scenario is a high exposure scenario resulting in the high risk quotients which were calculated for the forestry uses.

The EEC's for forest use and forest plantings were calculated using a direct application to water scenario. These estimates assume diflubenzuron is applied to a one acre body of water 6" deep. The direct application to water scenario addresses the concern that foliar treatments to forest trees or plantings may result in the pesticide dripping down onto waterbodies below the trees. It also

addresses the concern of direct spray onto waterbodies in forests. The direct application scenario lead to high risk quotients which were calculated for the forestry uses.

The use rates and application methods for cotton are similar to several other uses of diflubenzuron, such as soybeans and ornamentals. The forest scenario is representative of the mosquito use (direct application to water). The use on mushrooms is considered to be an indoor use. The only ecological concern with the use on mushrooms would be that of an accidental discharge.

The following table shows the estimated EECs for citrus, cotton and forest uses.

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs) FOR DIFLUBENZURON ON THE FOLLOWING CROPS:							
Crop	Application Method	Application Rate in lbs a.i./A	Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	60-day EEC (ppb)	90-day EEC (ppb)
Citrus	ground or aerial	0.6666	8.120	5.802	2.317	1.071	0.743
Cotton	ground or aerial	0.375 (6.3 ppb) @ 0.0625 lbs a.i./A	4.279	3.365	1.866	1.078	0.867
Forest Trees and Forest Plantings	Direct Application to Water	Application Rate in lbs a.i./A	EEC from Direct Application to Water				
		0.0156	11.744				
		0.0312	22.754				
		0.0625	46.242				
		0.125	91.750				

(a) Freshwater Fish

The RQs for freshwater fish were calculated using the results from the most sensitive species and the above EECs. They are shown in the following table.

Risk Quotients (RQ) for Freshwater Fish			
Crop/application rate	Species	Acute RQ (96-hr)	Chronic RQ (90-day)
Citrus/0.6666 lb. a.i./A	Bluegill	0.000060	N/A
	Rainbow trout	0.000058	N/A
	Fathead minnow	0.000012	0.00743
Cotton/0.375 lb. a.i./A	Bluegill	0.000031	N/A
	Rainbow trout	0.000030	N/A
	Fathead minnow	0.000008	0.00867
Forest Trees and Forest Plantings 0.0156 lbs. a.i./A	Bluegill	0.00009	N/A
	Rainbow Trout	0.00008	N/A
	Fathead Minnow	0.00002	0.117
Forest Trees and Forest Plantings 0.0312 lbs. a.i./A	Bluegill	0.00017	N/A
	Rainbow Trout	0.00016	N/A
	Fathead Minnow	0.00005	0.228
Forest Trees and Forest Plantings 0.0625 lbs. a.i./A	Bluegill	0.00034	N/A
	Rainbow Trout	0.00033	N/A
	Fathead Minnow	0.00009	0.462
Forest Trees and Forest Plantings 0.125 lbs. a.i./A	Bluegill	0.00068	N/A
	Rainbow Trout	0.00066	N/A
	Fathead Minnow	0.00018	0.918

Diffubenzuron does not exceed acute or chronic LOC's for freshwater fish (and amphibians), based on risk quotients using the acute LC₅₀ and chronic NOEL for the most sensitive freshwater fish species tested.

(b) Freshwater Invertebrates

The RQs for freshwater invertebrates were calculated using the toxicity results from the most sensitive species and the above EECs. They are shown in the following table.

Risk Quotients (RQ) for Freshwater Invertebrates			
Crop/application rate	Species	Acute RQ (96-hr)	Chronic RQ (21-day)
Citrus/0.6666 lb. a.i./A	<i>Daphnia magna</i>	2.19	> 38.5
Cotton/0.375 lb. a.i./A	<i>Daphnia magna</i>	1.15	> 31.1
Forest Trees and Forest Plantings 0.0156 lb. a.i./A	<i>Daphnia magna</i>	3.17	> 195.67
Forest Trees and Forest Plantings 0.0312 lb. a.i./A	<i>Daphnia magna</i>	6.14	> 379.17
Forest Trees and Forest Plantings 0.0625 lb. a.i./A	<i>Daphnia magna</i>	12.49	> 770.67
Forest Trees and Forest Plantings 0.125 lb. a.i./A	<i>Daphnia magna</i>	24.79	> 1529.17

Diiflubenzuron exceeds all LOCs based on risk quotients using the acute LC₅₀ and chronic NOELs for the most sensitive freshwater invertebrate species tested (Citrus, Cotton, Forest Trees and Forest Plantings uses). Use of diiflubenzuron is expected to cause adverse acute and chronic effects to non-endangered and endangered freshwater invertebrates.

Twelve freshwater invertebrate field studies were reviewed and all demonstrated similar effects attributed to diiflubenzuron when directly applied to an aquatic environment. Generally, aquatic invertebrate fauna (especially cladocerans) were markedly reduced with some recovery noted. The freshwater field studies were performed with the formulated product of diiflubenzuron (25% and 1% a.i.). Acute and chronic laboratory studies, performed with the technical grade of diiflubenzuron, also indicate that diiflubenzuron is very highly toxic to freshwater invertebrates.

From these data it can be concluded that these uses of diiflubenzuron will negatively affect the freshwater invertebrate populations. If there is a decrease in the various invertebrates this may cause adverse effects on the populations of higher organisms that feed on them. Higher organisms would be gamefishes, waterfowl, shorebirds, small mammals, reptiles, and amphibians.

(c) Estuarine and Marine Animals

The RQs for estuarine/marine animals were calculated using the most sensitive species and the above aquatic EECs. They are shown in the following table.

Risk Quotients (RQ) for Estuarine and Marine Organisms			
Crop/application rate	Species	Acute RQ (96-hr)	Chronic RQ (21-day)
Citrus/0.6666 lb. a.i./A	<i>M. bahia</i>	4.122	30.800
	<i>M. mercenaria</i>	0.025	N/A
	<i>F. heteroclitus</i>	0.00003 ⁽¹⁾	0.0149
Cotton/0.375 lb. a.i./A	<i>M. bahia</i>	2.172	24.880
	<i>M. mercenaria</i>	0.013	N/A
	<i>F. heteroclitus</i>	0.00002 ⁽¹⁾	0.0173
Forest Trees and Forest Plantings 0.0156 lb. a.i./A	<i>M. bahia</i>	5.959	156.53
	<i>M. mercenaria</i>	0.0367	N/A
	<i>F. heteroclitus</i>	0.00004 ⁽¹⁾	0.2348
Forest Trees and Forest Plantings 0.0312 lb. a.i./A	<i>M. bahia</i>	11.548	303.333
	<i>M. mercenaria</i>	0.0711	N/A
	<i>F. heteroclitus</i>	0.00008 ⁽¹⁾	0.4550
Forest Trees and Forest Plantings 0.0625 lb. a.i./A	<i>M. bahia</i>	23.472	616.53
	<i>M. mercenaria</i>	0.1445	N/A
	<i>F. heteroclitus</i>	0.0002 ⁽¹⁾	0.9248
Forest Trees and Forest Plantings 0.125 lb. a.i./A	<i>M. bahia</i>	46.573	1223.33
	<i>M. mercenaria</i>	0.286	N/A
	<i>F. heteroclitus</i>	0.0004 ⁽¹⁾	1.835

(1) Acute risk quotient is based on an acute study endpoint with the 25% formulation of diflubenzuron on *F. heteroclitus*.

(2) The 21-day EEC was used for the invertebrate chronic RQ and the 90-day EEC was used for the fish chronic RQ.

Diflubenzuron exceeds all LOC's based on RQ's using the acute LC₅₀'s and chronic NOEL's for the most sensitive estuarine/marine invertebrate species tested for the citrus, cotton, forest trees and forest plantings uses. Therefore use of diflubenzuron may cause adverse acute and chronic effects to marine/estuarine invertebrates. Endangered marine/estuarine invertebrate species may be affected acutely and chronically.

Diflubenzuron exceeds restricted use LOC's based on RQs using the acute estuarine/marine mollusk LC₅₀'s, for 0.0625 lbs ai/A and 0.125 lb ai/A application rates, for forest trees and forest plantings uses. Endangered species acute LOC's were exceeded at rates as low as 0.0312 lb ai/A for the forestry use.

Diffubenzuron exceeds chronic LOC's based on RQ's using the chronic NOEL for the most sensitive marine/estuarine finfish species tested for forest trees and forest plantings uses at the 0.125 lb ai/A application rate. Therefore use of diffubenzuron may adversely affect endangered and nonendangered marine/estuarine finfish from chronic exposures at the highest use rate for the forest trees and forest plantings use.

Three marine/estuarine invertebrate field studies were reviewed. Two demonstrated similar effects attributed to diffubenzuron when directly applied to an aquatic environment. Generally, aquatic invertebrate fauna were markedly reduced. The third marine/estuarine field study showed no effects. The marine/estuarine field studies were performed with the formulated product of diffubenzuron (25% a.i.). Acute and chronic laboratory studies, performed with the technical grade of diffubenzuron, also indicate that diffubenzuron is very highly toxic to marine/estuarine invertebrates.

From these data it can be concluded that these uses of diffubenzuron will adversely effect the estuarine/marine invertebrate populations. If there is a decrease in the various invertebrates this may cause adverse effects on the populations of higher organisms that feed on them. Some of these organisms would be crabs, bivalves, various crustaceans (ie shrimp), water fowl, shore birds, and gamefishes. Commercially important marine/estuarine invertebrates and finfish may be affected.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Because terrestrial and semi-aquatic plant toxicity data are not available, terrestrial and semi-aquatic plant risk assessments cannot be performed at this time for diffubenzuron.

(b) Aquatic Plants

Exposure to non-target aquatic plants may occur through either runoff or drift from aerial application.

Expected Aquatic Concentrations: The EEC's calculated above for aquatic animal exposure are also used for aquatic plants. The only available toxicity data for aquatic plants is the EC₅₀ for Selenastrum capricornutum (0.20 mg/L). This value was used to calculate the following risk quotients.

RQ and EEC ¹ Values for Aquatic Plant Species				
Use Site	Maximum Application Rate (lb. a.i./A)	Type of Plant	EEC (ppb)	Risk Quotient (EEC/EC ₅₀)
Citrus	0.6666	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	8.1209	0.0406
Cotton	0.375	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	4.2792	0.0213
Forest Trees and Forest Plantings	0.0156	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	11.744	0.0587
	0.0312	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	22.754	0.114
	0.0625	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	46.242	0.231
	0.125	vascular (<i>Lemna</i>)	N/A	N/A
		Algae or diatom	91.75	0.459

1) EEC's based on direct application to water for the forest trees and forest plantings uses.

Diiflubenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ for the freshwater alga species tested for the citrus, cotton, forest trees and forest plantings uses.

(4) Endangered Species

Acute and chronic LOCs for endangered species are exceeded for freshwater and estuarine/marine aquatic invertebrates for the citrus, cotton and forestry uses. A chronic LOC was exceeded for estuarine/marine fish for the highest forestry use rate (0.125 lb ai/A). The acute LOC for estuarine/marine mollusks was exceeded for the three highest forestry use rates.

The Endangered Species Protection Program is expected to become final in 1995. Limitations in the use of diiflubenzuron will be required to protect endangered and threatened species, but these

limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

b. Water Resources Risk Implications for Human Health

(1) Ground Water

Diiflubenzuron did not exceed any ground water LOCs.

(2) Surface Water

Diiflubenzuron is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore no MCL has been established for it and water supply systems are not required to sample and analyze for it. No drinking water Health Advisory Levels (HALs) have been established for it either. It is not in the HED list of "Apparent Exceeders (Chronic Effects and Cancer)". Due to its intermediate to high soil/water partitioning, the primary treatment processes employed by most surface water supply systems should be effective in removing substantial amounts of diiflubenzuron from drinking water.