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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Reregistration Eligibility Document for
Diflubenzuron (Shaughnessy #: 108201) (D208994)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

To: Larry Schnaubelt, PM 61
Special Review and Registration Division (H7508W)

The Ecological Effects Branch has completed the RED chapter for diflubenzuron (see attached). If there are any questions contact Andrew Bryceland 305-5746.



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C. ENVIRONMENTAL ASSESSMENT

1. Ecological Toxicity Data

EFED has adequate data needed 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 (LD₅₀) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC₅₀) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

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 ¹ Mallard Duck	1% Granular	>20,000 ppm	00060381 / 1976 Roberts	NA	Supplemental

Doc. Name: 00039080; Registration: 00039080

These results indicate that diflubenzuron is **practically non-toxic** to avian species on an acute oral and **slightly toxic** on an subacute dietary basis. The guideline requirements 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 through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard.

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 ¹		No effects up to 250 ppm	NA	NA	00099719 Booth / 1977	Supplemental
Bobwhite Quail ¹		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 ¹		No effects up to 250 ppm	NA	NA	00099730 Roberts / 1977	Supplemental

Data taken from Difenhydramin Registration Number 27306

Avian reproduction studies are required since repeat applications are allowed on all uses and potential reproductive impairment is suggested available reproductive data.

The avian reproductive studies indicate that diflubenzuron effects egg production in bobwhite quail and eggshell thickness in the mallard duck at concentrations greater than 500 ppm. The guideline requirements are fulfilled. (MRID #s: 416680-02; 416680-01; 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 such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an

acute oral LD₅₀ from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals (HED Tox Oneliners). This LD₅₀ is reported below.

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

The 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 if the proposed use will result in honey bee exposure.

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

There is sufficient information to characterize diflubenzuron as **non-toxic** to bees. The guideline requirement 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).

Freshwater Fish Acute Toxicity Studies					
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 results of the 96-hour acute toxicity studies indicate that diflubenzuron is **practically non-toxic** to freshwater fish. The guideline requirements for the technical grade and the 25% WP (wetable powder) formulation are fulfilled. (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.

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

There is sufficient information to characterize diflubenzuron as very highly toxic to aquatic invertebrates. The guideline requirements for the technical grade and the 25% WP formulation are fulfilled. (MRID 400980-01; 436658-01; 00003503; 408405-02)

(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.

The requirements 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 with oysters.

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

There is sufficient information to characterize Diflubenzuron as **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 with the 25% WP formulation is waved. (MRID #s: 436620-01; 402284-01; 413920-01; 00038612; 00038611; 00039088; 00060377; 602284-01; 00056150)

The results of the 96-hour acute toxicity study with *Fundulus heteroclitus* indicate that Diflubenzuron is **practically non-toxic** to marine/estuarine fish. This guideline requirement is fulfilled for the 25% wettable powder formulation, but is still

outstanding for the technical grade. (MRID #s: 00056150)
There is a high value associated with this data requirement. Testing with the technical grade of pesticides is a fundamental requirement of pesticide testing guidelines. It provides the Agency with a standard database that is highly valuable for comparative risk assessments.

(4) Freshwater and Estuarine/Marine Chronic Results

Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity 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.

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/Tompkins/1979	Repro. & Surv.	Supplemental
<i>Daphnia magna</i>	Formulation not ID'd	<0.09 ppb (Repro.)	0.09 ppb (Repro.)	<0.61 ppb (Surv.)	00010865 Leblanc/1975	Repro. & Surv.	Supplemental
Brine Shrimp (<i>Artemia salina</i>)	100	> 10 ppb	> 10 ppb		00073933 Cunningham/1975	Repro.	Supplemental
<i>Mysidopsis bahia</i>	99	No NOEL	0.075 ppb		436620-01 Nimmo/1977	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. The guideline requirements are not fulfilled for aquatic invertebrate life-cycle toxicity studies with freshwater and estuarine species using the technical grade active ingredient. (MRID #s: 2424; 00010865; 401306-01; 00073933; 408405-01) There is a high value associated with this data requirement. The submitted life-cycle test 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. The acute test results indicate that technical diflubenzuron is more toxic than the 25% WP. Using chronic test data for the 25% WP may underestimate the level of chronic risk to which freshwater invertebrates are exposed. (The risk quotients and field data indicate that freshwater and estuarine invertebrates are at high risk from

chronic exposure.) Furthermore, testing with the technical grade of pesticides is a fundamental requirement of pesticide testing guidelines. It provides the Agency with a standard database that is highly valuable for comparative risk assessments.

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.

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/1977	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 and marine/estuarine finfish. The guideline requirement is fulfilled for a fish life-cycle toxicity study with a freshwater species. However, the data is still outstanding for an estuarine species. (MRID #s: 00099755; 00099722) There is a high value associated with this data requirement. The submitted life-cycle study for mummichog 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 risk assessment indicates that fish are at high risk from chronic exposure but 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 valuable needed information.

(5) Aquatic Field Testing (excerpted from Registration Standard)

Twelve freshwater invertebrate field studies were reviewed and all 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. 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 larva 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) 00099092	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.

Three marine/estuarine invertebrate field studies were reviewed. Two demonstrated similar effects attributed to diflubenzuron when directly applied to an aquatic environment. One study showed no effects. The table below summarizes these field studies.

Estuarine Invertebrate Field Studies		
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.

c. Toxicity to Plants

(1) Terrestrial

Diflubenzuron is an insecticide. The Agency has proposed revisions to CFR 40, Part 158 that would require Tier 1 plant phytotoxicity testing for all insecticides. The revisions are expected to be finalized in 1995. No terrestrial plant studies have been submitted for diflubenzuron.

Species	% A.I.	Seedling emergence EC ₅₀	Vegetative vigor EC ₅₀
Dicot-		None	None
Monocot-		None	None

(2) Aquatic

Diflubenzuron is an insecticide. All insecticides require a Tier I data set (122-1, 122-2).

Exceptions: indoor uses, outdoor domestic uses (homeowner). Tier I test effects > 50% for aquatic plants triggers Tier II data requirements.

The following species should be tested:

Selenastrum capricornutum, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Toxicity data on the technical/TEP material is listed below:

Nontarget Aquatic Plant Toxicity Findings				
Species	% A.I.	EC ₅₀	MRID No. Author/Year	Fulfills Guideline Requirement
<i>Navicula pelliculosa</i> (Freshwater diatom)				
<i>Lemna gibba</i>				
<i>Selenastrum capricornutum</i>	Not Rept'd	0.20 mg/L	42487101 Berends/1992	Supplemental
<i>Skeletonema costatum</i>				
<i>Anabaena flos-aquae</i>				

Tier 1 aquatic plant studies for all five typical plant species have been required for diflubenzuron. This request is supported by CFR 158.540. The guideline requirements are not fulfilled.

(MRID #: 424871-01)

3. Exposure and Risk Characterization**a. Ecological Exposure and Risk Characterization**

Explanation of the Risk Quotient (RQ) and the Level 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. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC₅₀. The acute effect levels typically are:

- EC₂₅ (terrestrial plants),
- EC₅₀ (aquatic plants and invertebrates),
- LC₅₀ (fish and birds), and
- LD₅₀ (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption**Mammals, 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 affected

chronic RQ>	1	acutely Chronic risk, endangered species may be affected chronically,
Fish, 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 affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically
Plants		
<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
RQ>	1	High risk
RQ>	1	Endangered plants may be affected

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

(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 both a single (and multiple foliar - once again, modify to suit your needs) application rates is provided in the table below:

Crop	App. Rate (lbs a.i./A)	Food items	EEC (ppm)	Acute Risk Quotient (EEC/LC50)	Chronic Risk Quotient (EEC/NOEL)
Citrus	0.6666	Range Grasses (short)	159.984	0.0345	0.3200
		Long Grass	73.326	0.0158	0.1467
		Broad Leaf Plants	83.325	0.0180	0.1667
		Forage, Small Insects	38.663	0.0083	0.0773
		Seed Containing Pods	7.999	0.0017	0.0160
		Fruit	4.666	0.0010	0.0093
Cotton	0.125	Range Grasses (short)	30.000	0.0065	0.1800
		Long Grass	13.750	0.0030	0.0825
		Broad Leaf Plants	15.625	0.0034	0.0938
		Forage, Small Insects	7.250	0.0016	0.0435
		Seed Containing Pods	1.500	0.0003	0.0090
		Fruit	0.875	0.0002	0.0053
Forest Trees and Forest Plantings	0.125	Range Grass (short)	30.000	0.0065	0.0600
		Long Grass	13.750	0.0030	0.0275
		Broad Leaf Plants	15.625	0.0034	0.0313
		Forage, Small Insects	7.250	0.0016	0.0145
		Seed Containing Pods	1.500	0.0003	0.0030

	Fruits	0.875	0.0002	0.0018
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The following table discusses the Levels of Concern (LOC) for the various use rates. The short range grass Risk Quotient (RQ) was used for comparison to the LOC.

Analysis of the Level of Concern Criteria				
Use Site	Application Rate (lbs a.i./A)	Has the LOC for Endangered Species been Exceeded for Avian and Reptilian Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonendangered Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	No	No	No
Cotton	0.125	No	No	No
Forest Trees and Forest Plantings	0.125	No	No	No

Diflubenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive avian species tested (Citrus, Forest Trees, Forest Plantings, and Cotton uses). Therefore use of diflubenzuron does not cause unreasonable adverse effects to birds from acute and chronic exposures.

(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:

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

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	7595.73 ppm
Adult field mouse	13 gms	16 %	2.1 gms	28723.81 ppm
Least shrew	5 gms	110 %	5.5 gms	4218.18 ppm

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

The estimated LC₅₀ is then compared to the residues listed above to calculate a risk quotient (EEC/LC₅₀). The table below indicates the risk quotients for each of the following application rates:

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. Therefore its use is not at a risk to honey bees.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: Diflubenzuron is very highly toxic to both freshwater and marine/estuarine invertebrates. Refined EEC's were calculated for the citrus and cotton uses. The refined EEC is determined using environmental fate and transport computer models. The Pesticide Root Zone Model (PRZM1) was used to simulate pesticides in field runoff and the Exposure Analysis Modeling System (EXAMS II) to simulate pesticide fate and transport in an aquatic environment (one acre body of water).

Forest use and forest plantings EEC's are being calculated by the direct application to a one acre layer of water six inches deep. This is because the PRISM1, EXAMS II, and the GENEEC models do not fit this application scenario. The forest use model covers mosquito larvicide use.

The use rates and use applications for citrus and cotton encompass those for several other uses of diflubenzuron. Citrus is the model for the orchard type uses and cotton is the model for field type uses such as soybeans. The use on mushrooms is considered an indoor use. The only concern with the use on mushrooms would be that of an accidental discharge from the facility.

ESTIMATED ENVIRONMENTAL RISK (EER) VALUES							
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 applic. @ 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 form Direct Application to Water				
		0.0156	11.744				
		0.0312	22.754				
		0.0625	46.242				
		0.125	91.750				

(a) Freshwater Fish

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

Analysis of the Level of Concern Criteria				
Use Site	Application Rate (lb a.i./A)	Has the LOC for Endangered Species been Exceeded for Fish and Amphibian Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonsusceptible Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	No	No	No
Cotton	0.0375	No	No	No
Forest Trees and Forest Plantings	0.0156	No	No	No
	0.0312	No	No	No
	0.0625	No	No	No
	0.125	No	No	No

Diffubenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive freshwater fish species tested (Citrus, Cotton, Forest Trees and Forest Plantings uses). Therefore use of diflubenzuron does not cause unreasonable adverse effects to fish and amphibians from acute and chronic exposures.

(b) Freshwater Invertebrates

Risk Quotient (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	> 38.3
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

Analysis of the Level of Concern Criteria				
Use Site	Application Rate (lb a.i./A)	Has the LOC for Endangered Species been Exceeded for Freshwater Invertebrate Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonsusceptible Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	Yes	Yes	Yes
Cotton	0.375	Yes	Yes	Yes
Forest Trees and Forest Plantings	0.0156	Yes	Yes	Yes
	0.0312	Yes	Yes	Yes
	0.0625	Yes	Yes	Yes
	0.125	Yes	Yes	Yes

Diffubenzuron exceeds all LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive freshwater invertebrate species tested (Citrus, Cotton, Forest Trees and Forest Plantings uses). Therefore use of diflubenzuron 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 diflubenzuron 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 diflubenzuron (25% and 1% a.i.). Acute and chronic laboratory studies, performed with the technical grade of diflubenzuron, also indicate that diflubenzuron is very highly toxic to freshwater invertebrates.

From these data it can be concluded that if diflubenzuron enters a freshwater body it will adversely effect the invertebrate population. If there is a decrease in the various invertebrates this may cause an adverse effect 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

Risk Quotient (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 0.00625 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.

Analysis of the Level of Concern Criteria for Marine/Estuarine Finfish				
Use Site	Application Rate (lbs a.i./A)	Has the LOC for Endangered Species been Exceeded for Marine/Estuarine Finfish Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonendangered Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	No	No	No
Cotton	0.0375	No	No	No
Forest Trees and Forest Plantings	0.0156	No	No	No
	0.0312	No	No	No
	0.0625	No	No	No
	0.125	No	No	Yes (Chronic)

Analysis of the Level of Concern Criteria for Marine/Estuarine Mollusks				
Use Site	Application Rate (lbs a.i./A)	Has the LOC for Endangered Species been Exceeded for Marine/Estuarine Mollusk Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonendangered Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	No	No	No
Cotton	0.0375	No	No	No
Forest Trees and Forest Plantings	0.0156	No	No	No
	0.0312	Yes	No	No
	0.0625	Yes	Yes	No
	0.125	Yes	Yes	No

Analysis of the Level of Concern Criteria for Marine/Estuarine Invertebrates				
Use Site	Application Rate (lbs a.i./A)	Has the LOC for Endangered Species been Exceeded for Marine/Estuarine Invertebrate Species?	Has the LOC for Restricted Use Been Exceeded?	Has the LOC for High Risk to Nonendangered Species Been Exceeded? (Acute and Chronic)
Citrus	0.6666	Yes	Yes	Yes
Cotton	0.0375	Yes	Yes	Yes
Forest Trees and Forest Plantings	0.0156	Yes	Yes	Yes
	0.0312	Yes	Yes	Yes
	0.0625	Yes	Yes	Yes
	0.125	Yes	Yes	Yes

Diflubenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive marine/estuarine fish and mollusk species tested (Citrus and Cotton uses). Therefore use of diflubenzuron does not cause unreasonable adverse effects to marine/estuarine finfish and mollusks from acute and chronic exposures to non-forest uses.

Diflubenzuron does exceed 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. Therefore use of diflubenzuron may cause unreasonable adverse effects to endangered and nonendangered marine/estuarine finfish from chronic exposures at the highest forest trees and forest plantings use.

Diflubenzuron does exceed Restricted Use LOC's based on RQ's using the acute marine/estuarine mollusk LC₅₀'s, for 0.0625 lbs a.i./A and 0.125 lbs a.i./A use rates, for the forest trees and forest plantings uses. Therefore use of diflubenzuron may cause unreasonable adverse effects to marine/estuarine mollusks from acute exposures at the 0.125 lb. a.i./A use rate. Endangered species may be affected acutely at rates as low as 0.0312 lb. a.i./A.

Diflubenzuron exceeds all LOC's based on RQ's using the acute LC₅₀'s and chronic NOEL's for the most sensitive marine/estuarine invertebrate species tested (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.

Three marine/estuarine invertebrate field studies were reviewed. Two demonstrated similar effects attributed to diflubenzuron 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 diflubenzuron (25% a.i.). Acute and chronic laboratory studies, performed with the technical grade of diflubenzuron, also indicate that diflubenzuron is very highly toxic to marine/estuarine invertebrates.

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

(3) **Exposure and Risk to Nontarget Plants**

(a) **Terrestrial and Semi-aquatic**

Terrestrial and Semi-aquatic plant risk assessments will not be performed at this time for diflubenzuron. This is due to the complete lack of data.

(b) **Aquatic Plants**

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

Expected Aquatic Concentrations: Refined EEC's were calculated for the citrus and cotton uses. The refined EEC is determined using environmental fate and transport computer models. The Pesticide Root Zone Model (PRZM1) was used to simulate pesticides in field runoff and the Exposure Analysis Modeling System (EXAMS II) to simulate pesticide fate and transport in an aquatic environment (one acre body of water).

The risk assessment is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Algae and diatom risk assessment are useful indicators to determine impact to food sources of aquatic organisms. However, there are presently no data for *Lemna*.

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/EC50)
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.

Diflufenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ for the most sensitive freshwater alga species tested (Citrus, Cotton, Forest Trees and Forest Plantings uses). Therefore use of diflufenzuron does not cause unreasonable adverse effects to freshwater algae from acute and chronic exposures.

(4) Endangered Species

The Endangered Species Protection Program is expected to become final in 1995. Limitations in the use of diflubenzuron 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.

(5) Precautionary 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 washwater 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 washwater or rinsate. Consult with State agency in charge of fish and game before applying to public waters to determine if a permit is required.