



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

4-24-96

APR 24 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Review of a minor use registration of Dimilin
(Diflubenzuron) on rangegrass.

TO: Dennis Edwards, Jr.
PM 19
Registration Division

FROM: Anthony F. Maciorowski, Chief *Anthony Edwards 5/22/96*
Ecological Effects Branch
per Environmental Fate and Effects Division (H7507C)

EEB has reviewed the ecological effects portion of the petition for the use of diflubenzuron to control the range of caterpillar and grasshoppers on rangegrass in the North Central and Western United States. A risk assessment has also been completed on this use and is included with this memo. Since diflubenzuron is extremely toxic to aquatic invertebrates, any exposure to water to this chemical should be avoided. The registrant has addressed this concern by limiting the use of this chemical to an area where prairie potholes, the major source of water in the treatment region, are not present. This area includes Colorado, Montana (South of the Missouri River), Nebraska (West of State Highway 183), North Dakota (West of Missouri River), South Dakota (West of Missouri River) and Wyoming. EEB feels that this label language may not be sufficient to reduce exposure of aquatic invertebrates to diflubenzuron, so that this proposed use could potentially cause serious adverse effects to these nontarget organisms.

1/25

DP BARCODE: D220296

CASE: 009546
SUBMISSION: S495774

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/24/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE
RANKING : 2 POINTS ()
CHEMICALS: 108201 Diflubenzuron (ANSI) 24.0000%

ID#: 000400-00473 DIMILIN - 2F
COMPANY: 000400 UNIROYAL CHEMICAL CO INC
PRODUCT MANAGER: 19 DENNIS EDWARDS, JR. 703-305-6386 ROOM: CM2 207
PM TEAM REVIEWER: PAUL SCHROEDER 703-305-6602 ROOM: CM2 255
RECEIVED DATE: 10/10/95 DUE OUT DATE: 04/17/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 220296 EXPEDITE: N DATE SENT: 10/23/95 DATE RET.: / /
CHEMICAL: 108201 Diflubenzuron (ANSI)
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

| ASSIGNED TO | DATE IN | DATE OUT | ADMIN DUE DATE: 03/21/96 |
|--------------|----------|----------|--------------------------|
| DIV : EFED | 10/27/95 | / / | NEGOT DATE: / / |
| BRAN: EEB | 10/27/95 | / / | PROJ DATE: / / |
| SECT: RS1 | 10/27/95 | / / | |
| REVR : DBAYS | 10/27/95 | / / | |
| CONTR: | / / | / / | |

* * * DATA REVIEW INSTRUCTIONS * * *

Please run risk assessment. Increase tolerance on
rangegrass. See attachment on prairie pothole region
exclusion on label request. See cover letter.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|--------|----------------|----------|----------|-----|-----|-------|
| 220300 | EFGB/CRS1 | 10/23/95 | 03/21/96 | Y | N | Y |

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 |

¹ Data taken from Diflubenzuron Registration Standard 6/30/85

These results indicate that diflubenzuron is **practically non-toxic** to avian species on an acute oral and **slightly toxic** on a subacute dietary basis. The guideline requirements are fulfilled. (MRID #: 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 |

¹ Data taken from Diflubenzuron Registration Standard 6/30/85

The avian reproductive studies indicate that diflubenzuron effects egg production in bobwhite quail and eggshell thickness in the mallard duck. 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.

| 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 |

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 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 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.

| 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> | 97.6% | 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.

| 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 |

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 LC₅₀ or EC₅₀ is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC₅₀ or LC₅₀ value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC₅₀ or LC₅₀ 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 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/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>Mysidopsis bahia</i> | 97.6 | 45 pptr | 86 pptr | 62.2 pptr | 402375-01 Breteler/1987 401970-01 Breteler/1957 | Mortality Growth Repro. | Core |
| <i>Daphnia magna</i> | 97.6 | 40 pptr | 93 pptr | 60.9 | 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 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).

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 <i>et al.</i> (1977) 0009897 | 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 <i>et al.</i> (1975) 00071210 | 25% active wettable powder @ 0.18 lb. a.i./A applied to forest in Canada for Control of spruce budworm. Samples take 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 <i>et al.</i> (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 <i>et al.</i> (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. |

Three estuarine 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. |

c. Toxicity to Plants

(1) Terrestrial

Diffubenzuron 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.

| Nontarget Terrestrial Plant Toxicity Findings | | | |
|---|--------|-------------------------------------|-----------------------------------|
| Species | % A.I. | Seedling emergence EC ₂₅ | Vegetative vigor EC ₂₅ |
| 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 acutely |
| chronic RQ > | 1 | 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 LC₅₀ 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:

| Estimated Environmental Concentrations on Avian and Mammalian Dietary Food Items in PPM | | | | | |
|---|------------------------|-----------------------|-----------|--------------------------------|----------------------------------|
| Crop | App. Rate (lbs a.i./A) | Food items | EEC (ppm) | Acute Risk Quotient (EEC/LC50) | Chronic Risk Quotient (EEC/NOEL) |
| Rangegrass | 0.0156 | Range Grass (short) | 3.75 | 0.00075 | 0.0075 |
| | | Long Grass | 1.719 | 0.00034 | 0.0034 |
| | | Broad Leaf Plants | 1.953 | 0.00039 | 0.0039 |
| | | Forage, Small Insects | 0.906 | 0.00018 | 0.0018 |
| | | Seed Containing Pods | 0.188 | 0.00004 | 0.00038 |
| | | Fruits | 0.114 | 0.00002 | 0.00023 |

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 (Rangegrass use). 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 Mammalogy 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 rate lbs/acre |
| | Rangegrass 0.0156 |
| Meadow vole consuming range grasses | 0.00246 |
| Adult field mouse consuming seeds | 0.00004 |
| Least shrew consuming forage and insects | 0.0017 |

Diffubenzuron does not exceed the mammalian levels of concern for uses on Rangegrass.

(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**

The use of chronic NOELs to determine chronic risk is based on diflubenzuron's mode of action as a chitin inhibitor and data from aquatic field studies showing adverse effects to aquatic invertebrate populations. Therefore, for these reasons and to insure an adequate safety factor, the use of chronic NOELs is deemed appropriate in this aquatic chronic risk assessment.

Expected Aquatic Concentrations: Diflubenzuron is very highly toxic to both freshwater and marine/estuarine invertebrates.

Rangegrass use EEC is 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 GENECC models do not fit this application scenario.

| ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs) FOR | | | | | | |
|---|-----------------------------|--------------------------------|--------------------------------------|--|--|--|
| Crop | Application Method | | | | | |
| Range-grass | Direct Application to Water | Application Rate in lbs a.i./A | EEC form Direct Application to Water | | | |
| | | 0.0078 | 5.872 | | | |
| | | 0.0156 | 11.744 | | | |

(a) Freshwater Fish

| Risk Quotients (RQ) for Freshwater Fish | | | |
|---|----------------|------------------|---------------------|
| Crop/application rate | Species | Acute RQ (96-hr) | Chronic RQ (90-day) |
| Rangegrass/0.0078 lb. a.i./A | Bluegill | 0.00005 | N/A |
| | Rainbow trout | 0.00004 | N/A |
| | Fathead minnow | 0.00001 | 0.059 |
| Rangegrass/0.0156 lbs. a.i./A | Bluegill | 0.00009 | N/A |
| | Rainbow Trout | 0.00008 | N/A |
| | Fathead Minnow | 0.00002 | 0.117 |

| Analysis of the Level of Concern Criteria | | | | |
|---|-------------------------------|--|---|---|
| Use Site | Application Rate (lbs 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 Nonendangered Species Been Exceeded? (Acute and Chronic) |
| Rangegrass | 0.0078 | No | No | No |
| | 0.0156 | No | No | No |

Diflufenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the most sensitive freshwater fish species tested (Rangegrass use). Therefore use of diflufenzuron does not cause unreasonable adverse effects to fish and amphibians from acute and chronic exposures.

(b) Freshwater Invertebrates

| Risk Quotients (RQ) for Freshwater Invertebrates | | | |
|--|----------------------|------------------|---------------------|
| Crop/application rate | Species | Acute RQ (96-hr) | Chronic RQ (21-day) |
| Rangegrass 0.0078 lb. a.i./A | <i>Daphnia magna</i> | 1.59 | 146.8 |
| Rangegrass 0.0156 lb. a.i./A | <i>Daphnia magna</i> | 3.17 | 293.6 |

| Analysis of the Level of Concern Criteria | | | | |
|---|-------------------------------|---|---|---|
| Use Site | Application Rate (lbs 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 Nonendangered Species Been Exceeded? (Acute and Chronic) |
| Rangegrass | 0.0078 | Yes | Yes | Yes |
| | 0.0156 | Yes | Yes | Yes |

Diflufenzuron exceeds all LOC's based on RQ's using the acute LC₅₀ and chronic NOEL for the

most sensitive freshwater invertebrate species tested (Rangegrass use). 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 Quotients (RQ) for Estuarine and Marine Organisms | | | |
|--|------------------------|------------------------|---------------------|
| Crop/application rate | Species | Acute RQ (96-hr) | Chronic RQ (21-day) |
| Rangegrass/0.0078 lb. a.i./A | <i>M. bahia</i> | 2.978 | 130.46 |
| | <i>M. mercenaria</i> | 0.0184 | N/A |
| | <i>F. heteroclitus</i> | 0.00002 ⁽¹⁾ | 0.1174 |
| Rangegrass/0.0156 lb. a.i./A | <i>M. bahia</i> | 5.959 | 260.91 |
| | <i>M. mercenaria</i> | 0.0367 | N/A |
| | <i>F. heteroclitus</i> | 0.00004 ⁽¹⁾ | 0.2348 |

(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) |
| Rangegrass | 0.0078 | No | No | No |
| | 0.0156 | No | No | No |

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) |
|------------|-------------------------------|--|---|---|
| Rangegrass | 0.0078 | No | No | No |
| | 0.0156 | No | No | 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) |
| Rangegrass | 0.0078 | Yes | Yes | Yes |
| | 0.0156 | 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 (Rangegrass use). Therefore use of diflubenzuron does not cause unreasonable adverse effects to marine\estuarine finfish and mollusks from acute and chronic exposures.

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 (Rangegrass use). 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 diflufenzuron 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 diflufenzuron. 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:

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) |
| Rangegrass | 0.0078 | vascular (<i>Lemna</i>) | N/A | N/A |
| | | Algae or diatom | 5.872 | 0.0294 |
| | 0.0156 | vascular (<i>Lemna</i>) | N/A | N/A |

| | | | | |
|--|--|-----------------|--------|--------|
| | | Algae or diatom | 11.744 | 0.0587 |
|--|--|-----------------|--------|--------|

1) EEC's based on direct application to water for the Rangegrass use.

Diflufenzuron does not exceed LOC's based on RQ's using the acute LC₅₀ for the most sensitive freshwater alga species tested (Rangegrass use). 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 diflufenzuron 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.