United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-97-008
August 1997

Reregistration Eligibility Decision (RED)

Diflubenzuron

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case that includes the active ingredient diflubenzuron. The enclosed Reregistration Eligibility Decision (RED), which was signed on 5/22/97, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of your receipt of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Venus Eagle at (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative Susan Jennings at (703) 308-7130.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the receipt of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal**

concentration. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

DIFLUBENZURON

LIST A

CASE 0144

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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DIFLUBENZURON REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Arthur Grube	Economic Analysis Branch
Gabe Patrick	Biological Analysis Branch

Environmental Fate and Effects Assessment

Andrew Bryceland	Ecological Effects Branch
Mary Powell	Science Analysis and Coordination Staff
Gail Maske	Environmental Fate and Groundwater Branch

Health Effects Assessment

Edwin Budd	Toxicology Branch I
Jeff Evans	Occupational and Residential Exposure Branch
Richard Griffin	Risk Characterization and Analysis Branch
Steven Knizner	Reregistration Support Chemistry Branch
Tom Myers	Risk Characterization and Analysis Branch

Registration Support Risk Assessment

David Ritter	Registration Support Branch
Paul Schroeder	Insecticide-Rodenticide Branch

Risk Management

Susan Jennings	Reregistration Branch
Lawrence Schnaubelt	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
μg/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision (RED) addresses the reregistration eligibility of the pesticide diflubenzuron, N-[[(4-chlorophenyl)amino] carbonyl]-2,6-difluorobenzamide or 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea. Diflubenzuron is used primarily on citrus, cattle, cotton, forestry, mushrooms, ornamentals, pastures, soybeans, standing water, sewage systems, and wide-area general outdoor treatment sites. The insecticide behaves as a chitin inhibitor to inhibit the growth of many leaf-eating larvae, mosquito larvae, aquatic midges, rust mite, bollweevil, and flies.

Diflubenzuron was first registered in the United States in 1979 for use as an insecticide. The Agency issued a Registration Standard for diflubenzuron in September, 1985, (NTIS #PB86-176500). In November, 1991, the Agency issued a Data Call-In for diflubenzuron requiring additional residue chemistry and ecological effects data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and subsequent Data Call-In.

Reregistration Eligibility

EPA has completed its reregistration eligibility decision regarding the pesticide diflubenzuron, case 0144. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. This decision considered the requirements of the recently enacted "Food Quality Protection Act of 1996" that amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed after August 3, 1996, are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, the Food Quality Protection Act (FQPA, Public Law 104-170) requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibly of infants and children to the toxic effects of pesticide residue.

The Agency considered the appropriateness of an additional uncertainty factor to account for situations where available data indicate increased sensitivity of infants and children and concluded that it is not warranted based on an evaluation of the toxicology database. Regarding aggregate exposure, the Agency only considered dietary exposure because there are no residential or other non-occupational uses of diflubenzuron and exposure

to diflubenzuron from drinking water is not of concern. In the case of diflubenzuron, EPA has not yet determined whether or how to include this chemical in a cumulative risk assessment. This reassessment determination therefore does not take into account common mechanism issues. After EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier.

The Agency has determined that diflubenzuron, labeled and used as specified in this Reregistration Eligibility Decision, will not cause unreasonable risk to humans or the environment and that these uses are eligible for reregistration. The Agency is requiring additional toxicity, ecological effects, environmental fate, occupational and residential exposure, residue and product chemistry data that are expected to confirm the risk assessment.

Health Effects

The Agency has determined that there is evidence of non-carcinogenicity in humans for diflubenzuron (Group E). However, p-chloroaniline (PCA), a metabolite of diflubenzuron, is a probable human carcinogen (Group B2). The Agency has determined that the Q_1^* for PCA, based upon spleen sarcoma rates in male rats, is $6 \times 10^{-2}(mg/kg/day)^{-1}$ in human equivalents. The Agency has also determined that p-chlorophenylurea (CPU), a metabolite of diflubenzuron that is closely related to PCA with no adequate carcinogenicity data, is considered as having the same carcinogenicity potential (Q_1^*) as PCA. The sum of PCA and CPU residues in ingested food, plus the amount of the metabolites formed in vivo (2%), were used to estimate the dietary exposure of humans to the carcinogenic metabolites of diflubenzuron. The total cancer risk estimate for PCA and related metabolites for the overall U.S. population is 1×10^{-6}. Where no PCA or CPU are present, the toxicological endpoint for diflubenzuron *per se* will be used for risk assessments. The RfD is 0.02 mg/kg/day, based on the NOEL of 2.0 mg/kg/day in the 52-week chronic oral study in dogs with a safety factor of 100 to account for interspecies extrapolation and intraspecies variability.

A tolerance reassessment was performed and is included with this document. Data for cotton gin by-products, mushrooms, grass forage are essential to reassess the tolerances. Confirmatory data are also required for cottonseed, liver, milk, pasture grass hay, soybeans and walnuts.

Occupational/Residential Exposure and Risk

For occupational and residential exposure, the Agency is establishing a short-term toxicological endpoint of sulfhemoglobinemia observed in a mouse 14-day subchronic oral study. The NOEL in this study was 40 mg/kg/day and the LEL was 200 mg/kg/day. The intermediate term endpoint is methemoglobinemia observed in a 13-week subchronic feeding study in dogs. The NOEL was 2 mg/kg/day and the LEL was 6.24 mg/kg/day. Although the risk assessment produced low MOEs for certain mixing/loading activities, these risks are

expected to be minimized to acceptable levels by requiring mixers and loaders to wear a dust/mist respirator (TC-21C).

Environmental Fate, Ecological Effects and Risk

Diflubenzuron appears to be relatively non-persistent and immobile under normal use conditions. The major route of dissipation appears to be biotic processes (half-life of approximately 2 days for aerobic soil metabolism). Diflubenzuron is stable to hydrolysis and photolysis.

Available data indicate that it is unlikely that diflubenzuron will contaminate ground water or surface water. Additional adsorption/desorption data on the degradates are needed to confirm this conclusion. Additional storage stability data on diflubenzuron and its degradates are necessary to validate the submitted forestry dissipation study. To support aquatic uses, additional information is required for aerobic aquatic metabolism, aquatic (sediment) dissipation, accumulation in irrigated crops, and accumulation in aquatic non-target organisms. To estimate spray drift a drift field evaluation study is required, however, the registrants may elect to satisfy this requirement through participation in the Spray Drift Task Force.

The risk assessment conducted using available data indicates that levels of concern are not exceeded for avian species, mammals, insects or freshwater fish. Although the use of diflubenzuron is expected to cause some adverse chronic effects to estuarine/marine fish at the highest application rate (forestry), these effects are not as widespread as those associated with freshwater and estuarine/marine invertebrates. The use of diflubenzuron is expected to cause adverse acute and chronic effects to both freshwater and estuarine/marine invertebrates, including endangered species. To mitigate these risks, the Agency is requiring a 25-foot vegetative buffer strip to decrease runoff and to serve as a buffer zone for spray drift from ground applications. For aerial applications, the Agency is requiring a 150-foot buffer zone.

The risk to aquatic invertebrates is also expected to be substantial when diflubenzuron is applied to control mosquito larvae. Since this use involves direct application to water and/or near water, no mitigation is currently proposed.

Before reregistering the products containing diflubenzuron, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA, Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 USC *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, the FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines set forth in section 4 of FIFRA. Thus, the Agency is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of diflubenzuron. The document consists of six sections. Section I is the introduction. Section II describes diflubenzuron, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for diflubenzuron. Section V discusses the reregistration requirements for diflubenzuron. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Diflubenzuron
- **Chemical Name:** N-[[(4-chlorophenyl)amino] carbonyl]-2,6-difluorobenzamide or 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea
- **Chemical Family:** Urea derivative
- **CAS Registry Number:** 35367-38-5
- **OPP Chemical Code:** 108201
- **Empirical Formula:** $C_{14}H_9ClF_2N_2O_2$
- **Trade and Other Names:** Dimilin, Vigilante, Micromite, Adept
- **Basic Manufacturer:** Uniroyal Chemical Company, Incorporated

B. Use Profile

The following is information on the currently (up to and including August 1, 1995) registered uses with an overview of use sites and application methods. A detailed table of these uses of diflubenzuron is in Appendix A.

Type of Pesticide: Acaricide/Insecticide (insect growth regulator)

Use Sites:

Terrestrial Food/Feed Crops
Citrus, cotton, mushrooms, pastures, soybeans

Terrestrial Non-Food
Ornamentals, wide-area general outdoor treatment

Aquatic Non-Food
Standing water and sewage system uses

Forestry
Forest trees, forest lands

Residential Outdoor
Ornamentals

Indoor Food
Cattle

Target Pests: Many leaf-eating larvae of insects feeding on agricultural, forest and ornamental plants (e.g. gypsy moth, forest tent caterpillar, Nantucket pine tip moth, velvet bean caterpillar, Mexican bean beetle, green cloverworm, beet armyworm, mosquito larvae, aquatic midge, rust mite, bollweevil, citrus root weevil complex, West Indian sugarcane rootstalk borer/weevil, sciarid fly and face fly)

Formulation Types Registered: soluble concentrate, flowable concentrate, wettable powder, pelleted/tableted

Method and Rates of Application:

Equipment - aerial, airblast and hydraulic sprayers

Method - broadcast, compost treatment, soil incorporation, cattle bolus, spray, ultra low volume

Rates - see Appendix A

Timing - at pinhead square (cotton), before spawning (mushroom), post-harvest, as needed

Use Practice Limitations: Restricted Use Pesticide for sale and use by certified pesticide applicators or person under their supervision due to toxicity to aquatic invertebrates

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of diflubenzuron. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and

site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The following table summarizes diflubenzuron use by site:

Site	Acres Planted (000's)	% of Sites Treated	Volume Applied (000 lbs. a.i.)	Acres Treated (thousands)
Cattle (mostly dairy)		< 1	< 5	
Cotton	13,600	< 3	< 75	< 300
Forestry			< 50	< 750
Mushrooms		< 100	< 50	
Soybeans	59,300	< 1	< 75	< 300

These data, when available, are based on public and proprietary data and verified with data provided by the registrant. Adequate data are not available to estimate the use of diflubenzuron on citrus, ornamentals, walnuts or in mosquito control programs.

D. Data Requirements

Data requested in the September 1985 Registration Standard for diflubenzuron include studies on product chemistry, ecological effects, environmental fate, residue chemistry and human toxicity. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Dimilin, active ingredient diflubenzuron, was first registered in 1976 for use against gypsy moth larvae in forested areas, including Christmas tree plantations and nursery crops grown in proximity to gypsy moth infested areas. Most spraying against gypsy moth larvae is done using products containing either diflubenzuron or B.t. (Bacillus thuringiensis), due to their efficacy and minimal effects on non-target organisms.

Cotton was added to the registration in 1979 to control certain lepidopterous larvae and boll weevils during the growing season and at the end of the growing season to reduce the size of the boll weevil population. Use of diflubenzuron reduces the number of weevils overwintering, the number of eggs deposited by surviving weevils and the percentage egg hatch. It is useful in the campaign to eradicate boll weevils in the United States.

Soybeans were added to the registration in 1982 to control lepidopterous larvae such as green cloverworm and velvetbean caterpillar. Diflubenzuron is used particularly when there is a surge in the population of these larvae or resistance precludes use of standard insecticides.

Mushrooms were added to the label in 1983 primarily to control fungus gnats or mushroom flies. Diflubenzuron is incorporated into the casing when it is applied or as a drench after the casing is spread, covering the compost containing the spawn. These small flies, Sciara spp. and related fungus gnats are peculiar in that larvae may become sexually mature and reproduce without leaving the mushroom bed. Insecticides must be carefully incorporated into the compost and/or casing to assure acceptable results.

Boluses for cattle, first were registered in 1985 under the brand name Vigilante, are applied with a balling gun to control flies breeding in manure. The bolus stays in the stomach of treated animals, slowly eroding and releasing diflubenzuron which prevents molting by maggots of flies breeding in manure.

In 1985 control of mosquitoes breeding in irrigation water tailings, waste water drained from irrigated fields after furrow irrigation was completed, was added to the registration. This use was added using the 24(c), special local need process to make available an effective larvacide to control mosquitoes acting as vectors for equine encephalitis. This use is for waste water where fish and other non-target organisms are not of concern. A tolerance was established for pasture grass to support this use since livestock are allowed to graze in the area into which irrigation water tailings drain. Alabama, Florida, Hawaii, and Nevada have issued special local need registrations for control of mosquitoes in waste water.

Oranges, grapefruit, and tangerines were added to the registration in 1995 to control the citrus rust mite. Because of concern about the effects of drift from spray applications affecting non-target arthropods restrictions were attached to the registration of products containing diflubenzuron to be used on orange, grapefruit, and tangerine groves.

In July 1995 the patent and all other interests in diflubenzuron were acquired by Uniroyal Chemical Company. Uniroyal is continuing to develop products containing diflubenzuron with plans for adding to the label control of grasshoppers on rangeland, control of rice water weevil attacking rice, control of mites and insects on apples and pears, incorporation into animal feeds to control insects which breed in manure, and indoors to control household pests.

A Registration Standard for diflubenzuron was issued in September 1985 (NTIS #PB86-176500). The Agency issued a Data Call-In in November 1991 for

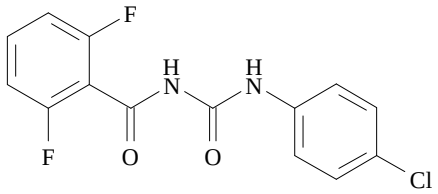
diflubenzuron requiring additional residue chemistry and ecological effects data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and subsequent Data Call-In.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Diflubenzuron [1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea] is an insecticide/acaricide (insect growth regulator) primarily used on cotton, mushrooms, forests, and ornamentals.

Figure A. 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea



Empirical Formula:	$C_{14}H_9ClF_2N_2O_2$
Molecular Weight:	310.7
CAS Registry No.:	35367-38-5
OPP Code No.:	108201

Diflubenzuron is a white crystalline solid with a melting point of 210-230 °C. Diflubenzuron is nearly insoluble in water (0.2 mg/L), but is soluble in organic solvents including acetonitrile (2 g/L), acetone (6.5 g/L), dimethylsulfoxide and dimethylformamide (120 g/L), and N-methylpyrolidone (200 g/L).

There are currently two diflubenzuron manufacturing-use products (MPs) registered to Uniroyal Chemical Company, Incorporated, under Pesticide Chemical Code 108201: the 95% technical (T; EPA Reg. No. 400-467) and 90% formulation intermediate (FI; EPA Reg. No. 400-466).

Data for preliminary analysis, guideline 62-1, pertaining to the presence of parachloroaniline using a method validated to 1 ppm remain outstanding. The registrant must submit data required for the TGAI and either certify that the suppliers of starting materials and the manufacturing processes for the TGAI and MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on diflubenzuron is adequate and will support reregistration eligibility, however, the following data are still required:

82-4 21-day inhalation toxicity rat

The Agency is requiring a repeat of the 21-day inhalation study to provide more accurate assessments of the inhalation hazards to workers and handlers exposed to diflubenzuron. This study is required to demonstrate a NOEL for methemoglobinemia and/or sulfhemoglobinemia. Methemoglobinemia results when large quantities of methemoglobin, caused by some chemicals that convert the ferrous iron in hemoglobin to ferric iron, accumulate in the blood. Methemoglobin may interfere with the oxygen carrying capacity of the blood. Sulfhemoglobinemia results when certain chemicals react with hemoglobin to form sulfhemoglobin, another abnormal form of hemoglobin, which again cannot react normally with oxygen. This study is expected to confirm the results of this risk assessment.

a. Acute Toxicity

The following table presents the results of the acute mammalian toxicity data for diflubenzuron:

Acute Mammalian Toxicity				
Test	**% AI**	**MRID**	**Results**	**Category**
Oral LD_{50}--rat	90%	00157103	> 5,000 mg/kg	IV
Dermal LD_{50}--rat	90%	00157104	> 2,000 mg/kg	III
Inhalation LC_{50}--rat	90%	00163311	> 2.49 mg/L	IV
Eye irritation--rabbit*	90%	00157105	Mild irritant	III
Dermal irritation--rabbit*	90%	00157106	No irritation	IV
Skin sensitization--guinea pig*	95%	42251101	Negative	N/A

* Data pertaining to eye irritation, dermal irritation and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

b. Subchronic Toxicity

Technical grade diflubenzuron was administered by gavage to male mice daily for 14 days at dose levels of 0 (control), 8, 40, 200, 1000 or 5000 mg/kg/day. At 15 days, significantly increased levels of methemoglobin were observed at 1000 and 5000 mg/kg/day and significantly increased levels of sulfhemoglobin were observed at dose levels of 200 mg/kg/day and above. The percentage of erythrocytes containing Heinz bodies was highly increased at 1000 and 5000 mg/kg/day. No effects on body weights or organs and tissues examined at autopsy were observed. The NOEL is 40 mg/kg/day. The LEL is 200 mg/kg/day, based on increased sulfhemoglobin. (MRID 00099713)

In a 28-day feeding study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 800, 4000, 20000 or 100000 ppm (equivalent to 0, 40, 200, 1000 or 5000 mg/kg/day). Methemoglobin was increased in males at all dose levels and in females at dose levels of 200 mg/kg/day and higher. Sulfhemoglobin was increased in all treated males and females. At 5000 mg/kg/day males and females experienced decreased erythrocyte counts, packed cell volumes and hemoglobin. Dose-related increases in spleen weights at all dose levels and in liver weights at dose levels of 200 mg/kg/day and higher were also observed. No NOEL was established in this study since treatment-related effects were observed at 40 mg/kg/day, the lowest dose level tested. The LEL is 40 mg/kg/day, based on increased methemoglobin in males, increased sulfhemoglobin in males and females and increased spleen weights in males and females. (MRID 00070018)

In a 13-week feeding study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 160, 400, 2000, 10000 or 50000 ppm (equivalent to 0, 8, 20, 100, 500 or 2500 mg/kg/day). Methemoglobinemia was observed in male and female rats at all dose levels. Sulfhemoglobinemia occurred in male and female rats at dose levels of 100 mg/kg/day and above. Heinz bodies were observed at dose levels of 500 and 2500 mg/kg/day. The study also notes decreased erythrocyte counts and decreased hemoglobin in male and female rats at all dose levels and increased reticulocytes at dose levels of 20 mg/kg/day and above. The terminal sacrifice showed elevated spleen and liver weights at dose levels of 20 mg/kg/day and higher. At all dose levels, histopathological examinations indicated dose related increases of hemosiderosis and congestion of the spleen, hemosiderosis and chronic hepatitis of the liver, and mild erythroid hyperplasia of the bone marrow. This study did not establish a NOEL since treatment-related effects were observed at the lowest dose level tested. The LEL is 8 mg/kg/day, based on increased methemoglobin and signs of hemolytic anemia, erythrocyte destruction in the spleen and liver and regeneration of erythrocytes in the bone marrow. A subsequent submission used regression analysis to calculate NOELs of 2.1 and 1.5 mg/kg/day for males and females, respectively, for methemoglobinemia and NOELs of 3.1 and 9.1 mg/kg/day

for males and females, respectively, for sulfhemoglobinemia. (MRIDs 00064550 and 00074534)

In a 14-week feeding study technical grade diflubenzuron was administered in the diet to mice at dose levels of 0 (control), 80, 400, 2000, 10000 or 50000 ppm (equivalent to 0, 12, 60, 300, 1500 or 7500 mg/kg/day). Methemoglobinemia and sulfhemoglobinemia (accompanied by Heinz bodies) were observed in male and female mice at all dose levels. The study noted decreased erythrocyte counts, decreased packed cell volume, and increased reticulocytes at dose levels of 60 mg/kg/day and higher. The terminal sacrifice showed the following effects: increased spleen weights at 60/mg/kg/day dose levels and above; increased liver weights and decreased seminal vesicle weights at dose levels of 300 mg/kg/day and above; and decreased kidney weights at dose levels of 1500 mg/kg/day and above. At dose levels of 60 mg/kg/day and above, histopathological examinations indicated hemosiderosis of the spleen and in the liver, hepatocytic enlargement, hepatocytic cytoplasmic vacuolation, inflammatory foci and necrosis in varying degrees. This study did not establish a NOEL. The LEL is 12 mg/kg/day, based on increased methemoglobinemia and sulfhemoglobinemia. A subsequent submission used regression analysis to calculate NOELs of 3.3 and 1.9 mg/kg/day for males and females, respectively, for methemoglobinemia and a NOEL of 2.6 mg/kg/day for males for sulfhemoglobinemia. (MRIDs 00074534 and 00114330)

In a 13-week feeding study technical grade diflubenzuron was administered in the diet to beagle dogs at dose levels of 0 (control), 10, 20, 40 or 160 ppm (equal to 0, 0.42, 0.84, 1.64 or 6.24 mg/kg/day). Ophthalmoscopic examinations were negative. Methemoglobinemia was observed in the dogs at 6.24 mg/kg/day (after 6 weeks). No gross necropsy, organ weight or histopathological changes were reported at any level that could be related to treatment. The NOEL is 1.64 mg/kg/day. The LEL is 6.24 mg/kg/day, based on increased methemoglobinemia. (MRID 00038706)

In a 21-day dermal study 21.5%, 10% or 4.64% suspensions of technical grade diflubenzuron were applied 5 days/week to New Zealand white rabbits at the rate of 1.5 mL/kg/day. The skin of one-half of the animals in each group was abraded. Slight erythema was occasionally observed in some animals, but was sporadic and could not be related to the test material. All groups treated with test material displayed increased methemoglobin. Gross necropsies, organ weight measurements and histopathological examination of tissues were negative. This study did not establish a NOEL since treatment-related effects were observed at the lowest dose level tested. The LEL is 69 mg/kg/day (based on a 4.64% suspension being applied at the rate of 1.5 mL/kg/day). (MRID 00038716)

In another 21-day dermal study, technical diflubenzuron (96.7% a.i.) was administered in 0.25% gum tragacanth in distilled deionized water to the dorsal skin on the backs of 10 rats/sex/dose at 0, 20, 500, or 1000 mg/kg bwt/day for 6 hour

periods each day. At 1000 mg/kg/day, dermal irritation was seen in the males as a trace of acanthosis and hyperkeratosis. Females also exhibited the same type and degree of dermal irritation at 1000 mg/kg/day. Kidney and liver changes of trace levels of mineralization and chronic inflammation of the liver were similar to that seen in the controls of both male and female test animals. Only increased absolute organ weight changes of testes were reported in the mid- and high-dose males. Relative organ weights were unaffected. There was no significant toxicity with regard to mortality, clinical signs, body weight changes, or food consumption. Hematological changes included elevated WBC count in males in the mid- and high-dose groups when compared to controls. Males exhibited small reductions in hemoglobin and hematocrit values at the 1000 mg/kg dose level. Though not statistically significant, the mid-dose males showed increasing instances of elevated methemoglobin, while that in the high-dose animals was significantly increased. Treated females at the top two doses showed reduced red blood cells, hemoglobin and hematocrit values ($p < 0.05$). The highest dose also showed elevated levels of methemoglobin. Erythrocyte morphology (anisocytosis), hypochromasia and polychromasia indicated +1 to +2 changes in both males and females indicating loss and replacement of red cells at the highest two doses. Slight numbers of +1 changes in both sexes at the lowest dose could not be discerned from control values. Based on the red blood cell changes, this study established an LOEL of 500 mg/kg/day and a NOEL of 20 mg/kg/day. (MRID 43954101)

A 21-day inhalation study designed to study methemoglobinemia exposed rats to dust concentrations of 0 (control), 0.121, 0.866 or 1.85 mg/liter of diflubenzuron 25% WP for 1 hour/day, 5 days/week for 3 weeks. An increase in methemoglobin was observed in all treated groups of both sexes. Reticulocyte counts were unaffected by treatment. This study did not establish a NOEL since treatment-related effects were observed at the lowest dose level tested. The LEL is 0.121 mg/liter of 25% WP. A new study is required. (MRID 00044325)

c. Chronic Toxicity

In a 104-week rat chronic feeding study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 10, 20, 40 or 160 ppm (equivalent to 0, 0.35, 0.70, 1.43 or 5.83 mg/kg/day in males and 0, 0.43, 0.88, 1.73 or 7.05 mg/kg/day in females). This study established a NOEL for methemoglobinemia and sulfhemoglobinemia in chronic oral rat studies. Examinations of blood were conducted at weeks 13, 26, 52, 78 and 102. Sulfhemoglobin and methemoglobin formation were assayed for the control, 40 and 160 ppm groups only. Sulfhemoglobin formation was non-detectable in this study. The NOEL for methemoglobinemia in this study was 1.43 mg/kg/day in males and 1.73 mg/kg/day in females. The LEL is 5.83 mg/kg/day in males and 7.05 mg/kg/day in females. (MRIDs 00044329 and 00099712)

In a 104-week rat chronic feeding study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 156, 625, 2500 or 10000 ppm (equivalent to 0, 7.8, 31, 125 or 500 mg/kg/day). Statistically significant increases in methemoglobin and sulfhemoglobin were consistently observed in male and female rats at 52 and 104 weeks at all treatment levels tested. The increases tended to be dose-related. At higher dose levels (particularly at 125 mg/kg/day and above), signs of hemolytic anemia were observed in males and females at 52 weeks. No such signs were observed at 104 weeks. At similar dose levels increased reticulocytes were also noted in females at 104 weeks and in both males and females at 52 weeks. Increased spleen and liver weights were observed in males and females at dose levels of 125 mg/kg/day and above. Histopathological signs of erythrocyte destruction and compensatory regeneration were observed in both males and females at dose levels of 7.8 mg/kg/day and higher. No NOEL was established in this study. The LEL is 7.8 mg/kg/day, the lowest dose level tested. (MRID 00145467)

In a 91-week mouse chronic feeding study technical diflubenzuron was administered in the diet to mice at dose levels of 0 (control), 16, 80, 400, 2000 or 10000 ppm (equivalent to 0, 2.4, 12, 60, 300 or 1500 mg/kg/day). Mortality, body weights, food consumption, blood chemistries and urinalyses were not affected by treatment. Dose-related, statistically significant increases in methemoglobin and sulfhemoglobin were consistently observed in male and female mice throughout the study at dose levels of 12 mg/kg/day and higher. A blue/gray discoloration of the skin and extremities as well as dark eyes accompanied the increased methemoglobin and sulfhemoglobin. At higher dose levels (particularly 300 mg/kg/day and above), both males and females showed signs of hemolytic anemia, erythrocyte destruction and compensatory regeneration. At similar dose levels, histopathological effects in the liver were also observed, including hepatocyte enlargement, hepatocyte vacuolation and congested/dilated centrilobular sinusoids. The study also reported increased platelet counts at dose levels of 60 mg/kg/day and higher in both males and females. The NOEL in this study is 2.4 mg/kg/day. The LEL is 12 mg/kg/day, based on methemoglobinemia and sulfhemoglobinemia. (MRID 00142490)

In a 52-week chronic oral study technical grade diflubenzuron was administered in gelatin capsules to beagle dogs once each day (7 days/week) at dose levels of 0 (control), 2, 10, 50 or 250 mg/kg/day. Except for a slight decrease in mean body weight gain observed in female dogs at 250 mg/kg/day, body weights were not affected. Ophthalmoscopic examinations, clinical chemistries and urinalyses were negative. Statistically significant increases in methemoglobin and sulfhemoglobin were observed in male and female dogs at dose levels of 10 mg/kg/day and above. Heinz bodies were also observed in the erythrocytes of male dogs at 250 mg/kg/day and in those of female dogs at dose levels of 50 mg/kg/day and above. At similar dose levels, signs of hemolytic anemia, destruction of erythrocytes and compensatory regeneration of erythrocytes were observed. These signs were accompanied by increased platelet counts in females. Absolute spleen and liver weights, but not

relative organ body weight ratios, increased in male dogs at 50 and 250 mg/kg/day. Organ weights did not increase in female dogs. The NOEL in this study is 2 mg/kg/day and the LEL is 10 mg/kg/day, based on methemoglobinemia and sulfhemoglobinemia. (MRID 00146174)

d. Carcinogenicity

In a 104-week carcinogenicity study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 156, 625, 2500 or 10000 ppm (equivalent to 0, 7.8, 31, 125 or 500 mg/kg/day). Mortality, clinical signs, body weights and food consumption were not affected by treatment. Increases in methemoglobin and sulfhemoglobin occurred at all treatment levels. Histopathological signs of erythrocyte destruction and compensatory regeneration were observed at dose levels of 7.8 mg/kg/day and higher. Signs of hemolytic anemia, increased reticulocytes and increased spleen and liver weights were noted at dose levels of 125 mg/kg/day and higher. Treatment with diflubenzuron was not associated with an increased incidence of neoplastic lesions in either males or females. Dosing was adequate since the highest dose level tested, 500 mg/kg/day, approached the limit dose of 1000 mg/kg/day for carcinogenicity studies and significant toxicity was observed at this dose level. (MRID 00145467)

In a 91-week carcinogenicity study technical grade diflubenzuron was administered in the diet to mice at dose levels of 0 (control), 16, 80, 400, 2000 or 10000 ppm (equivalent to 0, 2.4, 12, 60, 300 or 1500 mg/kg/day). Mortality, body weights and food consumption were not affected by treatment. Increases in methemoglobin and sulfhemoglobin were consistently observed in male and female mice throughout the study at dose levels of 12 mg/kg/day and higher. A blue/gray discoloration of the skin and extremities and dark eyes accompanied the increased methemoglobin and sulfhemoglobin. At higher dose levels (particularly 300 mg/kg/day and higher), signs of hemolytic anemia, erythrocyte destruction and compensatory regeneration were observed as were histopathological effects in the liver. Treatment with diflubenzuron was not associated with an increased incidence of neoplastic lesions in either males or females. Dosing was adequate since the highest dose tested, 1500 mg/kg/day, exceeded the limit dose of 1000 mg/kg/day for carcinogenicity studies. (MRID 00142490)

Carcinogenicity Studies on <u>p-Chloroaniline</u> (Metabolite of Diflubenzuron)

In a 24-month carcinogenicity study p-chloroaniline (PCA) of greater than 99% purity was administered by gavage (5 days/week) to rats at dose levels of 0 (control), 2, 6 or 18 mg/kg/day. Hematology examinations and methemoglobin measurements were conducted on 15 rats/sex/group at 6, 12, 18 and 24 months. Increased survival was observed in male rats at 2 and 6 mg/kg/day and in female rats at 2, 6 and 18 mg/kg/day relative to control rats. The study attributed the increased survival in these

treatment groups to a decreased incidence of mononuclear cell leukemia in the same groups. Mean body weights for treated male and female groups generally remained within 5% of the control male and female weights throughout the study. Hematology examinations and methemoglobin measurements showed mild hemolytic anemia and dose-related increases in methemoglobin at dose levels of 6 and 18 mg/kg/day. Male rats at 6 and 18 mg/kg/day and female rats at 18 mg/kg/day had blue extremities indicative of cyanosis. Histopathological examinations indicated non-neoplastic treatment-related effects in the spleen, liver, bone marrow and adrenal gland. A treatment-related increased incidence of uncommon sarcomas of the spleen was observed in the male rats in this study. These sarcomas included fibrosarcomas, hemangiosarcomas and osteosarcomas, many of which metastasized to other sites. The combined incidence of these sarcomas in male rats was 0/49, 1/50, 3/50 and 38/50 at dose levels of 0, 2, 6 and 18 mg/kg/day respectively. In female rats, 1 fibrosarcoma was observed at 6 mg/kg/day and 1 osteosarcoma at 18 mg/kg/day. No additional uncommon sarcomas of the spleen were observed in the female rats in this study. A marginally increased incidence of pheochromocytomas was also observed in the adrenal gland of male and female rats at 18 mg/kg/day. For male rats, the incidence was 13/49, 14/48, 15/48 and 26/49 and for female rats was 2/50, 3/50, 1/50 and 6/50 at dose levels of 0, 2, 6 and 18 mg/kg/day respectively. Decreased incidence of mononuclear cell leukemia and of malignant lymphomas were also noted in the treated male and female rats in this study. (National Toxicology Program (NTP) Report No. 351; July, 1989)

In a 24-month carcinogenicity study p-chloroaniline (PCA) of greater than 99% purity was administered by gavage (5 days/week) to mice at dose levels of 0 (control), 3, 10 or 30 mg/kg/day. Male mice experienced increased mortality at 10 mg/kg/day after 99 weeks, but not at 30 mg/kg/day. Mortality in female mice and mean body weights in both males and females were not affected. At 24 months, hemosiderin was observed in the Kupffer cells of the livers of male and female mice and in the renal tubules of female mice at 30 mg/kg/day. The livers of female mice exhibited a proliferation of hematopoietic cells at all treatment levels. Male mice exhibited increased incidence of combined hepatocellular adenomas/carcinomas. Incidence were 11/50, 21/49, 20/50 and 21/50 at dose levels of 0, 3, 10 and 30 mg/kg/day respectively. A dose-related increase in hepatocellular carcinomas caused the increase in combined tumors as follows: 3/50, 7/49, 11/50 and 17/50 at 0, 3, 10 and 30 mg/kg/day respectively. Many of these carcinomas metastasized to the lungs (1/50, 1/49, 2/50 and 9/50 at 0, 3, 10 and 30 mg/kg/day respectively). Male mice at 30 mg/kg/day experienced increased incidence of hemangiosarcomas in the spleen and/or liver of 4/50, 4/49, 1/50 and 10/50 at dose levels of 0, 3, 10 and 30 mg/kg/day respectively. Incidence of malignant lymphomas were decreased in the treated male and female mice. No evidence of carcinogenicity was observed in the female mice in this study. (National Toxicology Program (NTP) Report No. 351; July, 1989)

e. Developmental Toxicity

In a developmental toxicity study technical grade diflubenzuron was administered by gavage to groups of 24 female rats on days 6 through 15 of gestation at dose levels of 0 (control) or 1,000 mg/kg/day (limit-dose study). No maternal toxicity or toxicity to the developing fetus was observed. The NOEL for maternal toxicity is 1,000 mg/kg/day and the NOEL for developmental toxicity is greater than 1,000 mg/kg/day. (MRID 41703504)

In a separate developmental toxicity study technical grade diflubenzuron was administered by gavage to groups of 16 female rabbits on days 7 through 19 of gestation at dose levels of 0 (control) or 1,000 mg/kg/day (limit-dose study). No maternal toxicity or toxicity to the developing fetus was observed. The NOEL for maternal toxicity is greater than 1,000 mg/kg/day and the NOEL for developmental toxicity is 1,000 mg/kg/day. (MRID 41703505)

f. Reproductive Toxicity

In a 2-generation reproduction study technical grade diflubenzuron was administered in the diet to rats at dose levels of 0 (control), 500, 5000 or 50000 ppm (equivalent to about 0, 25, 250 or 2500 mg/kg/day). Starting at 6 weeks of age, F0 animals were treated continuously for 10 weeks prior to mating at 16 weeks of age until completion of weaning of all F1 litters at 21 days postpartum. Direct treatment of the F1 generation (28/sex/dose level) began at about 4 weeks of age and continued through mating at 16 weeks until weaning for all of the F2 litters. F0 and F1 adults exhibited treatment-related effects at all dose levels. The most prominent of these effects were increased methemoglobin levels, hemolytic anemia and signs of erythrocyte destruction. F0 and F1 animals exhibited additional signs of toxicity at 250 and 2500 mg/kg/day, including pathological effects in the spleen and liver. No effects on reproductive performance were observed at any dose level in F0 or F1 males or females. Litter and mean pup weights decreased slightly from birth to 21 days post-partum in F1 offspring at 2500 mg/kg/day. This study does not identify a NOEL for parental adults. The LEL is 25 mg/kg/day, based on methemoglobinemia, hemolytic anemia, destruction of erythrocytes, and pathological changes in the spleen and liver. The NOEL for reproductive performance in parental adults is 2500 mg/kg/day. The NOEL for developmental toxicity in progeny is 250 mg/kg/day and the LEL is 2500 mg/kg/day, based on decreased body weights in F1 pups from birth to 21 days post-partum. (MRID 43578301)

g. Mutagenicity

A Salmonella/mammalian microsome plate incorporation assay exposed strains TA98, TA100, TA1535, TA1537 and TA1538 to technical grade diflubenzuron with and without S9 metabolic activation at concentrations of 0, 8, 40, 200 or 1000

µg/plate. The high dose was selected on the basis of slight compound precipitation at 1000 µg/plate. Diflubenzuron was not cytotoxic with or without S9 activation in any of the Salmonella strains in this assay. There was no evidence of induced mutant colonies over background levels at any of the evaluated concentrations. (MRID 41703503)

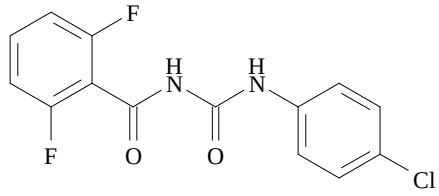
An in vitro chromosome damage assay exposed cultures of Chinese hamster ovary (CHO) cells to technical grade diflubenzuron with and without S9 metabolic activation. The test material was tested at concentrations up to cytotoxic/precipitating levels of 200-250 µg/mL. The test material did not increase the structural chromosome aberrations over background levels at any of the evaluated concentrations. (MRID 41703502)

An unscheduled DNA synthesis (UDS) assay exposed cultures of primary rat hepatocytes to technical grade diflubenzuron at concentrations ranging from 0.1 to 333 µg/mL. At the high dose of 333 µg/mL, cytotoxicity was observed (36% cell survival in an initial assay and 8% cell survival in a confirmatory assay). The test material did not cause an appreciable increase in net nuclear grain counts compared to the solvent control at any of the evaluated concentrations. Diflubenzuron did not induce a genotoxic effect in this assay system. (MRID 41703501)

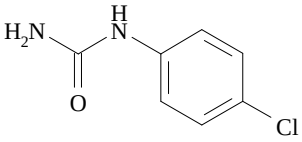
h. Metabolism

In an absorption, distribution, metabolism and excretion study diflubenzuron was administered by gavage as an oral dose of ^{14}C-diflubenzuron to male and female rats at single dose levels of 5 or 100 mg/kg or at a dose level of 5 mg/kg following 14 days of unlabeled diflubenzuron in the diet at a dose level of 5 mg/kg/day. An additional group of rats with cannulated bile ducts was also administered a single oral dose of 5 mg/kg of ^{14}C-diflubenzuron. The rats only partially absorbed diflubenzuron from the gastrointestinal tract. In the bile duct cannulated rats, about 33% of the administered dose was absorbed and about 50% of the 33% (17% of the administered dose) was excreted in the bile. By the seventh day 19-21% of the administered dose had been recovered from the urine and 77-80% from the feces of rats receiving the lower doses of 5 mg/kg. Also by the seventh day 3% of the administered dose had been recovered from the urine and 96% from the feces of rats receiving the higher dose of 100 mg/kg. Radioactivity in expired air was negligible. The half-life of radioactivity in blood was about 14 hours. Over 98% of the administered radioactivity had been excreted by the seventh day. Very little bioaccumulation in tissues was observed. The highest levels of radioactivity were observed in the erythrocytes and liver at 48 hours. Ten urinary metabolites were identified, including p-chloroaniline (PCA) and p-chlorophenylurea (CPU), which together accounted for about 2% of the administered dose (at 5 mg/kg). In the feces, only unchanged parent compound was detected. (MRIDs 41720901 and 41919001)

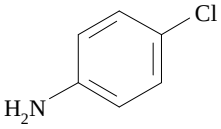
The chemical structures of diflubenzuron and its residues of concern in plants and animals are:



Diflubenzuron: 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea



4-chlorophenylurea: CPU



4-chloroaniline: PCA

i. Toxicology Endpoints of Concern

One day single dose oral studies in rats and mice indicated only marginal effects on methemoglobin levels at a dose level of 10,000 mg/kg of a 25% wettable powder formulation. Sulfhemoglobin levels and Heinz bodies were not affected. Therefore, there is no acute dietary endpoint and a risk assessment for acute dietary exposure (1 day) is not necessary.

The toxicology endpoint for short term occupational or residential exposure (1 to 7 days) is sulfhemoglobinemia based on the 14-day subchronic oral study in mice dosed with technical grade diflubenzuron. The NOEL in this study was 40 mg/kg/day and the LEL was 200 mg/kg/day. (MRID 00099713)

The toxicology endpoint for intermediate term occupational or residential exposure (1 week to several months) is methemoglobinemia based on the 13-week subchronic feeding study in dogs. Since the Agency does not use lower NOELs for shorter term exposures than for longer term exposures to conduct risk assessments, the NOEL of 1.64 mg/kg/day in this study is considered to be 2 mg/kg/day. The 2 mg/kg/day NOEL will be consistent with the NOEL of 2 mg/kg/day in the chronic study used to calculate the RfD. The LEL in this study was 6.24 mg/kg/day. (MRID 00038706)

In a dermal absorption study, young adult Sprague-Dawley rats were dosed dermally with ^{14}C-diflubenzuron at 0.005 and 0.05 mg/cm^2 (0.2 and 2.0 mg/kg). Exposure periods were 1, 4, and 10 hours for each dose. A standard material balance was performed at termination. All absorbed material was found in the carcass. Blood concentrations were below the limit of detection (less than 23 ng/mL). This is particularly important as the toxic effects occur in the blood. The pattern for diflubenzuron is typical of a chemical that enters the body through the skin, but cannot proceed further into the organism where it produces its toxic effect. In diflubenzuron this limitation is due to its very low water solubility (0.5 ppm). Based on this study, the dermal absorption rate for exposures of 1 to 10 hours is 0.5%. (MRID 44053101)

Carcinogenicity: Based on the available evidence, which included adequate carcinogenicity studies in rats and mice and a battery of negative mutagenicity studies, diflubenzuron *per se* is classified as Group E (evidence of non-carcinogenicity for humans). A metabolite of diflubenzuron, p-chloroaniline (PCA), is classified as Group B2 (probable human carcinogen) based on the results of a National Toxicology Program (NTP) study[1] which administered p-chloroaniline hydrochloride by gavage to rats and mice for 2 years. Please see the Carcinogenicity section above for a thorough discussion of this study. The results of several mutagenicity studies on PCA were also included in the same NTP report. PCA was mutagenic in Salmonella strains TA98 and TA100 with metabolic activation. PCA induced gene mutations in cultured mouse lymphoma cells with and without metabolic activation. In cultured Chinese hamster ovary (CHO) cells, treatment with PCA produced significant increases in sister chromatid exchanges (SCEs) with and without metabolic activation. Chromosomal aberrations were also significantly increased in CHO cells in the presence of metabolic activation.

The Agency has determined that the Q_1^* (estimated unit risk) for PCA, based upon spleen sarcoma rates in male rats, is 6.38 x 10^{-2} (mg/kg/day)$^{-1}$ in human equivalents. Where no PCA and/or CPU are present, the toxicological endpoint for diflubenzuron *per se* should be used for risk assessments.

j. Reference Dose

The RfD is 0.02 mg/kg/day, based on the NOEL of 2.0 mg/kg/day in the 52-week chronic oral study in dogs. The LEL in this study is 10 mg/kg/day, based on methemoglobinemia and sulfhemoglobinemia. When determining the RfD an uncertainty factor of 100 was included to account for the interspecies extrapolation and intraspecies variability. (MRID 00146174)

Likewise, the FAO/WHO joint committee on pesticide residues reviewed diflubenzuron in 1985 and established an Acceptable Daily Intake (ADI) of 0.02

[1] National Toxicology Program (NTP) Report No. 351; July, 1989

mg/kg/day. The ADI was based upon a one-year oral toxicity study in dogs with a NOEL of 2.0 mg/kg/day. A safety factor of 100 was applied to account for the interspecies extrapolation and intraspecies variability.

2. Exposure Assessment

a. Dietary

Tolerances are established for residues of diflubenzuron *per se* in/on various raw agricultural commodities and animal feeds *[40 CFR §180.377 (a) and (b), and 40 CFR §186.2000]*. Tolerances range from 0.05 ppm in/on soybeans to 3.0 ppm in/on rangeland grass. Tolerances of 0.05 ppm have also been established for residues of diflubenzuron in animal commodities. Adequate enforcement methods are available for the determination of these residues.

A National Toxicological Program (NTP) Report concluded that *p*-chloroaniline (PCA), a metabolite of diflubenzuron, may have oncogenic potential. The Agency has calculated a Q_1^* for PCA and has determined that definitive analytical data are needed on the presence of PCA and its potential precursors and metabolites containing the *p*-chlorophenylamine moiety. As indicated above, tolerances should be expressed in terms of the combined residues of diflubenzuron and metabolites convertible to PCA expressed as diflubenzuron.

171-4(a): Plant Metabolism

For purposes of reregistration and risk assessment, the qualitative nature of the residue in plants is adequately understood based on data from citrus, mushroom, and soybean metabolism studies. The residues of concern in plants are diflubenzuron, PCA and CPU.

Responding to reports that PCA may have oncogenic potential, in 1991 the Agency required a new metabolism study on cotton or soybean and required that the study use methodology capable of detecting PCA and CPU residues at the 1 ppb level. The Agency also concluded that the nature of the residue in mushrooms was adequately understood and cited two mushroom metabolism studies. In the first metabolism study, residues of parent, CPU, and 2,6-difluorobenzoic acid (DFBA) were qualitatively identified in mushrooms grown in [^{14}C]diflubenzuron treated compost. In a related residue study conducted at 0.5X and 1X the label rate, parent and CPU residues were found at comparable levels (~0.07 ppm) while DFBA residues (0.6 ppm) were about 10 times higher than the other metabolites. In the other mushroom metabolism study, residues of parent, CPU, DFBA and PCA were detected at up to 0.18, 0.6, 3.96, and 0.02 ppm, respectively, in mushrooms treated at less than 1X.

A separate mushroom metabolism study was submitted for reregistration purposes. Mushrooms were grown in either compost or casing soil which had been treated with diflubenzuron at 1X and 5X the maximum label rate respectively. For mushrooms grown in compost treated with diflubenzuron, the major identified radioactive residue was DFBA, accounting for 33% to 138% of Total Radioactive Residue (TRR) (0.04 to 0.33 ppm). CPU and PCA were identified, ranging from 0.2% to 0.4% TRR (0.005 - 0.001 ppm) and 0.6% to 2.7% TRR (0.001 to 0.004 ppm) respectively. Although bound residues accounted for up to 19% TRR (0.03 ppm), no efforts were made to release the bound residues. For mushrooms grown in casing treated with diflubenzuron, the major identified radioactive residue was DFBA, accounting for 82% to 224% TRR with ppm levels ranging from 5.3 to 8.8 ppm. CPU and PCA were identified, ranging from 0.3 to 2.3% TRR (0.02 - 0.08 ppm) and 0.04% to 4.7% TRR (0.002 to 0.16 ppm) respectively. No efforts were made to release the bound residues that were present at up to 0.42 ppm.

In a soybean metabolism study, greenhouse grown plants were treated by syringe with double-ring labeled [^{14}C]diflubenzuron at 0.25 lb ai/A (1X) at bloom and again 3 weeks later. Levels of radioactive residues in treated leaves and immature pods were not presented; however, more than 90% of the TRR remained as unchanged parent in leaves collected the day of the first application, leaves and pods collected the day of the second application, and leaves collected at harvest. No DFBA, CPU, or PCA was detected (LOD 0.05 - 0.16 ppm) in/on leaves and immature pods. Radioactive residue were 7.55-17.22 ppm in hulls and from less than 0.01 to 0.038 ppm in seeds collected at maturity, 6 weeks after the last application. In hulls, 81.4-97.9% of the TRR (6.57-17.5 ppm) was identified as unchanged parent; the metabolites CPU, DFBA, and PCA were non-detectable (less than 0.3 ppm). Radioactive residues in seeds were not characterized. These data indicate that diflubenzuron is not metabolized to any significant extent in soybeans and that diflubenzuron is not translocated (i.e., is non-systemic) in soybean plants.

In a citrus metabolism study, orange fruit and adjacent leaves were treated twice at a 14-day interval with [^{14}C]diflubenzuron at a rate equivalent to 0.31 lb ai/A (1x). Radioactive residues in fruit harvested 21 days after the second application consisted almost entirely of unchanged diflubenzuron (0.63 ppm); no detectable levels (less than 1 ppb) of PCA, CPU and DFBA were reported. (MRID 00156581)

171-4(b): Animal Metabolism

The nature of the residue in animals is adequately understood based on poultry and ruminant metabolism studies reflecting oral dosing. Terminal residues identified in animal tissues, milk, and eggs include diflubenzuron, 2-hydroxydiflubenzuron (2HDFB), 2,6-difluorobenzamide (DFBAM), DFBA, CPU, and PCA.

One ruminant metabolism study dosed dairy cows orally via capsule for up to 28 days with double ring-labeled [^{14}C]diflubenzuron at rates equivalent to 0.05, 0.5, and 5 ppm in the diet. At the 0.05 and 0.5 ppm dose levels, radioactive residues expressed in diflubenzuron equivalents were non-detectable in milk. At the 5 ppm dose level, radioactive residues in milk plateaued after 4 days between 0.0063 and 0.0134 ppm. After 28 days of dosing, radioactive residues in muscle, fat, and kidney were non- detectable at the 0.05 ppm, 0.5 ppm and 5 ppm dose levels. Radioactive residues in liver were 0.0071 ppm at the 0.05 ppm level, 0.0708 ppm at the 0.5 ppm level, and 0.54 ppm at the 5 ppm level.

The same study dosed an additional cow with [^{14}C]diflubenzuron at 250 ppm for 8 consecutive days before sacrifice. No detectable residues were found in muscle or fat, but residues were 1.038 ppm in kidney and 6.04 ppm in liver. Extraction and TLC analysis of liver residues isolated diflubenzuron (3.0% TRR), PCA (1.2% TRR), CPU (0.15% TRR), and DFBA (10.9% TRR). Although milk from the same animal was not completely characterized, it was determined that the parent compound was not present in the milk.

A subsequent ruminant metabolism study dosed four lactating goats orally via capsule for 3 consecutive days with double ring-labeled [^{14}C]diflubenzuron. Two goats were dosed at a rate of approximately 10 ppm in the diet and two at a rate of approximately 250 ppm. Based upon current tolerances, the theoretical maximum dietary burden of diflubenzuron is 11.29 ppm for dairy cattle treated with the controlled-release bolus (see section on Livestock Dietary Burden Calculations). Accordingly, the 10 and 250 ppm dose levels reflect 0.9X and 22X feeding levels, respectively.

Radioactive residues in the feces and urine accounted for approximately 88% of the administered dose for both low- and high-dose goats. After 3 days of dosing, TRRs in the low-dose (~10 ppm) goats were 0.007-0.009 ppm in milk, 0.217-0.262 ppm in liver, 0.016-0.019 ppm in kidney, at most 0.001 ppm in muscle, and at most 0.004 ppm in fat. TRRs in the high-dose (250 ppm) goats were 0.22 ppm in milk, 3.24-6.06 ppm in liver, 0.36-1.02 ppm in kidney, 0.02-0.05 ppm in muscle, and 0.12-0.30 ppm in fat. Radioactive residues were characterized in milk and liver. Extraction of milk released 85% of the TRR. The principle residues identified consisted of CPU (29-55% TRR) and 2,6-difluorobenzamide (DFBAM, 6-8% TRR). PCA was non-detectable (less than 0.001 ppm) in milk from both low- and high-dose goats. Extraction of liver detected 90% of the TRR. The principle residues identified consisted of diflubenzuron (7% TRR), 2-hydroxydiflubenzuron (7% TRR), CPU (16% TRR), and DFBAM (1% TRR). PCA was non-detectable in liver from the low dose goats, but accounted for approximately 0.4% of the TRR (0.011-0.028 ppm) in the liver of the high-dose goats.

In a poultry metabolism study, laying hens were dosed orally via capsule for 1-28 consecutive days with double ring-labeled [^{14}C]diflubenzuron at rates equivalent to 0.05, 0.5, and 5 ppm in the diet. Soybean seeds (0.05 ppm) and hulls (0.5 ppm) are the only poultry feed tolerances for diflubenzuron. Therefore, the maximum theoretical dietary exposure of poultry to diflubenzuron is 0.121 ppm with dose rates in the metabolism study equivalent to 0.41X, 4.1X and 41X the maximum theoretical dietary exposure.

Radioactive residues in eggs and tissues of hens plateaued by the tenth day of dosing. Total radioactive residues(TRR) of [^{14}C]diflubenzuron in hens from the 5 ppm dosing level were as follows: 0.078-1.16 ppm in fat; 0.059-0.453 ppm in liver; 0.068-0.338 ppm in kidney; less than 0.005 ppm in muscle; and from less than 0.032 to 0.833 ppm in eggs. After 7 days of dosing, tissue and egg samples from the 5 ppm dosing level were used for characterization of ^{14}C-residues. Diflubenzuron accounted for 100% of the TRR in fat, 63.4-66.3% of the TRR in muscle, 18.6% of the TRR in liver, 23.8% of the TRR in kidney, and 68.8% of the TRR in eggs. The metabolite CPU accounted for 13-22.1% of the TRR in muscle, 49.8% of the TRR in liver, 40% of the TRR in kidney, and 11.2% of the TRR in eggs. Minor amounts of DFBA were also isolated from muscle (7-9% TRR), liver (7.4% TRR), and eggs (3.7% TRR), small amounts of PCA were tentatively identified in some samples.

171-4(c) and (d): Residue Analytical Methods - Plants and Animals

Adequate analytical methodology is available for enforcing tolerances of diflubenzuron in/on plant and animal commodities. Three enforcement methods for diflubenzuron are published in PAM, Vol. II as Methods I, II, and III. Method I is a GC/ECD method that determines diflubenzuron in plants, as derivatized PCA. Method II is a GC/ECD method that can separately determine residues of diflubenzuron, 4-CPU, and PCA in eggs, milk, and animal tissues, each as derivatized PCA. A HPLC/UV method (Method III) is also available that determines diflubenzuron *per se* in eggs, milk, and animal tissues. Although all three methods have undergone successful Agency validations and are acceptable for enforcement purposes; Methods I and II are the preferred enforcement methods as these methods are easier to perform, have fewer interferences, and are more sensitive.

For residue data collection, adequate GC and HPLC methods are available for the analysis of diflubenzuron. Residue data submitted for tolerance reassessment were predominately collected using Methods I and III, or minor variations of these two methods.

Due to Agency concerns about residues of PCA in plant and animal commodities, the registrant is required to develop data collection methods capable of determining PCA residues down to 1 ppb levels.

The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix II) contains no information on diflubenzuron recovery using multiresidue methods PAM, Vol. I Sections 302, 303, and 304. The registrant has submitted Multiresidue testing data that the Agency has forwarded to the FDA.

171-4(e): Storage Stability

The reregistration requirements for storage stability data are not fully satisfied. Additional confirmatory storage stability data are required for grass forage, cottonseed, mushrooms, soybeans and walnuts. Additional confirmatory information regarding the stability of PCA and CPU in milk and liver are also required.

Acceptable storage stability studies have been conducted using fortified control samples of cottonseed, oranges, mushrooms, milk, eggs, and beef and poultry tissues. These data indicate that residues of diflubenzuron *per se* are stable in frozen cottonseed for up to 3 months, in frozen oranges for up to 16 months, and in mushrooms, beef tissue, milk, poultry muscle, and eggs stored at temperatures of at least -20 °C for up 12 months.

Data from fortified mushrooms are available. These data indicate that CPU is stable for up to 6 months in frozen mushrooms, however, no storage stability data are available for residues of PCA. If samples from the requested magnitude of the residue study on mushrooms are analyzed within 30 days of sampling, then no additional data will be required. Otherwise additional storage stability data for diflubenzuron metabolites in mushrooms are required.

Data are also available that appear to demonstrate the stability of residues of PCA and CPU in milk and liver stored frozen for 22 months at -10 °C; however, the actual dates of sample fortification, extraction and analysis are required before the Agency can evaluate these data. (MRIDs 41702102, 42060901 and 42494201-42494203)

The registrant has submitted information on storage intervals and conditions for residue samples used to support tolerances. Based upon these storage intervals and the available storage stability data, additional data are required depicting the stability of residues of diflubenzuron *per se* in frozen samples of cottonseed and grasses stored up to 6 months, walnuts stored up to 21 months, and soybean seeds stored up to 10 months. Storage stability data for soybean seeds, cottonseed, and walnuts may be generated using only one of these commodities.

171-4(k): Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: cottonseed, soybean seeds, pasture and

rangeland grass forage, orange, grapefruit, tangerine and walnuts. Adequate field trial data depicting residues of diflubenzuron following applications made according to the maximum or proposed use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Additional data are required on pasture grass hay, mushrooms, and cotton gin by-products.

Mushrooms: The available mushroom data are inadequate to support the 0.2 ppm tolerance on mushrooms; additional residue data are required. For purposes of risk assessment, results from the mushroom metabolism study will be used to estimate diflubenzuron, CPU and PCA levels in mushrooms.

Data are available from tests conducted in California and Pennsylvania in which diflubenzuron (WP) was incorporated into the mushroom composts at the time of spawning at 1 lb ai/2500 ft^2 (0.4X) and at the time of casing at 0.2 lb ai/2500 ft^2 (0.4X). Mature mushrooms were harvested at each of up to five breaks and were analyzed separately for residues of diflubenzuron *per se*, CPU, and DFBA. Residues of diflubenzuron *per se* were non-detectable, ranging from less than 0.01 to 0.049 ppm; residues of CPU ranged from less than 0.01 to 0.015 ppm; and residues of DFBA ranged from 0.01 to 0.353 ppm. Maximum total residues of diflubenzuron and CPU were 0.064 ppm. These data are inadequate as the compost was not treated at the maximum label rate and no data were provided on residues of PCA in the mushrooms.

Data are required depicting the residues of diflubenzuron, CPU and PCA in/on first, second, third, fourth, and fifth flush mushrooms treated at the maximum label rate (1 lb ai/1000 ft^2 at spawning and again at casing at 0.21 lb ai/1000 sq ft). The analytical method for PCA must be sensitive to the 1 ppb level. A minimum of three field trials are required with two independently composited samples being taken at each harvest for each test. Two field trials should take place in PA (60% of U.S. mushroom production) and one in CA (20% of U.S. mushroom production). All samples should be analyzed within 6 months of harvest and should be stored frozen (-20 C) until analysis. If samples are not analyzed within 30 days of harvest, storage stability data for PCA, preferably concurrent, should be generated reflecting the longest storage intervals.

171-4(l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for cottonseed, and soybeans. Acceptable processing studies are also available for citrus commodities. A summary of the available processing data is presented below.

Citrus: Processing studies indicate that residues of diflubenzuron *per se* concentrate by 0.2-1.9X in dehydrated citrus pulp and by 71-147X in citrus oil. Diflubenzuron

residues did not concentrate in citrus juice, wet pulp, or molasses. In addition, in the most recent orange metabolism study, residues of diflubenzuron *per se* concentrated by a factor of 68X in citrus oil processed from whole oranges bearing 0.63 ppm residues of [^{14}C]diflubenzuron. In this same study, the metabolites CPU, DFBA and PCA were non-detectable in both whole fruit (1 ppb) and oil (less than 2 ppb). Based on Agency policies, no additional tolerances are required for dried citrus pulp. (MRIDs 00153407, 00156581, 41079301 and 41079302)

Data are also available from a study in which orange juice was fortified with 0.52 ppm of diflubenzuron and pasteurized at 100 C for 15 minutes. Residues of PCA were non-detectable (less than 1 ppb) in the pasteurized juice.

Cottonseed: Residues of diflubenzuron do not concentrate in any cottonseed processed commodities. Therefore, no additional tolerances are required for the processed commodities of cottonseed.

Soybeans: Residues of diflubenzuron in commodities processed from soybean seeds fortified with diflubenzuron at 0.112 ppm were 0.92 ppm in hulls, less than 0.05 to 0.08 ppm in meal and crude and refined oils, and 0.19 ppm in soapstock. Concentration of residues occurred only in hulls (8.2X) and soapstock (1.7X). The available data adequately support the established tolerances soybean hulls (0.5 ppm) and soapstock (0.1 ppm).

As the commodity soybean soapstock has been deleted from Subdivision 0, Table II (June, 1994), the feed additive tolerance for soybean soapstock is no longer appropriate and should be revoked.

171-4(j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Tolerances of 0.05 ppm have been established for residues of diflubenzuron *per se* in eggs, milk, animal fat, meat, and meat by-products.

Livestock Dietary Burden Calculations: Based upon currently established tolerances, the maximum theoretical dietary burden of diflubenzuron residues is 11.29 ppm for beef cattle, 6.89 ppm for dairy cattle, 0.070 ppm for swine, and 0.121 ppm for poultry. Data used to calculate maximum dietary burdens of diflubenzuron for livestock are presented on the following page.

Potential Dietary Contributions of Diflubenzuron										
Feed Item	Toler-ance (ppm)	% Dry Matter	Percent in Feed				Maximum Dietary Intake (ppm)***			
			Beef Cattle	Dairy Cattle	Swine	Poultry	Beef Cattle	Dairy Cattle	Swine	Poultry
Grass forage (rangeland)	3.0	25	60	--*	NA	NA	7.20	--*	--	--
Grass forage (pasture)	1.0	25	60	70	NA	NA	2.40	2.80	--	--
Cottonseed	0.2	88	25	25	NA	NA	0.057	0.057	--	--
Soybean seed	0.05	89	15	20	25	20	0.008	0.011	0.014	0.011
Soybean hulls	0.5	90	20	20	10	20	0.111	0.111	0.056	0.111
Citrus pulp, dehydrated	0.5	91	33	33	10	NA	0.182	0.182	0.055	--
Bolus, controlled release**	--	--	--	--		--	4.00	4.00	--	--

* Lactating dairy cattle are not fed on rangeland

** The controlled released bolus has been calculated to contribute 4.0 ppm to the dietary burden for cattle

*** Maximum dietary burden for cattle calculations assume: i) cattle were treated with the controlled release bolus; ii) beef cattle diet was 60% grass forage (rangeland), 20% soybeans, 10% soybean hulls, and 10% cottonseed; and iii) dairy cattle diet was 70% grass forage (pasture), 10% soybeans, 10% soybean hulls, and 10% cottonseed.

For purposes of reregistration, acceptable data are available for residues of diflubenzuron in milk, meat, and fat of ruminants. In one cattle study, three groups of four lactating cows each were given daily oral doses of [^{14}C]diflubenzuron at levels of 0.05, 0.5, or 5.0 ppm in the diet for 28 days; and one additional cow was dosed for 8 days with [^{14}C]diflubenzuron at 250 ppm. All milk samples from the 0.05 and 0.5 ppm feeding levels contained no detectable (less than 0.001 ppm) radioactivity. Total radioactivity in milk at the 5 ppm level plateaued at 0.013 ppm within a few days and declined to non-detectable after a 4-day withdrawal period. The only radioactivity detected in tissues was in liver (0.54 ppm) at the 5 ppm level. Following 8 consecutive days of feeding at 250 ppm, radioactivity was 0.17-0.22 in milk, 1.038 ppm in kidney, and 6.04 ppm in liver; radioactivity was non-detectable (less than 0.337 ppm) in fat and muscle.

In another cattle study, lactating cows were dosed orally twice a day with diflubenzuron at either 25 or 250 ppm in the diet for up to 28 consecutive days. Residues of diflubenzuron were non-detectable (less than 0.05 ppm) in milk from both feeding levels sampled following 1 to 28 days of dosing. Residues of diflubenzuron were also non-detectable (less than 0.05 ppm) in the fat, muscle, liver, and kidneys of cows sacrificed after 8, 18, and 28 days of dosing at 25 ppm. For cows sacrificed after dosing at 250 ppm for 8, 18 and 28 days, residues of diflubenzuron were non-

detectable (less than 0.05 ppm) in the muscle and kidney, 0.06-0.08 ppm in fat, and 0.09-0.1 in liver.

Three additional ruminant feeding studies were also submitted for a cattle feed-through use for diflubenzuron. In two of these studies, six beef cattle and nine lactating dairy cows were dosed through their feed for 28 consecutive days with diflubenzuron at a rate of 0.2 mg ai/kg body weight, which was equivalent to approximately 13 ppm in the diet. Milk samples were collected after 0, 3, 7, 14, 21 and 28 days of dosing. The animals were sacrificed for tissue collection within 8 hours of consuming the final dose. Diflubenzuron residues were non-detectable (less than 0.01 ppm) in all milk and non-detectable (less than 0.05 ppm) in all tissue samples, except for one liver sample that contained 0.06 ppm of diflubenzuron. (MRIDs 00138248, 00155419, 00155420, 00155425 and 00155426)

In the third study, four dairy bull calves were fed diflubenzuron at a rate of 2.8 mg ai/kg body weight per day for 4-5 months and two were sacrificed. Then three others were fed at 1 mg ai/kg body weight per day for another year and sacrificed. The 2.8 and 1.0 mg/kg doses were equivalent to approximately 180 and 65 ppm, respectively. Following dosing at 2.8 mg/kg, residues of diflubenzuron were 0.02 ppm in liver and kidney, 0.04-0.08 ppm in fat, and less than 0.02 ppm in muscle. Diflubenzuron residues of were non-detectable (less than 0.02 ppm) in tissues from animals dosed at 1 mg/kg.

Residue data are also available to support the use of the 9.7% diflubenzuron bolus in beef and dairy cattle. In this study, dairy and beef cattle were each treated once with two 50 gram boluses of 10% diflubenzuron (2X the label rate). This dose was calculated to be equivalent to approximately 8 ppm in the diet. Diflubenzuron residues were non-detectable (less than 0.04 ppm) in milk collected 20, 30 and 60 days after treatment. In tissue samples collected 32, 62 and 99 days after treatment, diflubenzuron residues were non-detectable (less than 0.04 ppm) in muscle and kidney, from less than 0.04 to 0.06 ppm in fat, and from less than 0.04 to 0.07 ppm in liver.

Data are also available for residues of diflubenzuron in eggs, meat, meat byproducts, and fat of poultry. In one study, laying hens were orally dosed via capsule for 1-28 consecutive days at 0.05, 0.5, or 5 ppm of [^{14}C]diflubenzuron in the diet. Hens were sacrificed at 3- to 7-day intervals throughout the study. Total radioactive residues, expressed as diflubenzuron, ranged from non-detectable (less than 0.0006 ppm) to 0.0067 ppm in fat, kidney, liver, muscle, and eggs of hens dosed at 0.05 ppm, and were non-detectable (less than 0.005 ppm) to 0.044 ppm in fat, kidney, liver, muscle, and eggs of hens dosed at 0.5 ppm. Total radioactive residues in hens at the 5 ppm dosing level were 0.078-1.16 ppm in fat, 0.059-0.453 ppm in liver, 0.068-0.338 ppm in kidney, less than 0.005 in muscle and from less than 0.032 to 0.833 ppm in eggs. Residues of diflubenzuron *per se* were 0.21 ppm in fat for hens dosed at 5 ppm

(41X) for 7 days. After 24 days of dosing at 5 ppm, residues of diflubenzuron *per se* were 0.05 ppm in muscle and kidney, 0.16 ppm in liver, and 0.14 ppm in eggs.

Another study fed Black Barred Rock-Rhode Island Red (BBR/RIR) and White Leghorn (WL) hens feed containing diflubenzuron at 10 ppm (83X) for 15 weeks. Residues of diflubenzuron plateaued in eggs after approximately 2 weeks and remained constant at approximately 0.3-0.6 ppm for the remainder of the dosing period. Hens were sacrificed after a 3-day withdrawal period. For BBR/RIR hens, average residues of diflubenzuron were 1.17 ppm in fat, 0.12 ppm in liver, and non-detectable (less than 0.01 ppm) in muscle at the end of the dosing period. For WL hens, average residues of diflubenzuron were 1.85 ppm in fat, 0.45 ppm in liver, and non-detectable (less than 0.01 ppm) in muscle at the end of the dosing period.

Male Hubbard chickens in another study were dosed for 98 days with feed containing diflubenzuron at 2.5 and 250 ppm, five hens at each level. At the 2.5 ppm feeding level (21X), diflubenzuron residues were 2.2-6.9 ppm in fat, 0.09-0.45 ppm in muscle and skin, and 0.06-0.72 ppm in liver. At the 250 ppm feeding level, diflubenzuron residues were 23-62 ppm in fat, 0.9-3.3 ppm in muscle and skin, and 0.8-3.8 ppm in liver.

An additional study dosed New Hampshire and WL hens for six successive 3-week periods (18 weeks total) with feed containing diflubenzuron. For the first 3-week interval diflubenzuron in the feed was at 50 ppm; diflubenzuron in the feed was then halved at each successive 3-week interval (25, 12.5, 6.2, 3.1 and 1.6 ppm). Samples of eggs were collected at the end of each 3-week interval. Diflubenzuron residues in eggs were 0.03-0.05 ppm from the 1.6 ppm dosing level, 0.1-0.25 ppm from the 3.1 ppm dosing level, 0.23-0.55 ppm from the 6.2 ppm dosing level, 0.3-1.0 ppm from the 12.5 ppm dosing level, 0.9-2.1 ppm from the 25 ppm dosing level, and 1.2-2.9 ppm from the 50 ppm dosing level. Residues were always higher in WL eggs.

Several other poultry feeding studies have been submitted in conjunction with petitions for a feed-through use of diflubenzuron on poultry. In one study, ten Warren and WL hens were dosed with feed containing diflubenzuron at 7.2-8.7 ppm for 28 consecutive days. Eggs were sampled at the end of the second, third, and forth weeks and separated into yolks and whites; hens were sacrificed at the end of the dosing period. For the Warren hens, residues of diflubenzuron were 1.31-1.78 ppm in fat, 0.11-0.19 ppm in liver, 0.05-0.08 in muscle, 1.04-1.24 in egg yolks, and less than 0.04 ppm in egg whites. For the WL hens, residues of diflubenzuron were 1.96-3.13 ppm in fat, 0.48-0.61 ppm in liver, 0.13-0.19 in muscle, 1.74-2.42 in egg yolks, and less than 0.04 ppm in egg whites. (MRIDs 00144931, 00152501, 00156015, 00156779-00156783)

In another study, hens were fed diets containing diflubenzuron at 7.5 ppm for 80 days. Residues in eggs plateaued by the tenth day and remained constant at 0.33-0.46 ppm throughout the remainder of the dosing period.

165-1: Confined Rotational Crops

The nature of the residue in rotational crops is adequately understood for purposes of reregistration. Although the Agency concluded that the available confined rotational crop study was inadequate to fully satisfy guideline 165-1 reregistration requirements, another confined rotational crop study will not be required because the data were sufficient to allow the Agency to make regulatory conclusions regarding the need for limited rotational crop studies (guideline 165-2) and to comment on the appropriateness of the currently established plantback interval on diflubenzuron end-use product labels.

In the confined rotational crop study, [^{14}C]diflubenzuron was applied to a sandy loam soil at a rate equivalent to 1 lb ai/A (2.7X). The soil was aged in a greenhouse for approximately 1, 4, and 12 months prior to planting radish, spinach, and wheat as representative rotational crops. The total radioactive residues in the rotational crops were highest in commodities from the 1-month plant-back interval (PBI) and declined steadily at each increasing PBI interval. Radioactive residues in raw agricultural commodities (RACs) from the 1-month PBI were highest in radish tops (0.636 ppm) and lowest in spinach and wheat grain (about 0.06 ppm). In RACs from the 12-month PBI, ^{14}C-residues were less than 0.02 ppm in spinach, radish roots and tops, and wheat forage, and ranged from less than 0.039 to less than 0.104 ppm in wheat straw, grain, and hulls. The principle ^{14}C-residues identified in spinach were diflubenzuron and CPU, which together accounted for 31.2% of the TRR (0.019 ppm) in spinach from the 1-month PBI and 35.3% of the TRR (0.012 ppm) in spinach from the 4-month PBI. Minor amounts (about 3% TRR) of DFBA were also detected in spinach. In radish, the principle ^{14}C-residue isolated was CPU, accounting for 54.1% and 35.5% of the TRR in tops from the 1- and 4-month PBIs, respectively, and 21.9 and 8.6% of the TRR in roots from the 1- and 4-month PBIs, respectively. Minor amounts of diflubenzuron (less than 2% TRR) and DFBA (4-6% TRR) were also isolated. In wheat forage from the 1- and 4-month PBIs, only minor amounts (less than 5% TRR and less than 0.01 ppm) of diflubenzuron, DFBA, and CPU were detected although 50-62% of the TRR was solvent extractable. In addition, approximately 64% of the TRR remained unextracted from wheat straw from the 1- and 4-month PBIs. Of the ^{14}C-residues extracted from wheat straw (36% TRR), the major metabolites identified were DFBA (11-17% TRR) and CPU (7-17% TRR). ^{14}C-Residues in wheat grain and hulls were not characterized.

165-2: Field Rotational Crops

Residue data on field-grown rotational crops are not available. Although the

confined study was deemed inadequate, the available data indicate that diflubenzuron and CPU may exceed 0.01 ppm in rotational crops planted up to 4 months after a 1X application of diflubenzuron to the primary crop and in cereal grains planted up to 12 months after a 1x application. Since the registrant has indicated that they wish to maintain the 6-month PBI currently specified on their product labels, limited rotational field studies are required at two sites using a representative leafy vegetable, root and tuber vegetable, and a cereal grain. The six trials should be conducted on a specific crop in each of the three crop groups which the registrant intends to have as a rotational crop on the label. The soil and/or primary crop should be treated at the maximum label rate and the appropriate crops should be planted after the minimum aging interval. For the rotational crops, all of the plant parts prescribed in Subdivision 0, Table II (June, 1994) should be harvested and analyzed for the residues of concern (diflubenzuron, CPU, and PCA). These data are expected to confirm the conclusions reached in this risk assessment.

b. Occupational and Residential

Handler Exposures & Assumptions

EPA has determined that there is an exposure potential for mixers, loaders, applicators or other handlers using diflubenzuron. These handlers may be exposed to diflubenzuron when:

- Mixing/Loading prior to wide-area outdoor (forests, shelterbelts, aquatic systems), orchard crops (citrus, walnuts), field crops (soybeans, cotton, mushroom compost and casing soil treatments), greenhouse and field grown ornamentals (chrysanthemums) applications;
- Using aerial, ground-boom, airblast and hand-held equipment;
- Working as flaggers to support aerial applications; and
- Dispensing the oral bolus doses administered to livestock.

Mixer/loader/applicator (M/L/A) exposure data for diflubenzuron were not required previously, as no toxicological criteria had been triggered. Data for most of the M/L/A scenarios are provided in the Pesticide Handlers Exposure Database (PHED).

The daily exposure for handlers (mg ai/kg bw/day) is calculated using the following formula:

$$\text{Daily Exposure} = \frac{\text{unit exposure (mg ai/lb ai handled)} \times \text{lb ai/A} \times \text{daily acres treated}}{\text{body weight (70 kg)}}$$

Post-Application Exposures & Assumptions

EPA has determined that there is an exposure potential for persons entering treated sites. Potential exposures are to:

- Harvesters entering treated citrus orchards;
- Scouts and other crop advisors entering treated soybean and cotton fields;
- Harvesters and persons disbudding treated chrysanthemums;
- Mushroom house workers handling treated compost and casing soil;
- Mushroom harvesters;
- Swimmers in treated waters;
- People in residential locations being treated for ornamental infestations or by wide-area gypsy moth programs

There are no data available to address post-application exposure for persons reentering areas treated with diflubenzuron. Since most post-application exposures are intermediate-term exposures (greater than 1 week), these exposures are of concern. Due to the low dermal absorption of diflubenzuron, EPA will retain the 12-hour REI until confirmatory data are submitted and evaluated.

Although there are no data available to estimate swimmer exposure; it appears that sites treated with diflubenzuron would not be used for swimming. Based on the toxicologic concerns for diflubenzuron, a swimmer restriction is required for any current labels having use directions for treating aquatic sites.

There are no data available to evaluate bystander exposures for people in residential locations or forests treated with diflubenzuron; however, based on very low residues detected in forestry dissipation studies, substantial exposure, outside of contact with direct sprays is unlikely. In addition, since the dermal absorption rate is low, and exposure is expected to be of a short-term duration, bystander exposure data are not required at this time.

3. Risk Assessment

a. Dietary Risks

As stated earlier, a risk assessment for acute dietary exposure (1 day) is not necessary. The Agency did conduct a chronic dietary analysis using DRES to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. This analysis used tolerance level residues listed in Section IV. The group of non-nursing infants is the most highly exposed subgroup based on percentage of RfD, as shown below. Refinements in residue and percent crop treated information were considered in calculating the Anticipated

Residue Contribution (ARC) for those same population subgroups. Using the ARC, which is considered the more accurate estimate of dietary exposure, children from 1 to 6 years old were the most highly exposed subgroup. These exposure estimates were then compared to the RfD for diflubenzuron, 0.02 mg/kg/day, to calculate estimates of dietary risk.

Using Tolerances:

The Theoretical Maximum Residue Contributions for the overall U.S. population and the most affected subgroups from supported published tolerances are:

Overall U.S. population:	0.00190 mg/kg/day	10% RfD
Non-nursing infants:	0.00605	31%
Children, 1-6 years:	0.00517	26%

Using Anticipated Residues:

Using the ARCs for the overall U.S. population and subgroups from published supported tolerances, the chronic dietary risks to the most affected populations are:

Overall U.S. population:	0.000080 mg/kg/day	< 1% RfD
Non-nursing infants:	0.000163	< 1%
Children, 1-6 years:	0.000211	1%

Cancer risk from PCA and related metabolites:

Estimations of the carcinogenic risk to humans resulting from lifetime dietary exposure were performed for food commodities containing PCA and/or CPU. For the purpose of calculating dietary risk assessments, the Agency has developed the following procedure:

1) CPU (a diflubenzuron metabolite that is structurally related to PCA and for which no adequate carcinogenicity data are available) is considered as having the same carcinogenic potential (Q_1^*) as PCA;

2) The sum of PCA and CPU residues in ingested food are used to estimate the dietary exposure of humans to the carcinogenic metabolites of diflubenzuron; and

3) In addition to ingested residues of these two metabolites, amounts of PCA and/or CPU formed in vivo following ingestion of diflubenzuron are included when estimating the total exposure of humans to the carcinogenic metabolites of diflubenzuron. The in vivo conversion of ingested diflubenzuron to PCA

and/or CPU was estimated to be 2.0%, based on data in the rat metabolism study. (MRIDs 41720901 and 41919001)

The Agency used results from mushroom metabolism studies to determine the percent of total radioactive residue (TRR) present as PCA or CPU in mushrooms. Then, using tolerance levels for diflubenzuron in animal commodities, and adjusting for percent crop treated of feed items, total levels of PCA and related compounds were estimated for mushrooms (using 0.69 ppm / 100% crops treated) as 0.000015 mg/kg/day (9.4×10^{-7} Carcinogenic Risk) and for milk/liver (using anticipated residue / percent crops treated) of 0.000004 mg/kg/day (2.7×10^{-7} Carcinogenic Risk) based on the overall U.S. population.

Based on the results of a rat metabolism study, an assumption of a 2.0% conversion of diflubenzuron to PCA in humans is assumed for the PCA risk assessment. The upper bound of the total cancer risk estimate from PCA and related metabolites in the overall U.S. population is 1×10^{-6}. The U.S. population and all of the population subgroups have ARCs for chronic dietary risk from diflubenzuron well below the RfD when all tolerances or anticipated residues are considered. If additional uses are added to diflubenzuron for commodities not covered by this assessment, the total cancer risk estimate for diflubenzuron will increase.

b. Occupational Risks

The Agency has determined that the risks to humans resulting from dermal and/or inhalation exposures to PCA and/or CPU occurring during occupational or residential exposures to diflubenzuron are likely to be negligible, since exposure to these metabolites is not anticipated. Only in the event that direct exposure to one or more of these metabolites of diflubenzuron is demonstrated would it be necessary to perform such risk assessments.

Risk to Handlers

To quantify the risk to handlers from mixing/loading/applying diflubenzuron, the Agency has developed Margins of Exposure (MOEs) for each use pattern. Margins of Exposure provide a quantification of the likelihood of the expected exposure to reach the toxicological endpoint. The Agency considers MOEs to be acceptable if they are greater than 100. MOEs are calculated using the following formulae:

Short Term Exposure MOE =

$$\frac{\text{NOEL}}{\text{Dose}} = \frac{40 \text{ mg/kg/day}}{\text{Daily Exposure}}$$

Intermediate Term Exposure MOE =

$$\frac{\text{NOEL}}{\text{Dose}} = \frac{2\ \text{mg/kg/day}}{\text{Daily Exposure}}$$

Handler Risks from Agricultural/Horticultural Uses

Since there are no data to evaluate the handler exposure from the ULV formulation, mushroom applications and administering the oral bolus dose, the Agency has made several assumptions. For the mushroom use, the Agency assumed that the exposure to applicators will not exceed that to mixers/loaders. Assuming that a mushroom applicator would treat 5000 square feet per treatment, MOEs are greater than 100 for both short-term and intermediate-term exposure. For the oral bolus treatment, the Agency assumed that the use of balling guns to administer the pesticide would limit applicator exposure. The assessment also assumes that exposure from the ULV applications would not be greater than that of the airblast applications.

For the agricultural/horticultural applications, it is assumed that intermediate-term exposure applies to aerial applicators and those mixer/loaders supporting those aerial applications. Intermediate-term exposure is also expected to be of concern for commercial applicators treating cotton and soybeans with ground equipment. MOEs for short-term exposure are greater than 100 for handlers wearing long-sleeved shirts, long pants, and chemical resistant gloves. Some intermediate-term MOEs for mixer/loaders supporting aerial applications are below 100, however, these levels are increased to greater than 100 by the use of a dust/mist respirator (TC-21C).

Handler Risk from Forestry and Ornamental Applications

The treatment of trees and shrubs for insect pests (gypsy moth, Nantucket pine tip moth) includes the treatment of:

- Residential, municipal and shade tree areas;
- Recreational areas such as campgrounds, golf courses, parks, parkways;
- Ornamental, shade-tree, and forest nurseries;
- Forests;
- Shelterbelts; and
- Rights-of-way and other easements.

These treatments are made by using aircraft, airblast equipment, and hydraulic ground equipment (hand-gun). Exposure estimates for these handlers are provided in the table entitled "Forestry and Ornamental Uses, Summary Exposure/Risk Values for Handlers Using Diflubenzuron While Wearing Long-Sleeved Shirt, Long Pants, and Chemical Resistant Gloves."

Margins of Exposure (MOE) are acceptable to handlers with short-term exposure while wearing long-sleeved shirts, long pants, and chemical resistant gloves. However, some intermediate-term exposure MOEs are low for mixer/loaders handling wettable powders supporting aerial applications. These MOEs are greater than 100 when a dust/mist respirator (TC-21C) is used.

Handler Risk from Aquatic Uses

For aquatic treatments, granular formulations of diflubenzuron are applied using aerial and ground equipment. The wettable powder formulations are mixed with oil and sand to carry the pesticide through vegetation into the water. Exposure estimates for these handlers are provided in the following table entitled "Aquatic Uses, Summary Exposure/Risk Values for Handlers Using Diflubenzuron While Wearing Long-Sleeved Shirt, Long Pants, and Chemical Resistant Gloves."

Margins of Exposure (MOE) are acceptable for handlers during short- and intermediate-term exposures while wearing long-sleeved shirts, long pants, and chemical resistant gloves.

There is also a California Special Local Need (FIFRA 24(c)) registration for the treatment of anchor worms in ponds containing ornamental, bait, or aquarium feeder fish. Because each treatment lasts for 30 to 60 days and because of the limited scope of the operations, exposures and risks should be far less than those of the commercial applications discussed above.

Agricultural/Horticultural Uses

Summary Exposure/Risk Values for Handlers Using Diflubenzuron While Wearing Long-Sleeved Shirt, Long Pants, chemical resistant gloves

Exposure Scenario	Dermal Exposure (µg/lb ai)	Inhalation Exposure (μg/lb ai)	Application Rate (lb ai/cycle)	Daily Acres	Dermal Daily Dose (µg/kg/day)	Daily Inhalation Exposure (µg/kg/day)	Dermal/Inhalation Exposure (µg/kg/day)	Handler MOEs	
								Short-Term	Mid-Term MOE
Mixer/Loader Exposure with chemical gloves (such as waterproof gloves)									
Wettable powders-open bag [OB] (fixed aerial/field crops)	160	43.3	0.062 - 0.125	350	0.25 - 0.5	13 - 27 2.6 - 5.4 (dust/mist)	13.25 - 27.5 2.85 - 5.9 (dust/mist)	> 1000	73 - 150 339 -701 (dust/mist)
Wettable powders- OB (rotary aerial/field crops)	160	43.3	0.062 - 0.125	200	0.14 - 0.28	7.6 - 15	7.74 - 15.28	> 1000	131 - 258
Wettable powders- OB (airblast/non-bearing citrus)	160	43.3	0.31 - 0.62	5	0.02 - 0.04	0.96 - 1.9	0.98 - 1.94	> 1000	> 1000
Wettable powders- OB (airblast/citrus)	160	43.3	0.31	20	0.07	3.8	3.87	> 1000	517
Wettable powders- OB (airblast/postharvest cherry)	160	43.3	0.125 - 0.25	20	0.03 - 0.06	1.5 - 3	1.53 - 3.06	> 1000	654 - > 1000
Wettable powders- OB (airblast/walnuts)	160	43.3	0.25 - 0.5	20	0.06 - 0.11	3 - 6	3.06 - 6.11	> 1000	327 - 654
Wettable powders- OB (groundboom spray)	160	43.3	0.062 - 0.125	100	0.07 - 0.14	3.8 - 7.7	3.87 - 7.84	> 1000	255 - 517
Liquids/Flowable-open pour (fixed aerial/cotton)	43	1.2	0.062 - 0.125	350	0.07 - 0.13	0.4 - 0.8	0.47 - 0.93	> 1000	> 1000
Liquids/Flowables-open pour (rotary aerial/cotton)	43	1.2	0.062 - 0.125	200	0.04 - 0.08	0.2 - 0.4	0.24 - 0.48	> 1000	> 1000
Liquids/Flowables-open pour(groundboom/cotton)	43	1.2	0.062 - 0.125	100	0.02 - 0.04	0.1 - 0.2	0.12 - 0.24	> 1000	> 1000
Flaggers in perimeter of treatment area	40	0.3	0.062 - 0.125	350	0.06 - 0.13	0.1 - 0.2	0.16 - 0.33	> 1000	> 1000
Flaggers in treatment area	500	0.3	0.062 - 0.125	350	0.8 - 1.6	0.1 - 0.2	0.9 - 1.8	> 1000	> 1000
Applicator Exposure (without chemical resistant gloves)									
Aerial Application - fixed wing	5	0.07	0.062 - 0.125	350	0.01 - 0.02	0.02 - 0.04	0.03 - 0.06	> 1000	> 1000
Aerial Application - rotary wing	2.1	0.0018	0.062 - 0.125	200	0.00 - 0.00	0.02 - 0.03	0.02 - 0.03	> 1000	> 1000
Airblast Application - open cab	360	4.5	0.062 - 0.125	20	0.03 - 0.06	0.08 - 0.16	0.11 - 0.22	> 1000	> 1000
Ground-boom sprayer - open cab	15	0.7	0.062 - 0.125	100	0.01 - 0.01	0.06 - 0.13	0.07 - 0.14	> 1000	> 1000
High Pressure Hand Wand - greenhouse	1,800	79	0.125 - 0.25	2	0.00 - 0.00	0.03 - 0.06	0.28 - 0.56	> 1000	> 1000
Mixer/Loader/Applicator - with chemical resistant gloves (such as waterproof gloves)									
Low Pressure Handwand	4,100	31	0.125 - 0.25	2	0.07 - 0.15	0.11 - 0.22	0.18 - 0.37	> 1000	> 1000
Backpack/Knapsack	2,500	30	0.125 - 0.25	2	0.05 - 0.09	0.1 - 0.2	0.15 - 0.3	> 1000	> 1000

Forestry and Ornamental Uses

Summary Exposure/Risk Values for Handlers Using Diflubenzuron While Wearing Long-Sleeved Shirt, Long Pants, and Chemical Resistant Gloves

Exposure Scenario	Dermal Exposure (µg/lb ai)	Inhalation Exposure (µg/lb ai)	Application Rate (lb ai/cycle)	Daily Acres	Dermal Daily Dose (µg/kg/day)	Daily Inhalation Exposure (µg/kg/day)	Inhalation/Dermal Exposures (µg/kg/day)	Handler MOEs	
								Short-Term	Mid-Term
Mixer/Loader Exposure with chemical resistant gloves (such as waterproof gloves)									
Wettable powders-open bag (fixed aerial wide-area forestry)	160	43.3	0.016 - 0.125	1000	0.17 - 1.4	9.6 - 77 1.9 - 15.4 (dust/mist)	9.77 - 78.4 2.1 - 16.8 (dust/mist)	510 - > 1000	26 - 204 119 - 952 (dust/mist)
Wettable powders-open bag (Rotary aerial wide-area forestry)	160	43.3	0.016 - 0.125	350	0.062 - 0.5	3 - 27 0.6 - 5.4 (dust/mist)	3.1 - 27.5 0.66 - 5.9 (dust/mist)	> 1000	73 - 645 339->1K (dust/mist)
Wettable powders-open bag (airblast for forest nurseries/Christmas tree plantations)	160	43.3	0.016 - 0.125	20	0.004 - 0.029	0.2 - 1.5	0.2 - 1.53	> 1000	> 1000
Wettable powders-open bag (ground application using hand-gun type sprayers)	160	43.3	0.016 - 0.125	100	0.018 - 0.14	0.96 - 7.7	1 - 7.8	> 1000	256 - > 1000
Liquids/Flowable-open pour (fixed aerial for wide-area forestry)	43	1.2	0.016 - 0.125	1000	0.05 - 0.4	0.3 - 2	0.4 - 2.4	> 1000	833 - > 1000
Liquids/Flowables-open pour (rotary aerial for wide-area forestry)	43	1.2	0.016 - 0.125	350	0.018 - 0.145	0.094 - 0.75	0.11 - 0.9	> 1000	> 1000
Liquids/Flowables-open pour (airblast for forestry/nurseries/Christmas tree plantations)	43	1.2	0.016 - 0.125	20	0.001 - 0.008	0.005 - 0.043	0.006 - 0.05	> 1000	> 1000
Liquids/Flowables-open pour (ground application using hand-gun type sprayers)	43	1.2	0.016 - 0.125	100	0.005 - 0.038	0.028 - 0.21	0.033 - 0.25	> 1000	> 1000
Applicator Exposure (without chemical resistant gloves)									
Aerial application - fixed wing	5	0.07	0.016 - 0.125	1000	0.006 - 0.045	0.016 - 0.125	0.022 - 0.17	> 1000	> 1000
Aerial application - rotary wing	2.1	0.07	0.016 - 0.125	350	0.001 - 0.004	0.02 - 0.044	0.021 - 0.05	> 1000	> 1000
Airblast application - open cab	360	4.5	0.016 - 0.125	20	0.008 - 0.064	0.02 - 0.16	0.03 - 0.22	> 1000	> 1000
Hand gun - ornamentals	338	1.4	0.016 - 0.125	25	0.009- 0.075	0.008 - 0.063	0.017 - 0.14	> 1000	> 1000
Mixer/Loader/Applicator with chemical resistant gloves (such as waterproof gloves)									
Low pressure handwand	4,100	31	0.016 - 0.125	2	0.009 - 0.073	0.014 - 0.11	0.023 - 0.183	> 1000	> 1000
Backpack/Knapsack	2,500	30	0.016 - 0.125	2	0.006 - 0.045	0.013 - 0.11	0.02 - 0.16	> 1000	> 1000

Aquatic Uses

Summary Exposure/Risk Values for Handlers Using Diflubenzuron While Wearing Long-Sleeved Shirt, Long Pants, and chemical resistant gloves

Exposure Scenario	Dermal Exposure (µg/lb ai)	Inhalation Exposure (μg/lb ai)	Application Rate (lb ai/cycle)	Daily Acres	Dermal Daily Dose (µg/kg/day)	Inhalation Daily Dose (µg/kg/day)	Dermal/Inhalation Exposure (µg/kg/day)	Handler MOEs	
								Short-Term	Mid-Term
Mixer/Loader Exposure with chemical resistant gloves (such as waterproof)									
Wettable powders-open bag (fixed aerial for wide-area aquatic treatments)	160	43.3	0.025 - 0.04	500	0.14 - 0.23	7.73 - 12.37	7.87 - 12.6	> 1000	159 - 254
Applicator Exposure (without chemical resistant gloves)									
Aerial application - fixed wing	5	0.07	0.025 - 0.04	500	0.004 - 0.007	0.013 - 0.02	0.017 - 0.027	> 1000	> 1000

4. Food Quality Protection Act Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) require EPA to apply an additional 10-fold uncertainty (safety) factor unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity.

Because diflubenzuron has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

a. Potential Risks to Infants and Children

In determining whether an additional uncertainty factor is or is not appropriate for assessing risks to infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For purposes of assessing the pre- and post-natal toxicity of diflubenzuron, EPA has evaluated two developmental and one reproduction study. Based on current toxicological data requirements, the pre- and post-natal toxicity data base for diflubenzuron is complete. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of infants and children may be required.

Developmental and Reproductive Effects

The effects observed in the diflubenzuron developmental and reproduction studies can be summarized as follows:

In a developmental toxicity study, technical grade diflubenzuron was administered by gavage to groups of 24 Sprague-Dawley strain female rats on days 6 through 15 of gestation at dose levels of 0 (control) or 1000 mg/kg/day (limit-dose study). No maternal toxicity or toxicity to the developing fetus was observed. The NOEL for maternal toxicity is greater than 1000 mg/kg/day and the NOEL for developmental toxicity is 1000 mg/kg/day.

In a second developmental toxicity study, technical grade diflubenzuron was administered by gavage to groups of 16 New Zealand white strain female rabbits on days 7 through 19 of gestation at dose levels of 0 (control) or 1000 mg/kg/day (limit-dose study). No maternal toxicity or toxicity to the developing fetus was observed. The NOEL for maternal toxicity is greater than 1000 mg/kg/day and the NOEL for developmental toxicity is 1000 mg/kg/day.

In a 2-generation reproduction study, technical grade diflubenzuron was administered in the diet to Sprague-Dawley strain rats at dose levels of 0 (control), 500, 5000 or 50000 ppm (equivalent to about 0, 25, 250 or 2500 mg/kg/day). Starting at 6 weeks of age, F0 animals (32/sex/dose level) were treated continuously for 10 weeks prior to mating at 16 weeks of age and until completion of weaning of all F1 litters at 21 days post-partum. Direct treatment of the F1 generation (28/sex/dose level) was initiated at about 4 weeks of age and continued to mating at 16 weeks of age and until all of the F2 litters were weaned. Treatment-related effects were observed in F0 and F1 adults at all dose levels. The most prominent of these effects were increased methemoglobin levels, hemolytic anemia and signs of erythrocyte destruction. Additional signs of toxicity observed at 250 and 2500 mg/kg/day in F0 and F1 animals included pathological effects in the spleen and liver. No effects on reproductive performance were observed at any dose level in F0 or F1 males or females in this study. Regarding litter parameters, litter and mean pup weights were slightly decreased from birth to 21 days post-partum in F1 offspring at 2500 mg/kg/day. A NOEL for parental adults was not identified in this study. The LOEL is 25 mg/kg/day, based on methemoglobinemia, hemolytic anemia, destruction of erythrocytes, and pathological changes in the spleen and liver. The NOEL for reproductive performance in parental adults is 2500 mg/kg/day. The NOEL for developmental effects in offspring is 250 mg/kg/day. The LOEL is 2500 mg/kg/day, based on decreased body weights in F1 pups from birth to 21 days post-partum.

The developmental and reproductive data for diflubenzuron indicate that there is no evidence of an increased sensitivity to diflubenzuron from pre- or post-natal

exposures. In both the rat and rabbit developmental toxicity study, no maternal toxicity or toxicity to the developing fetus was observed at the highest dose tested. Further, no effects on reproductive performance were observed at any dose level in F0 or F1 males or females in the 2-generation reproduction study in which parental toxicity (methemoglobinemia, hemolytic anemia, destruction of erythrocytes, and pathological changes in the spleen and liver) was observed at all doses tested (i.e., a NOEL was not established). Therefore, the Agency has concluded that an additional uncertainty factor is not warranted for pre- and post-natal effects.

Uncertainty Factor

Based on the considerations outlined above, and the absence of any incident or epidemiological data for diflubenzuron, the Agency concludes that an additional uncertainty factor to account for any special sensitivity to infants and children is not warranted for the diflubenzuron risk assessment.

b. Aggregate Exposure/Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and all other exposures for which there is reliable information. These other sources of exposures include drinking water and non-occupational exposures, e.g., to pesticides used in and around the home. For estimating acute and chronic risks the Agency considers aggregate exposures from the diet and from drinking water. Exposures from uses in and around the home that may be of a short-term, intermediate or other duration may also be aggregated as appropriate for specific chemicals.

Diflubenzuron products are used as insect growth regulators and act by blocking the synthesis of chitin. Formulations of diflubenzuron are applied to agricultural crops (cherries, citrus, cotton, soybeans, walnuts, and mushrooms), ornamental crops (including greenhouse grown crops), forests and shelterbelts, aquatic systems, and as a feed through treatment for livestock. Diflubenzuron also has a wide-area general outdoor applications used to control gypsy moths and mosquitoes. Although diflubenzuron may be applied by certified applicators in residential areas; it is a restricted use pesticide and, therefore, is not available for use by homeowners.

Chronic Dietary Exposure - Food Source: Tolerances are established for residues of diflubenzuron *per se* in/on various raw agricultural commodities and animal feeds *[40 CFR §180.377 (a) and (b), and 40 CFR §186.2000]*. Tolerances range from 0.05 ppm in/on soybeans to 3.0 ppm in/on rangeland grass. Tolerances of 0.05 ppm have also been established for residues of diflubenzuron in animal commodities. Tolerances have been established for residues of diflubenzuron *per se* in soybean hulls (0.5 ppm) and soapstock (0.1 ppm).

Chronic Dietary Exposure - Drinking Water Source: No detections of diflubenzuron have been reported in the Agency's Pesticides In Ground Water Database and no incidents were found in OPP's Ecological Incident Information System.

Non-occupational Exposure: Diflubenzuron is a restricted use pesticide and therefore not available for use by homeowners. However, occupational uses of diflubenzuron may expose people in residential locations, parks, or forests treated with diflubenzuron. Based on very low residues detected in forestry dissipation studies, low dermal absorption rate (0.05%), and extremely low dermal and inhalation toxicity, these uses are expected to result in insignificant risk, and will, therefore, not be included in the aggregate risk assessment.

Acute Dietary Risk, food source: The Agency has concluded that an acute dietary risk assessment is not required for diflubenzuron because of its low acute oral toxicity. Therefore, an acute dietary risk assessment was not conducted.

Chronic Dietary Risk, food source: The chronic DRES analysis used tolerance level residues and 100% crop treated to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The TMRC for the overall U.S. population and the most affected subgroups are 10% of the RfD for the U.S. general population, 31% for non-nursing infants (younger than 1 year old), and 26% for children 1-6 years old. Refinements in residue and percent crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for those same population subgroups. The ARC is considered the more accurate estimate of dietary exposure. Using the ARC the dietary risks are calculated to be less than 1% of the RfD for the U.S. general population, less than 1% for non-nursing infants (younger than 1 year old), and 1% for children 1-6 years old.

Cancer Risk, food source: The Agency has determined that estimations of the carcinogenic risk to humans resulting from dietary exposure be performed for food commodities that contain PCA and/or CPU. For the purpose of calculating dietary risk assessments, the following procedure was recommended:

1) CPU should be considered to be potentially carcinogenic and to have the same carcinogenic potency (Q_1^*) as PCA;

2) The sum of PCA and CPU residues in ingested food should be used to estimate the dietary exposure of humans to the carcinogenic metabolites of diflubenzuron;

3) In addition to ingested residues of these two metabolites, amounts of PCA and/or CPU formed in vivo following ingestion of diflubenzuron should also be

included when estimating the total exposure of humans to the carcinogenic metabolites of diflubenzuron (estimated to be 2.0%, based on data in the rat metabolism study);

The cancer risk estimate for combined residues of PCA and related metabolites for the overall U.S. population is approximately 1 x 10^{-6}. The U.S. population and all the DRES subgroups have ARCs for chronic dietary risk from diflubenzuron well below the RfD when all tolerances or anticipated residues are considered.

Drinking water: Since no detections of diflubenzuron have been reported in the Agency's Pesticides In Ground Water Database and no incidents were found in OPP's Ecological Incident Information System, dietary risk from drinking water will be assumed to be negligible. Consequently neither a chronic nor an acute quantitative drinking water assessment was performed. Although data are not available to estimate residues of diflubenzuron degradates in drinking water, residue levels that could lead to significant risk are not expected. This conclusion may be reevaluated when additional required data on adsorption/desorption of degradates is received by the Agency.

Conclusions on Chronic Aggregate Exposure/Risk to Diflubenzuron

The Agency concludes that aggregate risks to the general U.S. population, and to the population subgroup of infants and children, resulting from diflubenzuron uses are not of concern.

The total dietary cancer risk for the published tolerances for the overall U.S. population is approximately 1 x 10^{-6}.

Since there are no detections of diflubenzuron in ground water, dietary risk from drinking water are expected to be negligible.

Based on very low residues detected in forestry dissipation studies, a low dermal absorption rate (0.05%), and extremely low dermal and inhalation toxicity, occupational uses of diflubenzuron in residential locations, parks, or forests are expected to result in insignificant risk to people in these areas and, therefore, will not be included in the aggregate risk assessment.

c. Cumulative Effects

In reassessing existing tolerances to determine whether they meet the standard for issuance of a tolerance under section 408 of the FFDCA, EPA is required to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also policies and methodologies for conducting cumulative risk assessments. While the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to fully resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will enable it to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments.

In reassessing tolerances before the Agency has developed an acceptable methodology to apply common mechanism of toxicity issues to risk assessments, the Agency will determine whether:

1) it has sufficient information to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances; or

2) it is unable to conclude that a pesticide does not share a common mechanism of toxicity with other substances.

For pesticides falling into the first category, the Agency will explain its determination and factor the determination into the tolerance reassessment. For pesticides falling into the second category, the Agency will conclude that it does not have sufficient available information concerning common mechanism of toxicity to scientifically apply that information to the tolerance decision, the reassessment decision will be reached based upon the best available and useful information for the individual chemical, and a risk assessment will be performed for the tolerance action assuming that no common mechanism of toxicity exists. However, reassessment decisions falling into the second category will be reexamined by the Agency after EPA establishes methodologies and procedures for integrating information concerning common mechanism into its risk assessments. In such circumstances, registrants should be on notice that the Agency at that time may well require pursuant to FIFRA section 3(c)(2)(B) the submission of such data as may be necessary to evaluate common mechanism of toxicity issues in a risk assessment.

In the case of diflubenzuron, EPA has not yet determined whether or how to include this chemical in a cumulative risk assessment. This reassessment determination therefore does not take into account common mechanism issues. After EPA develops a methodology for applying common mechanism of toxicity issues to

risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier.

C. Environmental Assessment

1. Ecological Toxicity Data

Most of the data requirements for assessing the ecological toxicity of diflubenzuron have been satisfied, however, an estuarine/marine toxicity study on fish (guideline 72-3a) is still required. The estuarine/marine fish toxicity data requirement was originally required by the September 1985 Registration Standard. An acceptable study was submitted using the 25% formulation, however, data are still needed using technical diflubenzuron that are expected to confirm the results of this risk assessment.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

To establish the toxicity of diflubenzuron to birds, the Agency requires an avian single-dose oral (LD_{50}) study and two subacute dietary studies (LC_{50}), one on waterfowl and the other on upland game bird. All studies must be performed using the technical grade of the active ingredient. The following tables summarize the available data:

Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} (mg/kg)	MRID	Toxicity Category	Guideline
Bobwhite Quail	99.4	> 5000	00073935	practically non-toxic	Yes
Mallard Duck	Technical	> 5000	00073936	practically non-toxic	Yes
Red-Winged Blackbird	Technical	> 3763	00038614	practically non-toxic	Supplemental

Avian Subacute Dietary Toxicity Findings					
Species	**% A.I.**	**LC_{50} (mg/kg)**	**MRID**	**Toxicity Category**	**Guideline**
Bobwhite Quail	Technical	> 4640	00039080	Slightly Toxic	Yes
Mallard Duck	Technical	> 4640	00038613	Slightly Toxic	Yes
Red-Winged Blackbird	1% Granular	> 20,000	00060381	NA	Supplemental

These results indicate that diflubenzuron is **practically non-toxic** to avian species on an acute oral dietary basis and **slightly toxic** on a subacute dietary basis. The guideline requirements for avian acute and subacute toxicity are fulfilled. (MRIDs 00038613, 00038614, 00039080, 00039085, 00060381, 00073935 and 00073936)

(2) Birds, Chronic

The Agency requires avian reproduction studies when birds may be repeatedly or continuously exposed to a pesticide. This determination is based on factors such as the pesticide's persistence, tendency to bioaccumulate, whether multiple applications are made, or if mammalian reproduction tests indicate a reproductive hazard. Avian reproduction studies were required for diflubenzuron because repeat applications may occur and reproductive impairment is suggested by the available data. The following table summarizes the available data.

Avian Reproduction Findings						
Species	**% A.I.**	**NOEL (ppm)**	**LOEL (ppm)**	**Endpoints Affected**	**MRID**	**Guideline**
Bobwhite Quail	97.6	500	1000	egg production	41668002	Yes
Mallard Duck	97.6	500	1000	eggshell thickness	41668001	Yes
Bobwhite Quail		No effects to 250	NA	NA	00099719	Supplemental

Avian Reproduction Findings						
Species	**% A.I.**	**NOEL (ppm)**	**LOEL (ppm)**	**Endpoints Affected**	**MRID**	**Guideline**
Bobwhite Quail Mallard		Reproductive parameters significantly affected @ 10 ppm (eggs embryonated) and 40 ppm (eggs laid) No effects to 40	NA	NA	00099862	Supplemental
Bobwhite Quail		No effects to 250	NA	NA	00099730	Supplemental

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

(3) Mammals

The Agency requires wild mammal testing on a case-by-case basis, depending on the results of the lower tier studies, use pattern, and pertinent environmental fate characteristics of a pesticide. In most cases, an acute oral LD_{50} from the submitted health effects data is used to determine toxicity to mammals. For diflubenzuron, the acute oral LD_{50} was 5000 mg/kg in both mice and rats, indicating that diflubenzuron is **practically non-toxic** to small mammals on an acute oral basis. (MRID 00157103)

(4) Insects

The Agency requires a honey bee acute contact LD_{50} study when pesticide use will result in honey bee exposure. Two studies conducted with technical diflubenzuron exhibited contact LD_{50}s of greater than 30 μg a.i./bee and 114.8 μg a.i./bee. One of the studies also exhibited an oral LD_{50} of greater than 30 μg a.i./bee. These results indicate that diflubenzuron is **non-toxic** to bees. The guideline requirement is fulfilled. (MRIDs 00040601 and 05001991)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

To establish the toxicity of a pesticide to freshwater fish the Agency requires at least two freshwater fish toxicity studies, one using a coldwater species (preferably rainbow trout) and the other a warmwater species (preferably bluegill sunfish). Both studies must use the technical grade of the active ingredient. The following table summarizes the available diflubenzuron data.

Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID	Toxicity Category	Guideline
Rainbow trout	Technical	140	00056150	Practically Non-toxic	Yes
Bluegill sunfish	Technical	135	00056150	Practically Non-toxic	Yes
Rainbow trout	Technical	> 100		Practically Non-toxic	Yes
Brook trout	Technical	> 50		Slightly Toxic	Supplemental
Channel catfish	Technical	> 100	40094602	Practically Non-toxic	Yes
Bluegill sunfish	Technical	> 100		Practically Non-toxic	Yes
Yellow perch	Technical	> 25		Slightly Toxic	Supplemental
Bluegill Sunfish	Technical	> 100	00056035	Practically Non-toxic	Supplemental
Fathead Minnow	Technical	> 500	00060376	Practically Non-toxic	Supplemental
Cutthroat trout	25% WP	57		Slightly Toxic	Supplemental
Rainbow trout	25% WP	240		Practically Non-toxic	Yes
Fathead Minnow	25% WP	> 100	40094602	Practically Non-toxic	Supplemental
Channel Catfish	25% WP	> 100		Practically Non-toxic	Supplemental
Bluegill Sunfish	25% WP	> 100		Practically Non-toxic	Yes
Bluegill Sunfish	25% WP	230		Practically Non-toxic	Yes
Rainbow trout	25% WP	195	00056150	Practically Non-toxic	Yes
Common Carp	25% WP	390		Practically Non-toxic	Supplemental
Rainbow trout	25% WP	342	00060384	Practically Non-toxic	Yes
Bluegill Sunfish	1% Granular	> 1000		Practically Non-toxic	Supplemental
Rainbow trout	1% Granular	> 1000	00060380	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 25% WP formulations. (MRIDs 00056035, 00056150, 00060380, 00060384 and 40094602)

(2) Freshwater Invertebrates

To assess the hazard of a pesticide to freshwater invertebrates the Agency requires a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies or midges. The following table summarizes the data available for diflubenzuron.

Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (ppb)	MRID	Toxicity Category	Guideline
Daphnia magna	Technical	48hr LC_{50} = 3.7	43665801	Very Highly Toxic	Yes
Gammarus pseudolimnaeus	95%	96hr LC_{50} = 45	40098001	Very Highly Toxic	Supplemental
Gammarus pseudolimnaeus (mature)	95%	96hr LC_{50} = 30	40094602	Very Highly Toxic	Supplemental
Daphnia magna	97.6%	48hr EC_{50} = 7.1	40840502	Very Highly Toxic	Yes
Daphnia magna	25%	48hr EC_{50} = 15	40098001	Very Highly Toxic	Supplemental
Daphnia magna	25%	48hr EC_{50} = 16	40094602	Very Highly Toxic	Supplemental
G. pseudolimnaeus	25%	96hr LC_{50} = 25	40094602	Very Highly Toxic	Supplemental

The results indicate that diflubenzuron is **very highly toxic** to freshwater aquatic invertebrates. Guideline requirements for freshwater invertebrate toxicity testing for the technical and 25% WP formulations are fulfilled. (MRIDs 40094602, 40098001, 40840502 and 43665801)

(3) Estuarine and Marine Animals

The Agency requires acute toxicity testing with estuarine and marine organisms 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. Therefore, the Agency requires a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study using oysters. The following table summarizes the available data.

Estuarine/Marine Acute Toxicity Findings					
Species	**% AI**	**LC_{50}/EC_{50} (ppb, ppm)**	**MRID**	**Toxicity Category**	**Guideline**
Mysidopsis bahia	99	2.0 ppb	43662001	Very Highly Toxic	Yes
Mysidopsis bahia	95	2.1 ppb	40098001	Very Highly Toxic	Yes
Quahogs (*Mercenaria*)	97.6	> 0.32 ppm	41392001	Highly Toxic	Yes
Grass Shrimp (*Palaemontes pugio*)	100	0.64 ppm	00038612	Highly Toxic	Supplemental
Mummichog (*Fundulus heteroclitus*)	25 WP	255 ppm	00056150	Practically non-toxic	Yes
Eastern Oyster (*Crassostrea virginica*)	25 WP	130 ppm	00038611	Practically Non-toxic	Supplemental
Quahogs (*Mercenaria mercenaria*); *Anodonta sp.*; *Uca pugilator*; *Carcinus maenas*	25 WP	> 1000 ppm	00039088	Practically Non-toxic	Supplemental

These 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% formulation is waived. No further data are required at this time.

Results of the 96-hour acute toxicity study indicate that diflubenzuron is **practically non-toxic** to marine/estuarine fish. No further data are needed to support the 25% wettable powder formulation, however, a confirmatory 96-hour acute toxicity study with an estuarine/marine fish is still outstanding for technical grade

diflubenzuron. (MRIDs 00038611, 00038612, 00039088, 00056150, 00060377, 40098001, 41392001, and 43662001)

(4) Freshwater and Estuarine/Marine Chronic Results

Aquatic Invertebrates

The Agency requires early life-stage tests or life-cycle tests if: 1) 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 2) any acute LC_{50} or EC_{50} is less than 1 mg/L; or 3) the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or 4) 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 either studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected, physicochemical properties indicate cumulative effects, or the pesticide is persistent in water (e.g. half-life greater than 4 days).

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

The Agency also required finfish chronic testing based on 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**	**MRID**	**Endpoints Affected**	**Guideline**
Daphnia magna	99	< 0.06 ppb	0.06 ppb	Test#2424 Beltsville	Reproduction Survival	Supplemental
Daphnia magna		< 0.09 ppb	0.09 ppb	00010865	Reproduction Survival	Supplemental
Brine Shrimp (*Artemia salina*)	100	> 10 ppb	>10 ppb	00073933	Reproduction	Supplemental
Mysidopsis bahia	99	None	0.075 ppb	43662001	Reproduction	Supplemental
Mysidopsis bahia	97.6	45 ppt	86 ppt	40237501	Mortality Growth Reproduction	Core
Daphnia magna	97.6	40 ppt	93 ppt	40840501	Survival Growth Reproduction	Core

The results indicate that diflubenzuron affects reproduction, growth and survival in freshwater invertebrates as well as reproduction in marine/estuarine invertebrates. The guideline requirement is fulfilled for the 25% WP formulation with a freshwater invertebrate. The guideline requirements are also fulfilled for aquatic invertebrate life-cycle toxicity studies with freshwater and estuarine species using the technical grade active ingredient. (Beltsville Lab Test 2424 and MRIDs 00010865, 00073933, 40130601 and 40840501)

Fish

The Agency requires a fish life-cycle test when an end-use product is intended to be applied directly to water or is expected to be transported to water from the intended use site, as long as 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 (ppm)**	**LOEL**	**MATC**	**MRID**	**End-point**	**Guideline**
Fathead minnow (*Pimephales promelas*)	99.4	0.10	>0.10 ppm	>0.10 ppm	00099755	None	Yes
Mummichog * (*Fundulus hetroclitus*)	Tech	0.05	NA	NA	00099722	None	Supplemental

* 4-10% of first generation juveniles (test and control) developed abnormally. Several different statistical analyses showed no dose-dependent reactions with respect to abnormalities or mortalities. No significant difference in growth (wet weight) and # eggs/female. Second generation showed no dose-dependent relationship for any observed relationship. Study did not provide adequate test of the effects of diflubenzuron on reproductive success.

These results indicate that diflubenzuron does not affect reproduction in freshwater fish. The guideline requirement is fulfilled for a freshwater fish life-cycle study; however, the submitted life-cycle study for estuarine/marine fish did not adequately test the effects on reproduction, a major objective of this test. The study was designed inadequately, since there were no dose-response reactions. The magnitude or types of chronic risk cannot be determined with the present study, however, no new data are being required. The available data are sufficient for the Agency to conduct a chronic risk screening for fish. (MRIDs 00099722 and 00099755)

(5) Aquatic Field Testing

Twelve freshwater invertebrate field studies were reviewed in the September 1985 Registration Standard. The following table summarizes these field studies.

Freshwater Invertebrate Field Testing		
Description	**Result**	**MRID**
1% granular product @0.1 and 0.2 lb. a.i./A applied to finger areas on residential-recreational lakes in CA. Observed 9 weeks post-treatment.	Reductions to cladocerans, copepods and amphipods.	05000841
25% WP @ 2.5, 5, and 10 ppb applied to farm pond and small lake	Crustacean zooplankton suppressed at all rates for up to 6 weeks, with recovery noted thereafter	00099897
25% WP @ 0.4 lb. a.i./A applied to small ponds in UT, post-treatment samples were taken 30 and 80 days.	Immature aquatic insect populations were reduced 30 days post-treatment.	00038213
25% WP @0.03 and 0.12 lb. a.i./A applied 4 times at 2-week intervals to small ponds in VA. Samples taken once pre- and once post-treatment	Cladocerans were reduced at both treatment levels.	00099791
25% WP @0.18 lb. a.i./A applied to forest in Canada to control spruce budworm. Samples take pre- and 3 days post-treatment.	Amphipod and aquatic beetle larvae populations removed. Copepods and ostracods may have been impacted	00071210
25% WP @0.03 lb. a.i./A applied 4 times at 2 week intervals to man-made ponds stocked with representative fauna. Samples taken pre-treatment and 10 days after final treatment.	Invertebrate populations were susceptible with cladocerans particularly depressed.	00099891
1% granular and 25% WP @ 0.025, 0.05 lb. a.i./A applied to replicated ponds. Observations were up to 13 days post-treatment.	Non-target organisms reduced, cladocerans affected more than the target species.	00099839
25% WP @ 0.01 to 0.25 lb. a.i./A applied to flooded rice fields. one sample was taken 80 days post-treatment.	Certain non-target aquatic insects reduced and others increased (due to reduction in predators).	00038212
25% WP @ 0.03, 0.12 lb. a.i./A applied to ponds 4 times at 2 week intervals in TX. Samples taken pre-treatment and 10 days after last treatment.	Certain benthic and zooplankton organisms reduced or eliminated at both treatment levels.	00039090
25% WP @ 0.03, 0.12 lb. a.i./A applied 4 times at 2 week intervals to ponds in AR. Samples taken pre-treatment and 10 days post-treatment.	Copepods reduced but minimally impact when applied in December.	00039091
25% WP @0.03, 0.12 lb. a.i./A applied 4 times at 2 week intervals to ponds in NC. Samples were taken pre- and 9 days post-treatment.	May have eliminated certain sensitive and reduced other species.	00039092

Freshwater Invertebrate Field Testing		
1% granular @ 0.02, 0.04 lb. a.i./A applied to marsh habitat on Fraser River, BC, Canada. Samples taken up to 71 days post-treatment	Reduced zooplankton and non-target insects.	00095416

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 are summarized below:

Estuarine Invertebrate Field Testing		
Description	**Result**	**MRID**
25% WP @0.025 lb. a.i./A applied six times to Louisiana coastal marsh over 18 months.	5 invertebrate taxa reduced and 15 increased.	00099678
25% WP @ 0.04, 0.1 and 0.2 lb. a.i./A applied up to 3 times to replicated semi-natural pools. Observations 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.	00099895
25% WP @0.03 and 0.12 lb. a.i./A applied 4 times at 2 week intervals to open water canals in Louisiana during the winter. Samples taken 3 day pre-treatment and 7 days post-treatment.	No apparent effects.	Union Carbide Corp. (1976)

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

Agency proposed revisions to CFR 40, Part 158 would require Tier 1 plant phytotoxicity tests for all insecticides, including diflubenzuron. Once these guidelines are finalized, the Agency may call in additional plant phytotoxicity data.

(1) Terrestrial

No terrestrial plant studies were submitted or are currently required for diflubenzuron.

(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 that show effects of more than 50% for aquatic plants trigger Tier II data requirements. Tier I testing should include *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flosaqua*e and a freshwater diatom.

A supplemental diflubenzuron study on *Selenastrum capricornutum* indicated an EC_{50} of 0.20 mg/L. The guideline requirements for aquatic plant testing are not fulfilled at this time. (MRID 42487101)

2. Environmental Fate

The environmental fate database is largely complete, however, the following data requirements are still outstanding:

162-4 Aerobic aquatic metabolism[2]
163-1 Adsorption/Desorption[3]
164-2 Aquatic (sediment) dissipation[5]
164-3 Forestry dissipation[4]
165-3 Accumulation in irrigation crops[5]
165-5 Accumulation in aquatic non-target organisms[5]
202-1 Drift field evaluation[5]

These data are not expected to significantly change the basic environmental fate assessment for diflubenzuron, but to confirm our position and increase our degree of certainty in estimating the environmental impact of the use of diflubenzuron. Please see the appropriate section below for a full discussion of each data requirement.

a. Environmental Fate Assessment

Based on acceptable laboratory and supplemental and acceptable field data, diflubenzuron appears to be relatively non-persistent and immobile under normal use

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[2] Required to support aquatic uses, 24(c) (Special Local Need/State) registrations in FL, CA, HI, NV and AL, for aquatic uses to control mosquitoes and/or midges in non-potable water, irrigation ditches, tailings, livestock wastewater lagoons, non-crop lakes, stockpiled rubber tires, sewage effluent, etc.

[3] Study should be conducted on CPU and bare ground data from typical use area(s) in the north

[4] Storage stability data are required for diflubenzuron and its degradates using the same type of soil, litter, and leaves that were used in the submitted forestry dissipation study. These data are necessary to validate the existing study.

[5] The registrants may elect to satisfy this requirement by participating in the Spray Drift Task Force.

conditions. The major route of dissipation appears to be biotically mediated processes (half-life of approximately 2 days for aerobic soil metabolism). Binding to soil organic matter appears to contribute to the dissipation of diflubenzuron (with K [n=1] values for sand clay, silty clay loam, silt loam, sand loam, sandy clay loam, clay, clay hydrosoil, and peat hydrosoil of 40, 40, 20, 25, 130, 110, 150, and 3500, respectively). Anaerobic aquatic metabolism was reported to be slower (half-life of approximately 34 days). Other laboratory data indicate that diflubenzuron is stable to hydrolysis (with an approximate half-life of 30-80 days for pH 5-9) and photolysis (with an approximate half-life of 80 days for aquatic) and is relatively immobile in soil (Rf values were 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 confirm the laboratory data with reported half-lives of 5.8 to 60 days. Diflubenzuron 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 - 78 days). Diflubenzuron has not been detected in well monitoring[6]. In addition, based on chemical and physical properties and LOCs, diflubenzuron 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 diflubenzuron appears to degrade to 4-chlorophenyl urea (CPU), reaching a maximum concentration of 30.8% of applied levels at 7 days post-treatment. The other major degradate, CO_2, was reported to reach a maximum concentration of 26.8% of applied levels by day 21 post-treatment. Three minor degradates, 2,6-difluorobenzoic acid, 2,6-difluorobenzamide, and p-chloroaniline, each reaching a maximum concentration of less than 10% of applied levels, were identified in the aerobic study. These metabolites were also discernible in an anaerobic metabolism study. Due to the stability of diflubenzuron to abiotic processes, limited data are available on the persistence and mobility of diflubenzuron metabolites. One column leaching study did report CPU in leachate (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.

Diflubenzuron appears 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.

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[6] National Summary-Pesticides in Ground Water Database-A Compilation of Monitoring Studies: 1971-1991 compiled by the EPA

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis (161-1)

Diflubenzuron 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. This data requirement is fulfilled. (MRIDs 40859801 and 41087801)

Photodegradation in water (161-2)

Diflubenzuron appears stable to unsensitized aqueous photolysis at pH 7. The data reported an extrapolated natural light half-life of 80 days. This data requirement is fulfilled. (MRIDs 40816301 and 41087802)

Photodegradation on soil (161-3)

Diflubenzuron 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 $^{14}CO_2$, 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. This data requirement is fulfilled. (MRID 42251201)

Aerobic soil metabolism (162-1)

Diflubenzuron, applied to sandy loam soil, was calculated to have a half-life of 2-14 days (depending on soil texture) when incubated at 24 ± 1°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 less than 10% of applied radioactivity were identified, as well. This data requirement is fulfilled. (MRIDs 00039473, 00039474, and 41722801)

Anaerobic soil metabolism (162-2 and 162-3)

Diflubenzuron degraded with a half-life of 2 to 14 days when applied to sandy loam soil and incubated at 14ºC and 24ºC. The major degradate, 4-chlorophenyl urea, reached a maximum concentration of 37% of applied radioactivity at days 2 to 14 (depending on temperature). The other major degradate, 2,6-difluorobenzoic acid, reached 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. This data requirement is fulfilled. (MRIDs 00040782 and 41837601)

Anaerobic aquatic metabolism (162-3)

The study reported a half-life of 34 days for diflubenzuron when applied to silt loam soil and incubated at 24ºC under anaerobic conditions. The study identified three degradates (2,6-difluorobenzoic acid, 4-chlorophenyl urea, and 4-chloroaniline) 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. This data requirement is fulfilled. (MRID 41837601)

(2) Mobility

Leaching/adsorption/desorption (163-1)

Two mobility studies containing column leaching data and adsorption/desorption data combined to fulfill the leaching/adsorption/desorption requirement. Reported 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) indicate that diflubenzuron is relatively 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.

^{14}C-Diflubenzuron residues (mainly p-chlorophenyl urea) were mobile in sandy loam-loamy sand, sandy loam, silt loam, and clay loam-clay soils treated with ^{14}C-diflubenzuron 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 each leachate was in the form of p-chlorophenyl urea.

^{14}C-Diflubenzuron was immobile in clay loam and silty clay loam soils (Rfs = 0.01 - 0.07) and had a low mobility in sandy loam soils (Rfs = 0.14 - 0.34), as well, based on a thin layer chromatography test. Although this technique is no longer acceptable for a guideline study, these data provided sufficient information to make a regulatory decision and the data requirement is fulfilled. (MRIDs 00039476, 00039477, 00040777 and 00157842)

(3) Accumulation

Bioaccumulation in Fish (165-4)

Diflubenzuron appears to accumulate and 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 ^{14}C-residues appeared to have peaked and leveled to a steady state concentration in all tissues. The maximum uptake tissue concentrations 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 ^{14}C-residues from all sampled tissue was reported for the 14 day depuration period. During the depuration period, ^{14}C-residues dropped to less than 0.06 mg/kg in fish tissues. This data requirement is fulfilled. (MRID 42258401)

(4) Field Dissipation

Terrestrial field dissipation (164-1)

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

The orchard and bare ground data reported similar observed half-lives (from 5.8 to 13.2 days), however, calculated half-lives for the California citrus and the Oregon apple orchards ranged from 68.2 to 78 days.

P-Chlorophenyl urea appears to be the major degradate in field dissipation data with maximum concentrations ranging from less than 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 of analytical methodology; however, the storage stability data could not adequately 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 post-treatment 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 post-treatment, 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. (MRIDs 00163853 and 41922201-41922210)

(5) Spray Drift

Droplet size spectrum (201-1)

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

Drift field evaluation (202-1)

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

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 feet was 0.22 $\mu g/ft^3$, and 0.02 $\mu g/ft^3$, respectively. (MRIDs 42151701 and 42151702)

Although additional drift field evaluation data are required to fully characterize diflubenzuron drift, this requirement may be satisfied by data from the Spray Drift Task Force, provided the registrant is a member. These data are currently under review and may ultimately affect the Agency's conclusions on diflubenzuron drift.

c. Water Resources

(1) 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 reason 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 (LOCs). No detections of diflubenzuron have been reported in EPA's Pesticides 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. While 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-chloroaniline (PCA) are toxicologically significant degradates of diflubenzuron. Since PCA is carcinogenic, metabolites that 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, the volume of water (rainfall plus irrigation) in the Louisiana and Arizona plots may have caused CPU to fall 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 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.

(2) Surface Water

Substantial amounts of diflubenzuron could be available for runoff to surface waters for several days to weeks post-application (half lives of 2 days to 2 weeks for aerobic soil metabolism, 2-14 days for anaerobic soil metabolism and 5.8, 13, 68, and 78 days for terrestrial field dissipation). The intermediate to high soil/water partitioning of diflubenzuron (K_ds of 20, 25, 40, 40, 120, 130 and a 150, SCS/ARS database K_{oc} of 9000) indicates that diflubenzuron runoff will often be primarily via adsorption to eroding soil. 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 X 10^{-9} atm*m^3/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 a variance in terrestrial laboratory and field half-lives of 2 to 78 days. Similar variations may occur in the rates of biodegradation in aquatic systems possibly with 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 and may vary substantially, ranging from low to intermediate. The persistence of diflubenzuron in aquatic systems with shorter hydrological residence times should be lower due to removal of diflubenzuron dissolved and adsorbed to suspended sediment. However, the intermediate to high soil/water partition coefficient indicates that much of the diflubenzuron in aquatic systems will be adsorbed to bottom sediment.

The two major degradates of diflubenzuron are 4-chlorophenyl urea in soil under both aerobic and anaerobic conditions and 2,6-difluorobenzoic acid under anaerobic conditions. There are not enough data to adequately assess the fate and mobility of those degradates.

3. Ecological Exposure and Risk Characterization

Levels of Concern (LOCs) are used to measure potential risk to nontarget organisms. There are two general categories of LOCs (acute and chronic) for each of the four non-target faunal groups and one category (acute) for each of two non-target floral groups. To determine if an LOC has been exceeded, a risk quotient (RQ) is derived and compared to the LOC. 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.

Typical acute effect levels include the EC_{25} for terrestrial plants, the EC_{50} for aquatic plants and invertebrates, the LC_{50} for fish and birds, and the LD_{50} for birds and mammals. Typical chronic test results include the no observed effect level (NOEL), sometimes referred to as the no observed effect concentration (NOEC) for avian and mammalian reproduction studies; and either the NOEL or the maximum allowable toxicant concentration (MATC) for chronic aquatic studies. 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

IF THE	LOC	PRESUMPTION
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

IF THE	LOC	PRESUMPTION
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

For this assessment, the diflubenzuron uses are categorized into three groups based on the application rate and use characteristics. The non-bearing citrus group includes non-bearing citrus trees, walnuts and cherries; the cotton group includes cotton, soybeans, pastures, ornamental herbaceous plants [chrysanthemums], and wide area and general indoor/outdoor treatments; while the forestry group includes forest trees and plantings, christmas tree plantations, pine, ornamentals, sewage systems, bogs, swamps, standing water, rights of way, and household or domestic dwellings. The assessment used application rates of 0.125 lb ai/A for the forestry and cotton groups, 0.312 lb ai/a for bearing citrus trees, and 0.666 lb ai/A for non-bearing citrus group.

a. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

Residues found on dietary food items following diflubenzuron application may be compared to LC_{50} values to predict hazard. The maximum residues of diflubenzuron on avian food items would not be expected to exceed 160 ppm (0.67 lb ai/a on short grass). Using this exposure and an avian LC50 of 4640 ppm yields an acute RQ of 0.03 and a chronic RQ of 0.32, neither of which exceeds the LOC for risk to birds. Since the maximum application rate did not indicate a risk to birds or endangered bird species, the lower application rates are expected to present minimal risk.

(2) Mammals

Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

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

The estimated LC_{50} values are shown in the following table.

Small Mammal Food Consumption (ppm) (Based on an LD_{50} = mg/kg)*				
Small Mammal	**Body Weight (g)**	**% Weight Eaten Daily**	**Food Consumed per day (g)**	**Estimated LC_{50} per day (ppm)**
Meadow vole	46	61	28.1	8185
Adult field mouse	13	16	2.1	30952
Least shrew	5	110	5.5	4545

* Based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

Using application rates ranging from 0.125 to 0.67 lb ai/A, the risk assessment estimated that the maximum residues on mammal food items is 160 ppm (0.67 lb ai/a on short grass). Using this maximum exposure and an estimated mammal LC_{50} of 4545, the assessment yields an acute RQ of 0.04, which does not exceed the LOC for risk to mammals. Since the maximum application rate did not indicate a risk to mammals, including endangered species, the lower application rates are not expected to result in acute risk to endangered or non-endangered mammals.

b. 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 EECs were calculated for the citrus and cotton usage groups. 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. The model simulated one application/year at 0.667 lbs ai/acre for citrus, with an assumed air blast drift of 3%, and 6 applications/year each at 0.063 lbs ai/acre for cotton, 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 for the citrus and cotton usage groups were calculated.

The standard models do not apply to the forestry usage group. 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 invertebrate resources may negatively affect these fisheries resources. The direct application scenario is a high-exposure scenario resulting in the high risk quotients calculated for the forestry usage group.

The EECs for the forestry usage group 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 used in the forestry usage group 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 usage group.

The use rates and application methods for cotton are similar to several other uses of diflubenzuron, such as soybeans and ornamentals. The forestry usage group 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 the citrus, cotton and forestry usage groups.

Estimated Environmental Concentrations (EECs)							
Usage Group	**Application Method**	**Application Rate (lbs a.i./A)**	**Initial EEC (ppb)**	**4-day EEC (ppb)**	**21-day EEC (ppb)**	**60-day EEC (ppb)**	**90-day EEC (ppb)**
Non-bearing Citrus*	ground or aerial	0.67	8.1	5.8	2.3	1.1	0.74
Cotton and Bearing Citrus*	ground or aerial	0.38 (6 @ 0.06)	4.3	3.4	1.9	1.1	0.87
Forestry	Directly to Water		**EEC from Direct Application to Water**				
		0.02	11.7				
		0.03	22.8				
		0.06	46.2				
		0.13	91.8				

* Use on citrus at 0.666 lb ai/A was modeled because it represents the maximum application rate for diflubenzuron. More typically, diflubenzuron is applied to bearing citrus at 0.3125 lb ai/A. EECs from this lower rate would probably be lower and may be closer to those estimated from the cotton use. The cotton EECs will therefore be used to represent exposure and risk to aquatic organisms from treating bearing citrus.

(1) 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			
Usage Group/Application Rate	**Species**	**Acute RQ (96-hr)**	**Chronic RQ (90-day)**
Non-bearing Citrus/ 0.67 lb ai/A	Bluegill	< 0.05	N/A
	Rainbow trout	< 0.05	N/A
	Fathead minnow	< 0.05	< 1.0
Cotton/0.38 lb ai/A and Bearing Citrus/ 0.3215 lb ai/A*	Bluegill	< 0.05	N/A
	Rainbow trout	< 0.05	N/A
	Fathead minnow	< 0.05	< 1.0
Forestry/0.016 lbs. a.i./A	Bluegill	< 0.05	N/A
	Rainbow Trout	< 0.05	N/A
	Fathead Minnow	< 0.05	< 1.0
Forest Trees and Forest Plantings 0.03 lbs. a.i./A	Bluegill	< 0.05	N/A
	Rainbow Trout	< 0.05	N/A
	Fathead Minnow	< 0.05	< 1.0
Forest Trees and Forest Plantings 0.06 lbs. a.i./A	Bluegill	< 0.05	N/A
	Rainbow Trout	< 0.05	N/A
	Fathead Minnow	< 0.05	< 1.0
Forest Trees and Forest Plantings 0.13 lbs. a.i./A	Bluegill	< 0.05	N/A
	Rainbow Trout	< 0.05	N/A
	Fathead Minnow	< 0.05	< 1.0

* The application rate for bearing citrus is slightly lower than that for cotton, however, the resulting exposure is expected to be similar enough to estimate risk.

Diflubenzuron does not exceed acute or chronic LOCs for freshwater fish (and amphibians), based on risk quotients using the acute LC_{50} and chronic NOEL for the most sensitive freshwater fish species tested.

(2) 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			
Usage Group/Application Rate	**Species**	**Acute RQ (96-hr)**	**Chronic RQ (21-day)**
Non-bearing Citrus/0.67 lb ai/A	*Daphnia magna*	2.2	> 38
Cotton/0.38 lb ai/A and Bearing Citrus/ 0.31 lb ai/A*	*Daphnia magna*	1.2	> 31
Forestry 0.02 lb ai/A	*Daphnia magna*	3.2	> 196
Forestry 0.03 lb ai/A	*Daphnia magna*	6.1	> 379
Forestry 0.06 lb ai/A	*Daphnia magna*	12.5	> 771
Forestry 0.13 lb ai/A	*Daphnia magna*	24.8	> 1529

* The application rate for bearing citrus is slightly lower than that for cotton, however, the resulting exposure is expected to be similar enough to estimate risk.

Diflubenzuron exceeds all LOCs based on risk quotients using the acute LC_{50} and chronic NOELs for the most sensitive freshwater invertebrate species tested (Citrus, Cotton, Forestry usage groups). 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 these uses of diflubenzuron may 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 gamefish, waterfowl, shorebirds, small mammals, reptiles, and amphibians.

(3) 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			
Usage Group / Application Rate	**Species**	**Acute RQ (96-hr)**	**Chronic RQ (21-day)***
Non-bearing Citrus/ 0.67 lb ai/A	*M. bahia*	4	51
	M. mercenaria	< 0.05	N/A
	F. heteroclitus	< 0.05**	< 1
Cotton/0.38 lb ai/A and Bearing Citrus/0.31 lb ai/A***	*M. bahia*	2	41
	M. mercenaria	< 0.05	N/A
	F. heteroclitus	< 0.05**	< 1
Forestry 0.02 lb ai/A	*M. bahia*	6	261
	M. mercenaria	< 0.05	N/A
	F. heteroclitus	< 0.05**	< 1
Forestry 0.03 lb ai/A	*M. bahia*	12	506
	M. mercenaria	< 0.05	N/A
	F. heteroclitus	< 0.05**	< 1
Forestry 0.06 lb ai/A	*M. bahia*	23	1028
	M. mercenaria	0.14	N/A
	F. heteroclitus	< 0.05**	< 1
Forestry 0.13 lb ai/A	*M. bahia*	47	2039
	M. mercenaria	0.29	N/A
	F. heteroclitus	< 0.05**	2

* 21-day EEC used for the invertebrate chronic RQ and 90-day EEC for the fish chronic RQ

** Acute risk quotient is based on an acute study endpoint with a 25% formulation on *F. heteroclitus.*

*** The application rate for bearing citrus is slightly lower than that for cotton, however, the resulting exposure is expected to be similar enough to estimate risk.

Diflubenzuron exceeds all LOCs based on RQs using the acute LC_{50}s and chronic NOELs for the most sensitive estuarine/marine invertebrate species tested for the citrus, cotton, and forestry usage groups. 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 LOCs based on RQs using the acute estuarine/marine mollusk LC_{50}s, for 0.06 lbs ai/A and 0.13 lb ai/A application rates, for forest trees and forest plantings uses. Endangered species acute LOCs were exceeded at rates as low as 0.03 lb ai/A for the forestry use.

Diflubenzuron exceeds chronic LOCs based on RQs using the chronic NOEL for the most sensitive marine/estuarine finfish species tested for the forestry usage group at the 0.13 lb ai/A application rate. Therefore use of diflubenzuron may adversely affect endangered and non-endangered marine/estuarine finfish from chronic exposures at the highest use rate for the forestry usage group.

The quotients to estimate risk to shrimp from runoff (cotton and citrus) exceed the LOC by sizeable margins lending higher certainty that effects will occur. However, of special note is the magnitude of the risk quotients if diflubenzuron is directly applied to shallow estuarine habitats. The frequency of this occurring is unknown, so the ecological significance of these numbers is uncertain. However, if direct application does occur, there is a strong probability that diflubenzuron will significantly impact estuarine/marine invertebrate populations.

Further support for this conclusion is based on three marine/estuarine invertebrate field studies that 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.

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 (e.g. shrimp), water fowl, shore birds, and gamefish. Commercially important marine/estuarine invertebrates and finfish may be affected.

c. Exposure and Risk to Nontarget Plants

(1) 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 diflubenzuron.

(2) Aquatic

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

Expected Aquatic Concentrations: The EECs calculated above for aquatic animal exposure are also used for aquatic plants. The only available toxicity data for aquatic plants is the EC_{50} for Selenastrum capricornutum (0.20 mg/L). This value was used to calculate the following risk quotients.

RQ and EEC* Values for Aquatic Plant Species				
Usage Group	**Maximum Application Rate (lb ai/A)**	**Type of Plant**	**EEC (ppb)**	**Risk Quotient (EEC/EC50)**
Non-bearing Citrus	0.67	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	8	0.04
Cotton and Bearing Citrus at 0.3125 lb ai/A**	0.38	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	4	0.02
Forestry	0.02	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	12	0.06
	0.03	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	23	0.11
	0.06	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	46	0.23
	0.13	vascular (*Lemna*)	N/A	N/A
		Algae or diatom	92	0.46

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

** The application rate for bearing citrus is slightly lower than that for cotton, however, the resulting exposure is expected to be similar enough to estimate risk.

Diflubenzuron does not exceed LOCs based on RQs using the acute LC_{50} for the freshwater alga species tested for the citrus, cotton, and forestry usage groups.

d. Endangered Species

Acute and chronic LOCs for endangered species are exceeded for freshwater and estuarine/marine aquatic invertebrates for the citrus, cotton and forestry usage groups. A chronic LOC was exceeded for estuarine/marine fish for the highest forestry use rate (0.13 lb ai/A). The acute LOC for estuarine/marine mollusks was exceeded for the three highest forestry use rates.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing diflubenzuron as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing diflubenzuron. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of diflubenzuron, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of diflubenzuron and to determine that diflubenzuron can be used, with mitigation imposed by this document, without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing diflubenzuron as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed and a list of additional data required for the technical formulation is contained in Section V of this document.

The Agency made its reregistration eligibility determination based upon the data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of diflubenzuron are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing diflubenzuron, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient diflubenzuron, the Agency has sufficient information on the health effects of diflubenzuron and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that diflubenzuron products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diflubenzuron. The total dietary cancer risk for the published tolerances for the overall U.S. population is approximately 1×10^{-6}. Since there are no detections of diflubenzuron in ground water, dietary risk from drinking water is expected to be negligible. Based on very low residues detected in forestry dissipation studies, a low dermal absorption rate, and extremely low dermal and inhalation toxicity, occupational uses of diflubenzuron in residential locations, parks, or forests are expected to result in insignificant risk to people in these areas. Therefore, the Agency concludes that products containing diflubenzuron, once labels have been amended to reflect the risk mitigation measures outlined in this RED, are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of diflubenzuron are eligible for reregistration under the conditions specified in this RED.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for diflubenzuron. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for diflubenzuron, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In

reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from diflubenzuron and other compounds that may have a similar mode/mechanism of toxicity.

Diflubenzuron is a restricted use pesticide and has no homeowner uses, however, diflubenzuron does have occupational uses in residential areas. Based on very low residues detected in forestry dissipation studies, a low dermal absorption rate, and extremely low dermal and inhalation toxicity, occupational uses of diflubenzuron in residential locations, parks, or forests are expected to result in insignificant risk to people in these areas. Additionally, residues/exposure to diflubenzuron in drinking water is not expected and therefore is not a concern (outstanding absorption/desorption data are expected to confirm this conclusion).

Due to the low acute oral toxicity of diflubenzuron, the Agency has determined that an acute dietary risk assessment is not required.

The chronic dietary risk assessment showed that the percent of the RfD utilized by dietary exposure to residues of diflubenzuron is less than 1% for the general U.S. population. Additionally, the total cancer risk estimates for PCA and related metabolites for the overall U.S. population is 1×10^{-6}.

In the case of diflubenzuron, EPA has not yet determined whether or how to include this chemical in a cumulative risk assessment. This reassessment determination therefore does not take into account common mechanism issues. After EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for diflubenzuron, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of diflubenzuron residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from diflubenzuron residues, EPA considered the completeness of the

database for developmental and reproductive effects, the nature and severity of the effects observed, and other information.

Based on the current data requirements, diflubenzuron has a complete database for developmental and reproductive toxicity. In the developmental studies no maternal toxicity or toxicity to the developing fetus was observed. In the reproduction study, no effects on reproductive performance were seen. Furthermore, no effects on reproductive performance were observed at any dose level in F0 or F1 males or females in the 2-generation reproduction study in which parental toxicity (methemoglobinemia, hemolytic anemia, destruction of erythrocytes and pathological changes in the spleen and liver) was observed at all doses tested (i.e., a NOEL was not established). Therefore, EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, the Agency has no epidemiological information suggesting special sensitivity of infants and children to diflubenzuron. Therefore, the Agency finds that the uncertainty factor (100X) routinely used in RfD calculations is adequately protective of infants and children, and an additional uncertainty factor is not warranted for diflubenzuron.

EPA estimates that diflubenzuron residues in the diet of non-nursing infants (less than 1 year) account for less than 1% of the RfD and 1% of the RfD for children aged 1-6 years. Furthermore, residues in drinking water are not expected. Therefore, the Agency has determined that there is reasonable certainty that dietary exposure to diflubenzuron will not cause harm to infants and children.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

2. Tolerance Reassessment

All tolerances for diflubenzuron residues are currently expressed in terms of diflubenzuron *per se* [40 CFR §180.377(a) and (b) and §186.2000]. The Agency's Metabolism Committee has concluded that the tolerance expression should be changed to address combined residues of diflubenzuron and metabolites convertible to

parachloroaniline (PCA), expressed as diflubenzuron. The following table summarizes the tolerance reassessment and recommended modifications in commodity definitions for diflubenzuron.

Tolerance Reassessment Summary for Diflubenzuron			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Tolerances listed under 40 CFR 180.377(a):			
Cattle, fat Cattle, mbyp Cattle, meat	0.05	0.05	
Cotton, seed	0.2	0.2	*Cotton, undelinted seed*
Eggs	0.05	0.05	
Goats, fat Goats, mbyp Goats, meat	0.05	0.05	
Grapefruit	0.5	0.5	
Hogs, fat Hogs, mbyp Hogs, meat	0.05	0.05	
Horses, fat Horses, mbyp Horses, meat	0.05	0.05	
Milk	0.05	0.05	
Mushrooms	0.2	TBD[7]	Data required
Orange	0.5	0.5	
Poultry, fat Poultry, mbyp Poultry, meat	0.05	0.05	
Sheep, fat Sheep, mbyp Sheep, meat	0.05	0.05	
Soybeans	0.05	0.05	*Soybean, seed*
Tangerine	0.5	0.5	
Walnuts	0.1	0.1	
Tolerances listed under 40 CFR 180.377(b):			
Grasses, pasture	1.0	1.0	*Grass, pasture, forage*
Grasses, range	3.0	3.0	*Grass, rangeland*
Feed Additive Tolerances listed under 40 CFR §186.2000:			
Soybeans, hulls	0.5	0.5	

[7] To be determined. Reassessment of tolerance(s) cannot be made at this time. Additional data are required.

Tolerance Reassessment Summary for Diflubenzuron			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Soybeans, soapstock	0.1	Revoke	Soybean soapstock is no longer a regulated commodity.
New Tolerances Required under 40 CFR §180.377(a):			
Cotton, gin by-products	None	TBD	Data are required.
Soybeans, forage	None	TBD	Data are required. Feeding restriction may be allowed.
Soybeans, hay	None	TBD	Data are required. Feeding restriction may be allowed.
New Tolerances Required under 40 CFR §180.377(b):			
Grass, pasture, hay	None	TBD	Data are required.
Proposed Tolerances under 40 CFR §180.377(a):			
Citrus oil	None	75.0	Petition pending (proposed under 40 CFR §185.2000).
Citrus pulp, dried	None	1.0	Petition pending (proposed under 40 CFR §186.2000)

Tolerances Listed Under 40 CFR §180.377(a):

Sufficient data are available to ascertain the adequacy of the established tolerances listed for cottonseed, soybeans, oranges, grapefruit, tangerines, and walnuts, provided that storage stability issues are adequately resolved. Additional magnitude of the residue data are required for mushrooms before the tolerance can be reassessed.

Sufficient data are also available to ascertain the adequacy of the established tolerances listed for milk, eggs, meat, meat byproducts, and fat from livestock. The available data adequately support the 0.05 ppm tolerances for diflubenzuron residues in milk, eggs, meat, fat, and meat byproducts.

Tolerances Listed Under 40 CFR §180.377(b):

The tolerances listed in 40 CFR §180.377(b) are for a regional registration as defined in 180.1(n) for residues of diflubenzuron *per se* in/on pasture and rangeland grass forage. Sufficient data are available to ascertain the adequacy of these established tolerances, provided that storage stability issues are adequately resolved. A petition (PP #5E4499) seeking an increase in the tolerance for rangeland grass from 3.0 to 5.0 ppm has been rejected.

Tolerances Listed Under 40 CFR §186.2000:

Sufficient data are available to ascertain the adequacy of the established feed additive tolerances listed for soybean hulls and soapstock. Since soybean soapstock is no longer a registered commodity, this tolerance should be revoked. The soybean hulls tolerance needs to be moved to 40 CFR §180.377(a).

New Tolerances Required Under 40 CFR §180.377(a):

Table II (June, 1994) indicates that data on cotton gin byproducts (cotton gin trash) are required. A tolerance must be proposed for this commodity once adequate data have been submitted and evaluated.

Proposed Tolerances Under 40 CFR §180.377(a):

A food additive tolerance (FAP#1H5301) is currently pending for residues of diflubenzuron in citrus oil in conjunction with the tolerances for oranges and grapefruit. Sufficient data are available to ascertain the adequacy of the proposed 75 ppm tolerance for residues of diflubenzuron in citrus oil and the Agency has recommended that this tolerance be established (proposed under 40 CFR §185.2000).

Feed additive tolerances are currently pending for residues of diflubenzuron in dried citrus pulp (FAP#5H5472). Sufficient data are available to ascertain the adequacy of the proposed 1 ppm tolerance for residues of diflubenzuron in dried citrus pulp and the Agency has recommended that this tolerance be established (proposed under 40 CFR §186.2000).

New Tolerances Required Under 40 CFR §180.377(b):

Table II (June, 1994) indicates that data on grass hay are required. Tolerances must be proposed for pasture grass hay once adequate data have been submitted and evaluated.

Codex Harmonization

Maximum residue limits (MRLs) have been established by Codex for various commodities. Codex MRLs and the applicable U.S. tolerances are listed in the following table. Codex and U.S. tolerance definitions are presently equivalent as both are expressed in terms of diflubenzuron *per se*, however, the Agency is recommending that the U.S. tolerance expression be changed to "the combined residues of diflubenzuron and metabolites convertible to *p*-chloroaniline, expressed as diflubenzuron." The Agency is basing its risk assessment on the total toxic residues of

diflubenzuron. Once this change is made Codex and U.S. tolerance definitions will no longer be compatible.

Codex MRLs and Applicable U.S. Tolerances.		
Commodity	**MRL (mg/kg)**	**U.S. Tolerance (ppm)**
Brussels sprouts	1	None
Cabbages, head	1	None
Citrus fruits	1	0.5
Cottonseed	0.2	0.2
Edible offal (Mammalian)	0.05	0.05
Eggs	0.05	0.05
Meat	0.05	0.05
Milks	0.05	0.05
Mushrooms	0.1	0.2
Plums (including prunes)	1	None
Poultry meat	0.05	0.05
Soybeans (dry)	0.1	0.05
Tomatoes	1	None

3. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

Acute Dietary

The Agency has determined that a risk assessment for acute dietary risk is not necessary, since one day single dose oral studies in rats and mice indicated no toxic effects other than marginal effects on methemoglobin levels at a dosage of 10,000 mg/kg of a 25% wettable powder formulation.

Chronic Dietary (including cancer)

The Agency has evaluated the chronic dietary risk associated with the use of diflubenzuron based on established and proposed tolerance levels. The RfD was established at 0.02 mg/kg/day based on a chronic toxicity (52-week) study in dogs with a NOEL of 2.0 mg/kg/day. The LEL in the same study was 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia. The chronic exposure analysis results in an ARC that is less than 1% of the RfD for

the overall U.S. population. Children, aged 1 to 6 years, comprise the subpopulation with the greatest exposure levels at 1% of the RfD. The Agency considers exposures of 100% or less of the RfD to be adequately protective.

The Agency also conducted a risk assessment to determine the dietary risk from the diflubenzuron metabolites PCA and CPU. The total cancer risk estimates for PCA and related metabolites for the overall U.S. population does not exceed the Agency's risk level of concern.

(2) Worker (Mixer/Loader/Applicator)

Short-Term and Intermediate Term

The Agency has determined that there is a potential dermal exposure to pesticide handlers. The risk assessment for short term exposure is based on a NOEL of 40 mg/kg/day indicated by the 14-day subchronic oral study in mice that displayed a toxicology endpoint of sulfhemoglobinemia. The MOEs for short term occupational exposure MOEs are acceptable (greater than 100) for handlers wearing long-sleeved shirts, long pants and chemical- resistant gloves.

The risk assessment for intermediate term exposure is based on a NOEL of 2 mg/kg/day from a 13-week subchronic feeding study in dogs with a toxicology endpoint of methemoglobinemia. The MOEs for intermediate term occupational exposure MOEs range from 26 to greater than 1000. These calculations, based on current label information, exceed the Agency's level of concern for 3 of the 34 scenarios. The risk for the unacceptable scenarios will be mitigated by requiring dust/mist respirators (TC-21C) for all mixers, loaders and applicators.

Regarding potential carcinogenic risks to humans resulting from dermal and/or inhalation exposures to PCA and/or CPU occurring during occupational or residential exposures to diflubenzuron, it has been determined that these risks are likely to be negligible since exposure to these metabolites is not anticipated. Only in the event that direct exposure to one or more of these metabolites of diflubenzuron is demonstrated would it be necessary to perform such risk assessments.

(3) Bystander

Due to very low residues detected in forestry dissipation studies, bystander exposure to people in residential locations or forests treated with diflubenzuron is unlikely, outside of contact with direct sprays. In addition, since the dermal absorption rate is low, and exposure is expected to be of a

short-term duration, risk to bystanders during wide-area general outdoor treatments is expected to be minimal.

Although there are no data available to estimate swimmer exposure in treated waters; it appears that sites treated with diflubenzuron would not be used for swimming. Based on the toxicologic concerns for diflubenzuron, a swimmer restriction is required for any current labels having use directions for treating aquatic sites.

b. Environmental

(1) Avian

The Agency has evaluated data to determine the acute and chronic effects of diflubenzuron to birds. The risk quotients for all uses were less than 0.5, the LOC for presuming adverse effects to avian species. The Agency concludes that there will be no adverse effects to birds resulting from the use of diflubenzuron.

(2) Mammals

The Agency has evaluated data to determine the acute and chronic effects of diflubenzuron to mammals. The risk quotients are all less than 0.5, the LOC for presuming adverse effects to mammalian species. Therefore, the Agency concludes that there will be no adverse effects to mammals resulting from the use of diflubenzuron.

(3) Insects

Based on acute honey bee studies, diflubenzuron is practically non-toxic to honey bees. Therefore, honey bees are not likely to be adversely affected by the use of diflubenzuron.

(4) Freshwater Fish

The Agency has evaluated data to determine the acute and chronic effects of diflubenzuron to freshwater fish. The risk quotients were all less than 0.1, the LOC for presuming adverse effects to endangered freshwater fish. The Agency concludes that there will be no adverse effects to freshwater fish resulting from the use of diflubenzuron.

(5) Aquatic Invertebrates

The Agency has evaluated data to determine the acute and chronic effects of diflubenzuron to aquatic invertebrates. The risk quotients range from 1 to greater than 1,500, exceeding all LOCs. Based on this assessment, the Agency concludes that the use of diflubenzuron is expected to cause adverse acute and chronic effects to non-endangered and endangered freshwater invertebrates. 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 gamefish, waterfowl, shorebirds, small mammals, reptiles, and amphibians.

Diflubenzuron is currently a Restricted Use pesticide due to its toxicity to aquatic invertebrates. After reviewing the data submitted to support reregistration, the Agency has determined that this classification is appropriate and that diflubenzuron should remain a Restricted Use pesticide.

To provide additional protection for aquatic invertebrates, the Agency and the registrant have agreed to the following risk mitigation measures:

- row crops and orchard uses must include a 150 foot buffer zone for aerial applications and a 25 foot vegetative buffer strip to decrease runoff in all cases. This buffer strip will also serve as a buffer zone for spray drift from ground applications.

- aerial applications must include the most current spray drift language (see description under Section V)

- all products must bear a hazards statement warning about possible adverse effects to aquatic organisms

(6) Estuarine and Marine Fish

The aquatic EEC from direct application of diflubenzuron to 6 inches of water, as would be expected from the forestry use, at the highest use rates (0.125 lb a.i./acre) exceeds the estuarine fish NOEL (50 ppb). This indicates the possibility of chronic risk to estuarine fish from this use. Since this application rate is not used on a widespread basis, the Agency believes that no additional risk mitigation is necessary.

(7) Estuarine and Marine Invertebrates

Diflubenzuron exceeds all LOCs based on RQs using the acute LC50s and chronic NOELs for the most sensitive estuarine/marine invertebrate species tested. Although this analysis indicates that estuarine/marine animal populations may be adversely effected by the use of diflubenzuron, the Agency believes that the risk mitigation measures discussed above will help to reduce this risk.

(8) Non-Target Plants

Although there is no acceptable data for plants, a supplemental study indicates that diflubenzuron does not exceed LOCs based on RQs using the LC_{50} for the freshwater alga species tested. Therefore, the Agency does not expect any adverse effects to non-target plants resulting from the use of diflubenzuron.

(9) Endangered Species

The Agency has concerns about the exposure of threatened and endangered aquatic invertebrate species to diflubenzuron as discussed above in the science assessment chapter. Endangered species LOCs have been exceeded for both acute and chronic effects for freshwater and estuarine/marine aquatic invertebrates. The risk mitigation measures specified above will reduce exposure and risk to threatened and endangered species.

(10) Surface Water

The Agency has determined that substantial amounts of diflubenzuron could be available for runoff to surface waters for several days to weeks post-application. This runoff is expected to be primarily via adsorption to eroding soil. Only in cases where the runoff volume is much greater than the sediment yield would dissolution in runoff water contribute significantly to the total pesticide runoff. Since much of the diflubenzuron in aquatic systems will be adsorbed to bottom sediment, the Agency does not expect diflubenzuron to contaminate surface waters.

(11) Ground Water

Diflubenzuron does not exceed any groundwater LOCs and no diflubenzuron detections have been reported in EPA's Pesticides in Ground Water Database. Although there are no indications that diflubenzuron *per se* is

a concern to groundwater, the Agency is requiring additional data to better understand the mobility and persistence of CPU in the environment.

4. Occupational Labeling Rationale

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Some of the registered uses of diflubenzuron are within the scope of the Worker Protection Standard and some uses are outside the scope of the WPS. Those uses that are outside the scope of the WPS including the following:

- mosquito abatement, gypsy moth control, or similar government-sponsored wide-area public pest control programs;
- on livestock or other animals;
- aquatic sites for mosquito control;
- plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit; and

- those uses not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way, in hedgerows and fencerows and in other non-crop areas.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

Occupational-Use Products (WPS and Non-WPS Uses)

The PPE requirements will pertain to both the WPS and non-WPS uses, since the potential exposure to occupational handlers is similar for all uses.

For each occupational end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc), then EPA may establish minimum or baseline handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient. EPA will then compare the minimum PPE requirements with the PPE designated on the basis of the acute toxicity of each end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders and persons cleaning equipment) chemical-resistant aprons.

All Formulations

The data EPA used to assess the handler risks resulting from exposures to diflubenzuron were based on exposure scenarios where mixers/loaders supporting ground and aerial applications and mixer/loader/applicators using hand-held application equipment wore chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes and socks. Therefore, chemical-resistant gloves are required for all such handlers for all formulations, except oral bolus pellet or tablet formulations.

Oral bolus Pellet or Tablet Formulations

There are no special risk concerns that warrant the establishment of active-ingredient-based minimum (baseline) PPE for handlers of oral bolus formulations because the use of balling guns to administer the pesticide is expected to limit applicator exposure.

Wettable Powder Formulations

There are no special risk concerns for handlers based on their potential for **short-term** exposure to wettable powders. The MOEs for short-term exposures were calculated as being acceptable for mixers, loaders, flaggers and applicators of such formulations.

For **intermediate-term** exposure, EPA has determined that regulatory action must be taken for mixers and loaders. The MOEs for mixer/loaders supporting aerial agricultural/horticultural and wide-area tree insect applications are not acceptable unless dust/mist filtering respirators (and chemical-resistant gloves) are worn. As a prudent risk-reduction measure, the Agency is requiring dust/mist filtering respirators (and chemical-resistant gloves) for all mixers and loaders handling wettable powder formulations to support aerial applications. For mixer/loaders supporting ground applications, tree insect uses, chemical-resistant gloves plus long-sleeved shirts and long pants will provide acceptable MOEs.

Liquid/Flowable Formulations

For the liquid/flowable formulations, EPA has determined that no regulatory action must be taken for handlers based on their potential for short-term or intermediate-term exposure. The MOEs for short-term and intermediate-term exposures were calculated as being acceptable for mixers, loaders, flaggers and applicators of such formulations.

Homeowner-Use Products

There are at this time no known formulations of diflubenzuron intended for home use.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established on the basis of the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS RED is established at 12 hours. A 48 hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REIs established by the Agency prior to the promulgation of the WPS: product-specific REIs established on the basis of adequate data and interim REIs that are longer than those that would be established under the WPS.

For occupational end-use products containing diflubenzuron as an active ingredient, EPA is retaining the interim 12-hour restricted-entry interval for each use of the product that is within the scope of the Worker Protection Standard (WPS). The basis for this recommendation is that diflubenzuron has a low dermal absorption rate, however, diflubenzuron also has a toxicological endpoint of concern for systemic toxicity for intermediate-term exposure that impacts several post-application scenarios. These post-application scenarios (such as citrus and chrysanthemum harvest) have the potential for higher exposure than some of the handler scenarios identified in this RED. This interim REI shall be in effect until specific reentry data are submitted and reviewed. EPA notes that the WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. EPA believes that existing WPS protection is sufficient to mitigate post-application exposures of workers who contact surfaces treated with diflubenzuron.

The WPS interim REI in effect until now was 12 hours (based on acute dermal Toxicity Category III). The WPS interim REI was established through labeling modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry by workers if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

There are special risk concerns about the wettable powder and liquid/flowable formulations, since diflubenzuron has a toxicological endpoint of concern for systemic toxicity and low MOEs for some handlers. In addition, there are no data to evaluate the post-application risk to this chemical. Due to diflubenzuron's low dermal absorption rate EPA is not establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established based on the acute toxicity of the active ingredient. Since diflubenzuron is classified as category III for eye irritation potential, protective eyewear is not required.

Occupational-Use Products (Non-WPS Uses)

The Agency is establishing entry restrictions for all non-WPS occupational uses of diflubenzuron end-use products. For specific language, refer to Section V of this document.

5. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in the future. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of diflubenzuron for the above eligible uses has been reviewed and determined to be substantially complete. However, in order to more fully understand the effects of diflubenzuron and confirm the assumptions upon which this reregistration eligibility decision is based, the following data are required:

72-3	Estuarine/Marine toxicity fish
82-4	21-day inhalation
132-1(a)	Foliar residue dissipation (tree crops such as citrus, medium-height crops such as cotton or soybeans, and greenhouse-grown crops such as chrysanthemums)
132-1(b)	Soil residue dissipation (mushroom crops only)

133-3,4	Dermal and inhalation passive dosimetry exposure[8]
162-4	Aerobic aquatic metabolism
163-1	Adsorption/Desorption (on CPU and bare ground data from typical use areas in the north)
164-2	Aquatic (sediment) dissipation
164-3	Forestry dissipation
165-2	Field rotational crops
165-3	Accumulation in irrigated crops
165-5	Accumulation in aquatic non-target organisms
171-4c	Residue analytical methods
171-4e	Storage stability
171-4k	Magnitude of residue in plants
202-1	Field drift evaluation

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an insecticide for the following uses:_____ (fill blank only with those uses that are being supported by MP registrant)."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under Directions for Use to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

B. End-Use Products

[8] Requirement may be satisfied with data generated by the Agricultural Reentry Task Force and Outdoor Residential Exposure Task Force, provided the registrant is a member.

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Restrictions prohibiting the cutting of treated grass hay for livestock must be deleted from all labels. All labels allowing repeated applications must be amended to list the minimum retreatment interval.

Non-granular End-Use Products

"This pesticide is toxic to aquatic invertebrates. For terrestrial uses, 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."

Aquatic Use Sites (mosquito larvicides)

"This pesticide is toxic to aquatic invertebrates. Fish and aquatic inverterates 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."

"Do not use in potable water or in water used for swimming."

Row Crop and Orchard Uses

"Do not apply within 25 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries."

3. Occupational/Residential Labeling

a. PPE Requirements for Pesticide Handlers

All end-use products containing diflubenzuron have only one active ingredient. Therefore, all labels must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Products intended Primarily for Occupational Use

Minimum (baseline) PPE requirements -- Some of the registered uses of diflubenzuron are within the scope of the WPS and some are outside the scope of the WPS. The minimum (baseline) PPE requirements pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure is similar for WPS and nonWPS uses.

Oral Bolus Pellet/Tablet Formulations

There are no minimum (baseline) PPE requirements for diflubenzuron end-use products formulated as oral bolus pellets or tablets.

Wettable Powder Formulations

The minimum (baseline) PPE for **applicators and other handlers (other than mixers and loaders)** for all occupational uses of diflubenzuron end-use products formulated as wettable powders is:

"Applicators and other handlers (other than mixers and loaders must wear:
-- Long-sleeved shirt and long pants
-- Chemical-resistant gloves
-- Shoes plus socks
-- A dust/mist respirator (MSHA/NIOSH approval number TC-21C)"

The minimum **mixer/loader** (baseline) PPE requirements for occupational uses of diflubenzuron end-use products formulated as wettable powders in water soluble packets:

"Mixers and loaders must wear:
-- Long-sleeved shirt and long pants
-- Chemical-resistant gloves
-- Shoes plus socks
-- A dust/mist respirator (MSHA/NIOSH approval number TC-21C)"

Liquid and Flowable Formulations

The minimum (baseline) handler PPE requirements for occupational uses of diflubenzuron end-use products formulated as liquids or flowables is:

"Applicators and other handlers (other than mixers and loaders must wear:
-- Long-sleeved shirt and long pants
-- Chemical-resistant gloves when mixing and loading and also when using hand-held equipment
-- Shoes plus socks"

Actual end-use product PPE requirements -- The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in labeling -- The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Products Intended primarily for Occupational Use

WPS uses

Restricted-entry interval -- a 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products with WPS uses(see tests in PR Notices 93-7 and 93-11).

Early-entry personal protective equipment (PPE) --
The PPE required for early entry following applications of both the wettable powder and flowable concentrate formulations is:

-- Coveralls
-- Chemical-resistant gloves,
-- Shoes plus socks

Placement in labeling -- The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7.

Non-WPS uses

Entry restrictions-- For all applications (except aquatic sites and wide-area government-sponsored pest control programs, such as for mosquito or gypsy-moth control):

"Do not enter or allow others to enter the treated area until sprays have dried."

Placement in labeling --

If WPS uses are also on the label: Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate non-WPS entry restriction in that box.

If no WPS uses are on the label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

4. Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing diflubenzuron that are intended primarily for occupational use.

Application Restrictions (except wide-area government-sponsored pest control programs, such as for mosquito or gypsy-moth control):

"Do not apply this product in a way that will contact workers of other persons, either directly or through drift. Only protected handlers may be in the area during application."

"Do not apply this product to bodies of water where swimming is likely."

Engineering Controls:

--For all formulations:

"When handlers use closed systems (including water soluble bags), enclosed cabs or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should was hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Respirator Type:

The following type of respirator is appropriate to mitigate diflubenzuron inhalation concerns:

"A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)

Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing diflubenzuron. For specific language, refer to Section V of this document.

5. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

> Do not apply within 150 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.
>
> Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.
>
> The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.
>
> 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
>
> 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
>
> Where states have more stringent regulations, they shall be observed.
>
> The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.
>
> The following aerial drift reduction advisory information must be contained in the product labeling:
>
> [The Spray Drift Labeling section is advisory in nature and does not supersede the mandatory label requirements.]
>
> **INFORMATION ON DROPLET SIZE**
>
> The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger

droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell diflubenzuron products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
BEEF/RANGE/FEEDER CATTLE (MEAT)			Use Group: INDOOR FOOD									
Bolus, When needed, Handgun	P/T	NA	.01069 lb 550 lb animal	*	NS NS	NS	NS	NS	NS			CAL
CHERRY			Use Group: TERRESTRIAL FOOD CROP									
Spray, Postharvest, Not on label	WP	NA	.25 lb A	*	NS 3/1 yr	NS	NS	NS	NS	OR		C46
COTTON (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Foliar, Ground	FlC	NA	.125 lb A	*	6 NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
Directed spray, Foliar, Ground	FlC	NA	.125 lb A	*	NS NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
Spray, At pinhead square, Aircraft	FlC	NA	.125 lb A	*	NS NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
Spray, At pinhead square, Ground	FlC	NA	.125 lb A	*	NS NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
Spray, Foliar, Aircraft	FlC	NA	.125 lb A	*	6 NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
	WP	NA	.125 lb A	*	NS NS	.375 lb	NS	5	.5 d			C92, CCB
Spray, Foliar, Ground	FlC	NA	.125 lb A	*	NS NS	.375 lb	NS	5	12 h			C46, C92, C94, CAL, CCB
	WP	NA	.125 lb A	*	NS NS	.375 lb	NS	5	.5 d			C92, CCB
Ultra low volume, When needed, Aircraft	FlC	NA	.0625 lb A	*	NS NS	.375 lb	NS	NS	.5 d	AL		C46
Ultra low volume, When needed, Ground	FlC	NA	.0625 lb A	*	NS NS	.375 lb	NS	NS	.5 d	AL		C46

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
DAIRY CATLE (LACTATING OR UNSPECIFIED)					Use Group: INDOOR FOOD							
Bolus, When needed, Handgun	P/T	NA	.01069 lb 550 lb animal	*	NS	NS	NS	NS	NS	NS		CAL
DAIRY CATTLE (NON-LACTATING)					Use Group: INDOOR FOOD							
Bolus, When needed, Handgun	P/T	NA	.01069 lb 550 lb animal	*	NS	NS	NS	NS	NS	NS		CAL
GRAPEFRUIT					Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray, Foliar, Ground	WP	NA	.3125 lb A	*	NS	NS	NS	.3125 lb	NS	2 d	FL 013	C46, C92, C94, CAL, GH3, H01(21)
					Geo.013: In Florida, except do not apply east of U.S. Highway #1, south and east of State Road #846/832, or south of West Palm Beach Canal.							
INTERMITTENTLY FLOODED AREAS/WATER					Use Group: AQUATIC FOOD CROP							
Broadcast, Not on label, Aircraft	WP	NA	.04 lb A	*	NS	NS	NS	NS	10	NS	CA	C97
Broadcast, Not on label, Ground	WP	NA	.04 lb A	*	NS	NS	NS	NS	10	NS	CA	C97
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
IRRIGATION SYSTEMS				Use Group: AQUATIC FOOD CROP								
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
LAKES/PONDS/RESERVOIRS (WITH HUMAN OR WILDLIFE USE)				Use Group: AQUATIC FOOD CROP								
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI	CAH
Spray, When needed, Boat	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA	
Spray, When needed, Ground	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA	
MUSHROOM HOUSES/MUSHROOM CASING SOILS				Use Group: GREENHOUSE FOOD CROP								
Compost treatment, Before spawning, Spawning machine	WP	NA	1 lb 1K sq.ft	*	NS	NS	NS	NS	NS	.5 d		C92
Compost treatment, Not on label, Spawning machine	WP	NA	1 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h		C92, C94, CAL
Compost treatment, When needed, Spawning machine	SC/L	NA	1 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h	PA	C46, CAL, CAU
Soil treatment (mushroom casing), Not applicable, Not on label	WP	NA	.2109 lb 1K sq.ft	*	NS	NS	NS	NS	NS	.5 d		C92
	WP	NA	.2109 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h		C92, C94, CAL

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
MUSHROOM HOUSES/MUSHROOM CASING SOILS (con't)				Use Group: GREENHOUSE FOOD CROP (con't)								
Soil treatment (mushroom casing), When needed, Drencher	SC/L	NA	.2109 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h	PA	C46, CAL, CAU
Soil treatment (mushroom casing), When needed, Soil incorporation equipment	SC/L	NA	.2109 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h	PA	C46, CAL, CAU
ORANGE				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray, Foliar, Ground	WP	NA	.3125 lb A	*	NS	NS	NS	.3125 lb	NS	2 d	FL 013	C46, C92, C94, CAL, GH3, H01(21)
					Geo.013: In Florida, except do not apply east of U.S. Highway #1, south and east of State Road #846/832, or south of West Palm Beach Canal.							
PASTURES				Use Group: TERRESTRIAL FEED CROP								
Broadcast, When needed, Aircraft	WP	NA	.04 lb A	*	NS	6/1 yr	NS	NS	7	NS	013	CAL, G01(1), G87
					Geo.013: Restricted to counties in Central California areas where irrigated pastures are found.							
Broadcast, When needed, Ground	WP	NA	.04 lb A	*	NS	6/1 yr	NS	NS	7	NS	013	CAL, G01(1), G87
					Geo.013: See above							
SOYBEANS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP								
Spray, Foliar, Aircraft	FlC	NA	UC	*	2	NS	NS	NS	21	12 h	CA	C46, C92, C94, CAL, CCB, H01(21)
	WP	NA	.0625 lb A	*	2	NS	NS	NS	NS	.5 d	CA	C92, CCB, G17, G31, GC9, H01(21)
	WP	NA	.0625 lb A	*	2	NS	NS	NS	NS	NS	CA	CAL, CCB, GG, GN7, H11(21)
Spray, Foliar, Ground	FlC	NA	UC	*	2	NS	NS	NS	21	12 h	CA	C46, C92, C94, CAL, CCB, H01(21)

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

SOYBEANS (UNSPECIFIED) (con't) — Use Group: TERRESTRIAL FOOD+FEED CROP (con't)

	WP	NA	.0625 lb A	*	2	NS	NS	NS	NS	.5 d	CA		C92, CCB, G17, G31, GC9, H01(21)
	WP	NA	.0625 lb A	*	2	NS	NS	NS	NS	NS	CA		CAL, CCB, GG, GN7, H11(21)

STREAMS/RIVERS/CHANNELED WATER — Use Group: AQUATIC FOOD CROP

Spray, When needed, Boat	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA		
Spray, When needed, Ground	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA		

TANGERINES — Use Group: TERRESTRIAL FOOD+FEED CROP

Spray, Foliar, Ground	WP	NA	.3125 lb A	*	NS	NS	NS	.3125 lb	NS	2 d	FL	013	C46, C92, C94, CAL, GH3, H01(21)

Geo.013: In Florida, except do not apply east of U.S. Highway #1, south and east of State Road #846/832, or south of West Palm Beach Canal.

WALNUT (ENGLISH/BLACK) — Use Group: TERRESTRIAL FOOD CROP

Spray, When needed, Ground	WP	NA	.5 lb A	*	3	NS	1.5 lb	NS	21	NS	CA		C46, H01(28)

NON-FOOD/NON-FEED

CHRISTMAS TREE PLANTATIONS — Use Group: TERRESTRIAL NON-FOOD CROP

Spray, Foliar, Aircraft	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	AR		C46
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	MS		
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	OK		
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	TN		C46

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
CHRISTMAS TREE PLANTATIONS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS		CAL
Spray, Foliar, Ground	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d		C92
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS		CAL
Spray, Foliar, Low volume ground sprayer	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	AR	C46
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	MS	
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	OK	
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	TN	C46
CITRUS FRUITS				Use Group: GREENHOUSE NON-FOOD CROP								
Spray, Nonbearing, Ground	WP	NA	.01435 lb 1K sq.ft	*	NS	NS	NS	NS	AN	.5 d	FL	C46
				Use Group: TERRESTRIAL NON-FOOD CROP								
Spray, Nonbearing, Aircraft	WP	NA	.625 lb A	*	NS	NS	NS	NS	AN	.5 d	FL	C46
Spray, Nonbearing, Ground	WP	NA	.625 lb A	*	NS	NS	NS	NS	AN	.5 d	FL	C46
DRAINAGE SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Broadcast, May, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	10	NS	CA	C97
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
DRAINAGE SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Spray, When needed, Boat	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA		
Spray, When needed, Ground	WP	NA	.25 lb A	*	NS	NS	NS	1.5 lb	AN	NS	CA		
FOREST NURSERY PLANTINGS (FOR TRANSPLANT PURPOSES)				Use Group: TERRESTRIAL NON-FOOD CROP									
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
FOREST PLANTINGS (REFORESTATION PROGRAMS)(TREE FARMS, TREE PLANTATIONS				Use Group: FORESTRY									
Ground spray, Foliar, Airblast	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	.125 lb A	*	2	1/1 yr	NS	NS	7	12 h			C46, CAL, CAU
FOREST TREES (ALL OR UNSPECIFIED)				Use Group: FORESTRY									
Ground spray, Foliar, Airblast	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	.125 lb A	*	2	1/1 yr	NS	NS	7	12 h			C46, CAL, CAU
Spray, Foliar, Aircraft	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
FOREST TREES (ALL OR UNSPECIFIED) (con't)				Use Group: FORESTRY (con't)									
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL
Spray, Foliar, Ground	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL
Spray, Foliar, Mist blower	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	NS			CAL
GOLF COURSE TURF				Use Group: TERRESTRIAL NON-FOOD CROP									
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
GREENHOUSE-EMPTY				Use Group: INDOOR NON-FOOD									
Indoor general surface treatment, When needed, Sprayer	WP	NA	.0375 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL
INDUSTRIAL WASTE DISPOSAL SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI		CAH

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
INTERMITTENTLY FLOODED AREAS/WATER				Use Group: AQUATIC NON-FOOD OUTDOOR									
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI		CAH
LAKES/PONDS/RESERVOIRS (WITHOUT HUMAN OR WILDLIFE USE)				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI		CAH
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Soil drench treatment, When needed, Drencher	WP	NA	.0375 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL
Soil treatment, When needed, Shaker jar	WP	NA	.0375 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle		Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL AND/OR SHADE TREES					Use Group: GREENHOUSE NON-FOOD CROP								
Chemigation, Foliar, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h			C92, C94, CAL
Chemigation, When needed, Irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Chemigation, When needed, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Soil drench treatment, When needed, Drencher	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Soil treatment, When needed, Low pressure ground sprayer	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Spray, Foliar, Ground	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL		C46
Spray, Foliar, Sprayer	WP	NA	.00625 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h			C92, C94, CAL
Spray, When needed, Ground	WP	NA	.125 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL
					Use Group: TERRESTRIAL NON-FOOD CROP								
Spray, Foliar, Aircraft	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL		C46
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	AR		C46
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	MS		
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	OK		

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL AND/OR SHADE TREES (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	TN	C46
Spray, Foliar, Ground	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d		C92
	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL	C46
Spray, Foliar, Low volume ground sprayer	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	AR	C46
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	MS	
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	OK	
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	AN	NS	TN	C46
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h		C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h		C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h		C46, CAL, CAU
Spray, Foliar, Aircraft	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS		CAL
Spray, Foliar, Ground	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS		CAL
Spray, Foliar, Mist blower	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	NS		CAL
ORNAMENTAL HERBACEOUS PLANTS				Use Group: GREENHOUSE NON-FOOD CROP								
Chemigation, Foliar, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h		C92, C94, CAL
Chemigation, When needed, Irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year cycle	Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL HERBACEOUS PLANTS (con't)				**Use Group: GREENHOUSE NON-FOOD CROP (con't)**								
Chemigation, When needed, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL
Soil drench treatment, When needed, Drencher	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL
Soil treatment, When needed, Low pressure ground sprayer	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL
Spray, Foliar, Ground	WP	NA	.25 lb A	*	NS	NS	NS	NS	AN	.5 d	FL	C46
Spray, Foliar, Sprayer	WP	NA	.00625 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h		C92, C94, CAL
Spray, When needed, Ground	WP	NA	.125 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h		C92, C94, CAL
			Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, Foliar, Aircraft	WP	NA	.25 lb A	*	NS	NS	NS	NS	AN	.5 d	FL	C46
Spray, Foliar, Ground	WP	NA	.25 lb A	*	NS	NS	NS	NS	AN	.5 d	FL	C46
			Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Spray, Foliar, Not on label	WP	NA	.25 lb A	*	NS	NS	NS	NS	7	.5 d		C92
ORNAMENTAL NONFLOWERING PLANTS				**Use Group: GREENHOUSE NON-FOOD CROP**								
Chemigation, Foliar, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h		C92, C94, CAL
Chemigation, When needed, Irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL
Chemigation, When needed, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h		C92, C94, CAL

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL NONFLOWERING PLANTS (con't)				Use Group: GREENHOUSE NON-FOOD CROP (con't)									
Soil drench treatment, When needed, Drencher	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Soil treatment, When needed, Low pressure ground sprayer	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Spray, Foliar, Sprayer	WP	NA	.00625 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h			C92, C94, CAL
Spray, When needed, Ground	WP	NA	.125 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL
ORNAMENTAL PONDS/AQUARIA				Use Group: AQUATIC NON-FOOD RESIDENTIAL									
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: GREENHOUSE NON-FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	NS	NS	NS	NS	NS	12 h			C92, C94, CAL
Chemigation, When needed, Irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Chemigation, When needed, Sprinkler irrigation	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL

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←(s0p10H←&l8C←(s3BCase 0144 [Diflubenzuron] Chemical 108201 [Diflubenzuron]
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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle		Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				**Use Group: GREENHOUSE NON-FOOD CROP (con't)**									
Soil drench treatment, When needed, Drencher	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Soil treatment, When needed, Low pressure ground sprayer	WP	NA	.009375 lb 1K sq.ft	*	4	NS	NS	NS	28	12 h			C92, C94, CAL
Spray, Foliar, Ground	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL		C46
Spray, Foliar, Sprayer	WP	NA	.00625 lb 1K sq.ft	*	NS	NS	NS	NS	7	12 h			C92, C94, CAL
Spray, When needed, Ground	WP	NA	.125 lb 1K sq.ft	*	NS	NS	NS	NS	28	12 h			C92, C94, CAL
				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, Foliar, Aircraft	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL		C46
Spray, Foliar, Ground	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.25 lb/100 gal	*	NS	NS	NS	NS	AN	.5 d	FL		C46
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Spray, Foliar, Aircraft	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle		Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)									
Spray, Foliar, Ground	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL
Spray, Foliar, Mist blower	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	NS			CAL
RECREATIONAL AREAS				Use Group: TERRESTRIAL NON-FOOD CROP									
Ground spray, Foliar, Airblast	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	UC	*	2	NS	NS	NS	7	12 h			C46, CAL, CAU
Spray, Foliar, Aircraft	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL
Spray, Foliar, Ground	WP	NA	.0625 lb A	*	NS	NS	NS	NS	NS	NS			CAL
Spray, Foliar, Mist blower	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d			C92
	WP	NA	.0625 lb A	*	NS	1/1 yr	NS	NS	NS	NS			CAL
REFUSE/SOLID WASTE SITES (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL		C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV		C46

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←(s0p16.66H←&l5.45C←(s0B

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
REFUSE/SOLID WASTE SITES (OUTDOOR) (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI	CAH
SEWAGE SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Broadcast, May, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	10	NS	CA	C97
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46
Spray, Not on label, Not on label	WP	NA	.025 lb A	*	NS	NS	NS	NS	10	NS	HI	CAH
SHELTERBELT PLANTINGS				Use Group: FORESTRY								
Ground spray, Foliar, Airblast	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h		C46, CAL, CAU
Ground spray, Foliar, Hydraulic sprayer	SC/L	NA	.125 lb A	*	2	NS	NS	NS	7	12 h		C46, CAL, CAU
Low volume spray (concentrate), Foliar, Aircraft	SC/L	NA	.125 lb A	*	2	1/1 yr	NS	NS	7	12 h		C46, CAL, CAU
Spray, Foliar, Aircraft	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d		C92
Spray, Foliar, Ground	WP	NA	.125 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d		C92
WIDE AREA/GENERAL OUTDOOR TREATMENT (PUBLIC HEALTH USE)				Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast, Not on label, Not on label	WP	NA		*	NS	NS	NS	NS	NS	NS	HI	CAH

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←(s0p16.66H←&l5.45C←(s0B

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
WIDE AREA/GENERAL OUTDOOR TREATMENT (PUBLIC HEALTH USE) (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
Broadcast, When needed, Aircraft	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46, CCB, GA1
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46, CCB, GA1
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46, CCB, GA1
Broadcast, When needed, Ground	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	AL	C46, CCB, GA1
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	FL	C46, CCB, GA1
	WP	NA	.05 lb A	*	NS	NS	NS	NS	NS	NS	NV	C46, CCB, GA1
WIDE AREA/GENERAL OUTDOOR TREATMENT (QUARANTINE/ERADICATION USE)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Spray, Foliar, Mist blower	WP	NA	.03125 lb A	*	NS	2/1 yr	NS	NS	7	NS		CAL
Spray, Nurserystock, Aircraft	WP	NA	.03125 lb A	*	NS	2/1 yr	NS	NS	7	.5 d		C92
	WP	NA	.03125 lb A	*	NS	2/1 yr	NS	NS	7	NS		CAL
Spray, Nurserystock, Ground	WP	NA	.03125 lb A	*	NS	2/1 yr	NS	NS	7	.5 d		C92

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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

FlC	: FLOWABLE CONCENTRATE
P/T	: PELLETED/TABLETED
SC/L	: SOLUBLE CONCENTRATE/LIQUID
WP	: WETTABLE POWDER

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight

nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

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USE LIMITATIONS CODES

C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.
C97 : Water from treated systems may not be used for irrigation or spraying of agricultural crops, lawns, or ornamental plants, or for watering cattle, goats, hogs, horses, poultry or sheep, or for human consumption.
CAH : Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES Permit.
CAL : Do not contaminate water, food or feed.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
CCB : Rotational/plant back crop restriction.
G01 : __ day(s) pregrazing interval.
G17 : Do not graze dairy animals in treated areas.
G31 : Do not graze meat animals in treated areas.
G87 : Do not harvest or feed hay to livestock.
GA1 : Do not graze treated areas or feed crop refuse to livestock.
GC9 : Do not graze or forage crop grown in treated soil or cut for hay or silage.
GG : Do not cut green forage or hay for livestock feed.
GH3 : Do not graze livestock in treated orchards or cut treated cover crops for feed.
GN7 : Do not allow livestock to graze treated foliage.
H01 : __ day(s) preharvest interval.
H11 : __ day(s) preharvest interval (grain).
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

013 : Other
AL : Alabama
AR : Arkansas
CA : California
FL : Florida
HI : Hawaii
MS : Mississippi
NV : Nevada
OK : Oklahoma
OR : Oregon
PA : Pennsylvania
TN : Tennessee

REENTRY INTERVAL ABBREVIATIONS

d : day(s)
h : hour(s)

UNIT DESCRIPTIONS

A : acre
gal : gallon
lb : pound
lb animal : Not in LUIS Unit Conversion Vocabulary File
sq.ft : square foot

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Diflubenzuron covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Diflubenzuron in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	00143356, 00155176, 00161933, 00162464
61-2	**Start. Mat. & Mnfg. Process**	All	00143356, 00155176, 00161933, 00162464
61-3	**Formation of Impurities**	All	00143356, 00155176, 00161933, 00162464
62-1	**Preliminary Analysis**	All	00155175, 40718001, 40718002, 42759501 42759502, 41126001 - DATA GAP
62-2	**Certification of limits**	All	40718001, 40718002, 41126001
62-3	**Analytical Method**	All	00161933, 00162464, 40718001, 40718002 41126001, 42446901, 42446902
63-2	**Color**	All	00143356, 00161933, 00162464
63-3	**Physical State**	All	00143356, 00161933, 00162464
63-4	**Odor**	All	00143356, 00161933, 00162464
63-5	**Melting Point**	All	00143356, 00161933
63-6	**Boiling Point**	All	WAIVED - Not required for a solid.
63-7	**Density**	All	00143356, 00161933, 00162464
63-8	**Solubility**	All	00143356, 00161933, 41669601
63-9	**Vapor Pressure**	All	00143356, 00161933
63-10	**Dissociation Constant**	All	00143356, 00161933
63-11	**Octanol/Water Partition**	All	00143356, 00161933
63-12	**pH**	All	00143356, 00161933, 00162464

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	All	00143356, 00161933
63-14	**Oxidizing/Reducing Action**	All	00162464
63-15	**Flammability**		WAIVED - Not required for a solid.
63-16	**Explodability**	All	41349501
63-17	**Storage stability**	All	41664901
63-18	**Viscosity**		WAIVED - Not required for a solid.
63-19	**Miscibility**		WAIVED - Not required for a solid.
63-20	**Corrosion characteristics**	All	00162464, 42267601
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	**ABC**	00038614, 00073936, 00073935
71-2A	**Avian Dietary - Quail**	**ABC**	00038613
71-2B	**Avian Dietary - Duck**	**ABC**	00039080
71-3	**Wild Mammal Toxicity**	**ABC**	00157103
71-4A	**Avian Reproduction - Quail**	**ABC**	41668002, 00099862, 00099719, 00099730
71-4B	**Avian Reproduction - Duck**	**ABC**	41668001, 00099862
72-1A	**Fish Toxicity Bluegill**	**ABC**	00056150, 40094602**,** 00056035
72-1B	**Fish Toxicity Bluegill - TEP**	**ABC**	40094602**,** 00056150**,** 00060380
72-1C	**Fish Toxicity Rainbow Trout**	**ABC**	00056150**,** 40094602
72-1D	**Fish Toxicity Rainbow Trout- TEP**	**ABC**	40094602**,** 00056150**,** 00060380**,** 00060384
72-2A	**Invertebrate Toxicity**	**ABC**	43665801**,** 40840502**,** 40094602, 40098001
72-2B	**Invertebrate Toxicity - TEP**	**ABC**	40094602**,** 40094602**,** 40098001

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
72-3A	**Estuarine/Marine Toxicity - Fish**	**ABC**	DATA GAP
72-3B	**Estuarine/Marine Toxicity - Mollusk**	**ABC**	41392001
72-3C	**Estuarine/Marine Toxicity - Shrimp**	**ABC**	43662001, 40098001, 00038612
72-3D	**Estuarine/Marine Toxicity Fish-TEP**		00056150
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		00038611, 00039088
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		WAIVED
72-4A	**Early Life Stage Fish**	**ABC**	00099755
72-4B	**Life Cycle Invertebrate**	**ABC**	00010865, 00073933, 43662001, 40237501 40840501
72-5	**Life Cycle Fish**	**ABC**	00099722
72-7B	**Actual Field - Aquatic Organisms**	**ABC**	05000841, 00099897, 00038213, 00099791 00071210, 00099891, 00099839, 00038212 00039090, 00039091, 00039092, 00095416 00099678, 00099895
122-2	**Aquatic Plant Growth**		42487101
141-1	**Honey Bee Acute Contact**		00040601, 05001991
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	**ABC**	00157103

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**ABC**	00157104
81-3	**Acute Inhalation Toxicity - Rat**	**ABC**	00163311, 00044325
81-4	**Primary Eye Irritation - Rabbit**	**ABC**	00157105
81-5	**Primary Dermal Irritation - Rabbit**	**ABC**	00157106
81-6	**Dermal Sensitization - Guinea Pig**	**ABC**	42251101
82-1A	**90-Day Feeding - Rodent**	**ABC**	00099713, 00070018, 00064550, 00074534 00074534, 00114330
82-1B	**90-Day Feeding - Non-rodent**	**ABC**	00038706
82-2	**21-Day Dermal - Rabbit/Rat**	**ABC**	00038716, 43954101
82-4	**90-Day Inhalation - Rat**	**ABC**	DATA GAP
83-1A	**Chronic Feeding Toxicity - Rodent**	**ABC**	00044329, 00099712, 00145467, 00142490
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	**ABC**	00146174
83-2A	**Oncogenicity - Rat**	**ABC**	00145467
83-2B	**Oncogenicity - Mouse**	**ABC**	00142190
83-3A	**Developmental Toxicity - Rat**	**ABC**	41703504
83-3B	**Developmental Toxicity - Rabbit**	**ABC**	41703505
83-4	**2-Generation Reproduction - Rat**	**ABC**	43578301
84-2A	**Gene Mutation (Ames Test)**	**ABC**	41703503
84-2B	**Structural Chromosomal Aberration**	**ABC**	41703502

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
84-4	**Other Genotoxic Effects**	**ABC**	41703501
85-1	**General Metabolism**	**ABC**	41720901, 41919001
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	**ABC**	DATA GAP
132-1B	**Soil Residue Dissipation**	**ABC**	DATA GAP
133-3	**Dermal Passive Dosimetry Exposure**	**ABC**	DATA GAP
133-4	**Inhalation Passive Dosimetry Exposure**	**ABC**	DATA GAP
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	**ABC**	40859801, 41087801
161-2	**Photodegradation - Water**	**ABC**	40816301, 41087802
161-3	**Photodegradation - Soil**	**ABC**	42251201
162-1	**Aerobic Soil Metabolism**	**ABC**	00039473, 00039474, 41722801
162-2	**Anaerobic Soil Metabolism**	**ABC**	00040782, 41837601
162-3	**Anaerobic Aquatic Metabolism**		41837601
162-4	**Aerobic Aquatic Metabolism**		DATA GAP
163-1	**Leaching/Adsorption/Desorption**	**ABC**	00039476, 00039477, 00040777, 00157842 - DATA GAP (degradate)
164-1	**Terrestrial Field Dissipation**	**ABC**	00163853, 41922201 - 41922210
164-2	**Aquatic Field Dissipation**		DATA GAP
164-3	**Forest Field Dissipation**		DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
165-1	**Confined Rotational Crop**	**ABC**	43274101
165-2	**Field Rotational Crop**	**ABC**	DATA GAP
165-3	**Accumulation - Irrigated Crop**		DATA GAP
165-4	**Bioaccumulation in Fish**	**ABC**	42258401
165-5	**Bioaccumulation - Aquatic NonTarget**		DATA GAP
201-1	**Droplet Size Spectrum**	**ABC**	42151701
202-1	**Drift Field Evaluation**	**ABC**	42151701, 42151702 - DATA GAP
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	**AB**	00038268, 00099672, 00099683, 00099767 00099778, 00099794, 00099807, 00099844 00099877, 00099881, 00157108, 00161967 00164237, 40480601, 40659701, 41079301 41079302, 41208901, 41208902, 41272501 42127701, 42652801, 43483401
171-4B	**Nature of Residue - Livestock**	**AB**	00040159, 00064922, 00070185, 00070186 41702101, 41079301, 41702102, 42060901 42494201, 42494202, 42494203, 42622201
171-4C & 4D	**Residue Analytical Method - Plants & Animals**	**AB**	00029737, 00029742, 00040767, 00040770 00070181, 00070183, 00070184, 00070187 00070700, 00071822, 00071823, 00099683 00099684, 00099686, 00099774, 00099779 00109460, 41702102, 42895401 - DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	**Storage Stability**	**AB**	00075521, 00155956, 40678901, 41720102 42127801, 42494201, 42900301, 43003701 - DATA GAP
171-4J	**Magnitude of the Residue in Meat/Milk/Poultry & Eggs**	**AB**	00029741, 00029742, 00070185, 00138248 00155419, 00155425, 00029741, 00070185 00155420, 00155426, 00029737, 00029739 00070186, 00156780, 00156781, 00156782 00029737, 00029739, 00070186, 00156780 00156783, 40424649
171-4K	**Crop Field Trials**	**AB**	
	<u>Legume Vegetables</u>		
	Soybeans		00099781, 42473701
	<u>Foliage of Legume Veg.</u>		
	Soybeans, Forage and Hay		00099803 - DATA GAP
	<u>Citrus Fruits</u>		
	Grapefruit		00075520
	Oranges		00075520, 00153407, 00156581

REQUIREMENT		USE PATTERN	CITATION(S)
	Pome Fruits		
	Apples		00147410, 40279401, 40279402, 40279403 40376701, 40870601 - DATA GAP
	Pear		00147410, 00096673, 00099802, 00147410 40376701, 40870601 - DATA GAP
	Tree Nuts Group		
	Walnuts		40403901
	Grass Forage, Fodder and Hay Group		
	Grass, pasture, forage		00028435, 00109464
	Grass, pasture, hay		DATA GAP
	Grass, rangeland, forage		00143695, 40448701, 404499101
	Miscellaneous Commodities		
	Cottonseed		00038272, 00099694, 42855901, 43225701
	Cotton, gin by-products		DATA GAP
	Mushrooms		00109460, 00157108, 40870501, 42652701 43371301 - DATA GAP
171-4L	**Processed Food**	**AB**	
	Apples		00147410 - DATA GAP
	Citrus		00075520, 41079301, 41079302, 41208902

Data Supporting Guideline Requirements for the Reregistration of Diflubenzuron

REQUIREMENT	USE PATTERN	CITATION(S)
	Cottonseed	00009694
171-5	**Reduction of Residues**	N/A
171-6	**Proposed Tolerance**	
171-7	**Support for Tolerance**	
171-13	**Analtyical Reference Standard**	

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00038212	Steelman, C.D.; Farlow, J.E.; Breaud, T.P.; et al. (1975) Effects of Insect Development Inhibiting Chemicals on *Psorophora columbiae* (Dyar and Knab) and Non-target Aquatic Insect Species in Rice Fields. (Unpublished study received Feb 10, 1976 under 6G1744; prepared by Louisiana State Univ., Depts. of Entomology and Experimental Statistics, submitted by Thompson-Hayward Chemical Co., Kansas City, KS; CDL:094969-G)
00038213	Booth, G.M. (1975) The Impact of Dimilin W-25 on Non-target Invertebrates in Ponds Located in Salt Lake County, Utah. Final rept. (Unpublished study received Feb 10, 1976 under 6G1744; prepared by Brigham Young Univ., Dept. of Zoology, submitted by Thompson-Hayward Chemical Co.; Kansas City, KS; CDL:094969-H)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option.

Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Reqistrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and

are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may

choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an

agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by

anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly

articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data

intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Reqistrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision,

EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and

associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must

submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

   unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

DIFLUBENZURON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Diflubenzuron.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Diflubenzuron. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this Diflubenzuron Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Diflubenzuron are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Diflubenzuron are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Diflubenzuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact at (703) .

All responses to this Notice for the Product Specific data requirements should be submitted to:

Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Diflubenzuron**

DIFLUBENZURON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Diflubenzuron.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Diflubenzuron. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Diflubenzuron Generic Data Call In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Diflubenzuron are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Diflubenzuron are needed. These data are needed to fully complete the reregistration of all eligible Diflubenzuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Susan Jennings at (703) 308-8021.

All responsades to this Notice for the generic data requirements should be submitted to:

Susan Jennings, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Diflubenzuron

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Reqistrant's Response Form.

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A Terrestrial food
B Terrestrial feed
C Terrestrial non-food

D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am

identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

EPA'S BATCHING OF PRODUCTS CONTAINING DIFLUBENZURON AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient diflubenzuron, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. The registrant has several options to participate with all or some other registrants, or to deal only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. TRB must approve any new formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or

Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient diflubenzuron.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	400-466	diflubenzuron ... 90%	solid
	400-467	diflubenzuron ... 95%	solid
2	400-461	diflubenzuron ... 25%	powder
	400-464	diflubenzuron ... 25%	powder
	400-465	diflubenzuron ... 25%	powder
	400-468	diflubenzuron ... 25%	powder
	400-469	diflubenzuron ... 25%	powder
	400-700	diflubenzuron ... 25%	powder
	400-472	dilfubenzuron ...10.4%	tablet
	AL93000400	diflubenzuron ... 25%	powder
	AR87000500	diflubenzuron ... 25%	powder
	CA85004100	diflubenzuron ... 25%	powder
	CA85004101	diflubenzuron ... 25%	powder
	CA85004102	diflubenzuron ... 25%	powder
	CA85004103	diflubenzuron ... 25%	powder
	CA87004900	diflubenzuron ... 25%	powder
	CA94000400	diflubenzuron ... 25%	powder

	CA97001900	diflubenzuron	... 25%	powder
	CA97002000	diflubenzuron	... 25%	powder
	CA97002100	diflubenzuron	... 25%	powder
	FL91001400	diflubenzuron	... 25%	powder
	FL94000800	diflubenzuron	... 25%	powder
	FL96001400	diflubenzuron	... 25%	powder
	HI94000300	diflubenzuron	... 25%	powder
	LA96001100	diflubenzuron	... 25%	powder
	MS87000200	diflubenzuron	... 25%	powder
	NV94000300	diflubenzuron	... 25%	powder
	OK89000300	diflubenzuron	... 25%	powder
	OR88001300	diflubenzuron	... 25%	powder
	TN87000400	diflubenzuron	... 25%	powder
	400-474	diflubenzuron	... 40.4%	solid
	PA95000900	diflubenzuron	... 40.4%	solid

Table 2 lists the product the Agency was unable to batch. This product was not batched because it was not considered to be similar to other products in terms of acute toxicity. The registrant of this product is responsible for meeting the acute toxicity data requirements for it individually. This product may not cite acute toxicity/ irritation data derived from any other products in this RED. The registrant may cite pre-existing data conducted on their individual product if it exists and meets current Agency standards.

Table 2.

Registration Number	Percent Active Ingredient	
37100-27	diflubenzuron	... 26.7%

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires
3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX E - LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents for Diflubenzuron that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact at (703)-.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Diflubenzuron.

The following documents are part of the Administrative Record for Diflubenzuron and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria