



Reregistration Eligibility Decision (RED)

Dichlobenil



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 number 0263, dichlobenil. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 20, 1997, 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 ingredients 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 is due 90 days from the receipt of this letter. The second set of required responses is 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.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, 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. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any 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 pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

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 Bonnie Adler at (703) 308-8523. Address any questions on required generic data to the Special Review and Reregistration Division representative Dana Lateulere at (703) 308-8044.

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, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; 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 time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. 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, but are not required to, 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 703-605-6000).

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

DICHLORBENIL

LIST A

CASE 0263

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

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DICHLORBENIL REREGISTRATION ELIGIBILITY DECISION TEAM

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Special Review and Reregistration Division

Linda Propst	Reregistration Branch
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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 ₁₀	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
µg/L	Micrograms per liter
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 Observable 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.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide dichlobenil. This decision includes a comprehensive reassessment of the required data and the use patterns of currently registered products. On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. These two Federal statutes provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3rd are accordingly being evaluated under the new standards imposed by FQPA.

The primary focus of FQPA is to require a more comprehensive evaluation of pesticide risks to infants and children from their diet, but also from non-food exposures such as drinking water and residential type exposures when issuing or reassessing tolerances. Specifically, based on available information, the Agency will be evaluating 1) aggregate risks of a particular pesticide from various exposure routes and 2) the cumulative effects of a pesticide and other substances that have a common mode of toxicity. Consideration of aggregate risks and cumulative effects with respect to the general population will also be considered in issuing or reassessing tolerances. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effect of pesticide residue.

Dichlobenil (2,6-dichlorobenzonitrile) is a herbicide used on cranberry bogs, dichondra, ornamentals, blackberry, raspberry, and blueberry fields, apple, pear, filbert and cherry orchards, vineyards, hybrid poplar-cottonwood plantations, and rights-of-way to control weeds; and sewers to remove roots. The Agency can not make a decision as to the eligibility of the sewer treatment and the granular backpack application of dichlobenil at this time because additional data are needed to evaluate exposure of mixer/loader/applicators for these uses. Under FIFRA, The Agency has concluded that the remaining uses, labeled and used as specified in this document, will not cause unreasonable risks to humans or the environment. Therefore, all products are eligible for reregistration except for those registered for application to sewer sites or granular backpack application.

The Agency has reassessed food tolerances for the combined residues of the herbicide dichlobenil (2,6-dichlorobenzonitrile) and its metabolite 2,6-dichlorobenzamide (BAM) under the standards of FQPA and determined that the existing tolerances with amendments and changes as specified in this document meet the safety standards of FQPA. Based on available information, there is reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to dichlobenil or BAM residues. An additional uncertainty factor for sensitivity to infants and children was not needed to assess the risk of dichlobenil. Drinking water monitoring data for both dichlobenil and its BAM metabolite are required to confirm this assessment.

Insufficient information is available for the Agency to make a determination of whether or not dichlobenil shares a common mode of toxicity with other chemicals.

To mitigate risks of potential developmental toxicity to workers the Agency is requiring, among other changes, the use of personal protective equipment; reentry intervals of 24 hours for horticultural/ nursery uses; reentry intervals of 12 hours for all other uses; open windows or exhaust fan during sewer treatment application to inhabited buildings; soil incorporation or watering-in of dichlobenil for horticultural uses, such as use on dichondra, soil or gravel in liners that house ornamental stock, and for all soil uses around established ornamental trees and shrubs, and other non crop areas such as buildings, fences, and other structures is required. It is also recommended that products primarily intended for homeowner use be watered-in. Re-entry would be restricted until the soil is dry following the watering-in of the product.

Dichlobenil and its metabolite BAM have the potential to leach into ground water, but only limited detection data are available. To address these concerns the Agency is requiring a ground water advisory on labels, and a drinking water monitoring study. In addition a ground water monitoring study is required for the hybrid cottonwood sites outside of Oregon and Washington desert areas. To reduce environmental risks to birds, mollusks, fish, invertebrates, and non-target plants, a reduction of the 20 lb. ai/A maximum application rate to 10 lbs ai/A is being imposed. In addition, to mitigate acute risks to endangered birds, the Agency is requiring that the label for the 10G formulation impose soil incorporation. Additional data for re-entry exposure, residue chemistry, forestry dissipation, drinking water, and ground water monitoring are being required to be submitted to confirm the Agency's risk assessment and conclusions. Avian reproduction data are being required to enable the Agency to assess chronic risks to birds. To assess the reregistration eligibility of sewer sites and granular backpack application sites, data are required for estimation of inhalation and dermal exposure to mixer/loader/applicators.

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 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. Thus, EPA 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 best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of dichlobenil including the risk to infants and children for any potential dietary (food source and drinking water), residential (dermal, inhalation or non-dietary ingestion), and cumulative effects as stipulated under the FQPA.

The document consists of six sections. Section I is the introduction. Section II describes dichlobenil, 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 dichlobenil. Section V discusses the reregistration requirements for

dichlobenil. 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(s) are covered by this Reregistration Eligibility Decision:

- ! **Common Name:** Dichlobenil
- ! **Chemical Name:** 2,6-dichlorobenzonitrile
- ! **Chemical Family:** Benzonitrile
- ! **CAS Registry Number:** 1194-65-6
- ! **OPP Chemical Code:** 027401
- ! **Empirical Formula:** C₇H₃Cl₂N
- ! **Trade and Other Names:** Casoron, Norosac, Barrier, Dyclomec, H 133, Prefix D, Decabane, and DCBN
- ! **Basic Manufacturer:** Uniroyal

B. Use Profile

The following is information on the currently registered uses for dichlobenil with an overview of use sites and application methods. A detailed table of **dichlobenil** uses is in Appendix A.

Type of Pesticide: Herbicide

Mechanism of action:

Inhibits germination of actively dividing meristems. Acts primarily on growing points and root tips.

Use Sites:

TERRESTRIAL FOOD CROP

Nut Crops [filbert (hazelnut)]; Pome Fruits [pear]; Small Fruits [blackberry, blueberry, cranberry, raspberry (black, red)]; Stone Fruits [cherry]

TERRESTRIAL FOOD+FEED CROP

General Soil Treatments and Composting [compost/compost piles, soil, preplant/outdoor]; Pome Fruits [apple]; Small Fruits [grapes]

TERRESTRIAL NON-FOOD CROP

Agricultural Uncultivated Areas [agricultural rights-of-way/fencerows/hedgerows, agricultural uncultivated areas]; Nonagricultural Uncultivated Areas [industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, paved areas (private roads/sidewalks), recreational area]; Ornamental Lawns and Turf

TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Industrial Preservatives [adhesives, industrial]; Ornamental Lawns and Turf; Ornamental Woody Shrubs and Vines; Ornamental and/or Shade Trees

AQUATIC NON-FOOD INDUSTRIAL

Aquatic Sites [drainage systems, sewage systems]

FORESTRY

Forest Trees [forest plantings (reforestation programs, tree farms, tree plantations, etc.), all or unspecified forest trees, hybrid cottonwood/poplar plantations, shelterbelt plantings]

Target Pests for Single Active Ingredient:

Weeds: dandelion, prickly oxtongue (preemergence), tree roots

Formulation Types Registered:

Type: Technical Grade Active Ingredient

Form: Not identified/solid 98.0000 to 99.5000%

Type: Manufacturing Product

Form: Not identified/solid 85.0000%

Wettable powder 85.0000%

Type: End use product

Form: Granular 1.0000 to 10.0000%

Liquid-ready to use 0.5000%

Soluble concentrate/solid 0.5000%

Wettable powder 0.5500 to 85.0000%

Method and Rates of Application:

Types of Treatment

Broadcast; Foam application; Perimeter treatment; Prepaving treatment; Sewer treatment; Soil incorporated treatment; Soil treatment

Equipment

Aircraft; By hand; Foam applicator; Foam-making generator; Glove; Granule applicator; Ground; Not on label; Package applicator; Rod; Soil incorporation equipment; Toilet bowl; Tractor-mounted granule applicator

Timing

Bearing; December; Early spring; Early winter; February; January; Late fall; Nonbearing; November; Nurserystock; Postemergence; Postharvest; Prebloom; Spring; Stool bed; When needed; Winter

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the uses of dichlobenil. 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.

According to the Agency's records, dichlobenil is registered on more than 20 agricultural and six non-agricultural use sites. Based on proprietary and non-proprietary usage data from 1993 - 1995, approximately 150,000 - 225,000 pounds active ingredient are used to treat about 55,000 - 95,000 acre treatments in the aggregate. The agricultural sites represent nearly 58 percent of this total of which ornamental plants, trees, and turf represent 66 percent of the agricultural total and 38 percent of the aggregate total. Other important sites include the homeowner use which represents 51 -62 percent of the non-agricultural total and 22 - 26 percent of the aggregate total as well as cranberries represent 16 percent of the agricultural total and approximately ten percent of the aggregate total. There is not one major region or state which accounts for the majority of the usage.

The following table summarizes the pesticides use by site.

Percent of Various U.S. Crops Treated Annually with Dichlobenil, 1993 - 1995

Site/1	Acres Grown/2 (000)	Acres Treated/3 (000)	Percent Crop Treated	Pounds AI Applied (000)	Major Region or State
Agricultural Sites					
Apple	457.1	5 - 10	1 - 2	1 - 5	NC, IL, IN
Blackberry	4.8	<1 - 1	<1 - 21	<1 - 1	OR
Blueberry	35.1	<1 - 1	<1 - 3	<1 - 1	NW
Cherry	93.4	<1 - 1	<1 - 1	<1 - 1	CO
Cranberry	29.6	10 - 15	34 - 51	15 - 20	MA, OR, WI
Filbert	27.0	1 - 2	3 - 8	2 - 4	OR
Golf Courses	1,202	<1 - 1	<1 - 1	<1 - 1	Nationwide
Grape	757.4	1 - 2	<1 - 1	1 - 5	CA, NW
Nectarine*	27.4	<1 - 1	<1 - 1	<1 - 1	CA
Orange*	675.6	<1 - 1	<1 - 1	<1 - 1	CA
Ornamental Plants	701.6	5 - 10	<1 - 2	30 - 40	Nationwide
Ornamental Trees	--	5 - 10	--	15 - 25	Nationwide
Ornamental Turf	--	5 - 10	--	15 - 20	--
Peach*	176.4	<1 - 1	<1 - 1	<1 - 1	NC, OR
Pear	70.2	<1 - 1	<1 - 1	<1 - 1	OR
Plums/Prune*	127.9	<1 - 1	<1 - 1	<1 - 1	NW
Raspberry	12.2	<1 - 1	<1 - 1	<1 - 1	OR, OH
Ag Totals	N/A	42 - 69	N/A	89 - 129	N/A

Percent of Various U.S. Crops Treated Annually with Dichlobenil, 1993 - 1995

Site/1	Acres Grown/2 (000)	Acres Treated/3 (000)	Percent Crop Treated	Pounds AI Applied (000)	Major Region or State
Non-agricultural Sites					
Aquatic*	--	<1 - 1	--	4 - 8	CA, FL
Homeowner	--	10 - 15	--	40 - 50	NW
Sewers	--	<1 - 1	--	5 - 10	Nationwide
Under asphalt	--	<1 - 1	--	5 - 10	West
Rights of ways	--	1 - 2	--	5 - 10	NW
Hedge/fence rows	--	1 - 5	--	5 - 10	Midwest
Non ag Totals	N/A	15 - 25	N/A	64 - 98	N/A
Aggregate Totals	N/A	57 - 94	N/A	153 - 227	N/A

-- Unknown

/1 - Site identification based on REFS.

/2 - Acres grown based on USDA, Agricultural Census, and state statistics.

/3 - Multiple acres treated represents the total number of acre treatments.

Data based on proprietary and non-proprietary sources, USDA, and state statistics.

* Dichlobenil is no longer registered for nectarine, peach, plum, prune, lakes, ponds, or impoundments as well as clover, fig, mango, nuts (other than filberts) or citrus use sites. (Use deletion requests published in FR Notices dated 8/23/95, 11/1/95, 2/28/96, and 4/17/96.)

Please note that cottonwood-poplar hybrid plantation use site information is not included in this table because this use was just recently registered and information about poundage used at this site is unavailable.

D. Data Requirements

Data requested in the Registration Standard for Dichlobenil issued March, 1987 include studies on product chemistry, toxicology, ecological effects, environmental fate, and residue chemistry. Appendix B includes all data requirements identified by the Agency needed to support reregistration for currently registered uses.

E. Regulatory History

Dichlobenil was registered in the United States in 1964 for use as a herbicide. A Registration Standard for dichlobenil was issued on March 23, 1987. The Dichlobenil Registration Standard required several studies including new product chemistry data for the technical. Analysis for polychlorinated dibenzo-para-dioxins and dibenzofurans and nitrosamines was required because dichlobenil is a polyhalogenated cyclic compound. A Data Call-In (DCI) was issued on June 9, 1987 requiring product chemistry data to assess the potential formation of halogenated dibenzo-p-dioxin or dibenzofuran contaminants. The Dichlobenil Product and Residue Chemistry Reregistration Standard Update was issued 7/31/91, and required additional product chemistry data, as well as analyses for dioxins and nitrosamines for the Solvay Duphar 99.5% technical and 85% formulation intermediate. DCIs were issued November 22, 1993 for dichlobenil requiring data to assess: toxicity to estuarine organisms, dermal toxicity and exposure, volatility, spray drift, and magnitude of residues in potable water, fish, irrigated crops and cherries; in March 17, 1994 to assess mixer/loader/applicator exposure; and on October 18, 1995, a DCI was issued for re-entry exposure data. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and subsequent DCIs.

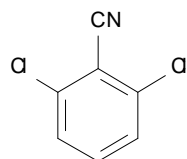
The basic producer of the dichlobenil technical is Uniroyal Chemical Company. Their technical registrations (EPA Reg. No. 400-175 and 400-462) were previously held by Solvay Duphar. However, on July 10, 1995 the Agency accepted the transfer of all Solvay Duphar products to Uniroyal Chemical. PBI Gordon's technical registration (EPA Reg. No. 2217-680) is repackaged from a Uniroyal product, and therefore is not subject to additional generic data requirements.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Description of Chemical

Dichlobenil (2,6-dichlorobenzonitrile) is a selective herbicide.



Empirical Formula: $C_7H_3Cl_2N$

Molecular Weight: 172.0

CAS Registry No.: 1194-65-6

Shaughnessy No.: 027401

Identification of Active Ingredient

Dichlobenil is a white crystalline solid with a melting point of about 144°C. The vapor pressure of dichlobenil is 0.088 Pa at 20°C. At 25°C, technical dichlobenil is practically insoluble in water (0.0021 g/100 ml) and slightly soluble in most organic solvents (i.e., 5.3 g/100 ml in xylene, 1.5 g/100 ml in ethanol, and 0.37 g/100 ml in cyclohexane). Dichlobenil is stable at elevated temperatures and in acidic media.

Manufacturing-use Products

There are six dichlobenil manufacturing-use products (MPs), all of which were registered before the Dichlobenil Reregistration Standard issued 3/23/87. A list of the dichlobenil MPs subject to a reregistration eligibility decision is presented in Table 1 below.

Table 1: Dichlobenil MPs

Formulation	EPA Reg. No.	Registrant
99% T	400-175	Uniroyal Chemical Company, Inc.
85% FI	400-176	
99% T	400-462	
85% FI	400-463	
99% T	2217-680	PBI/Gordon Corporation
85% FI	2217-677	

The registrations for the 400-462 and 400-463 were previously held by Solvay Duphar. However, on July 10, 1995 the Agency accepted the transfer of all Solvay Duphar products to Uniroyal Chemical. Currently, there are two technical products for dichlobenil, a 99% T (EPA Reg. No. 400-175) and a 99% T (EPA Reg No. 400-462). The 99%T was originally a Duphar product (EPA Reg. No. 37100-4). EPA Registration 400-175 was a re-package of 37100-4.

Solvay Duphar submitted all new product chemistry data including dioxin and furan analyses in support of a new manufacturing process. None of the 15 target analytes were found at or above the specified levels of quantification (LOQs). Therefore, the requirements to analyze technical dichlobenil for dioxin and furans have been fulfilled.

Revised Confidential Statements of Formula (CSFs) for 400-175 and 400-462 were submitted for review. The revised CSFs are adequate. The CSF refers to the product as technical dichlobenil greater than or equal to 98%; the label claim should be the nominal concentration 99% (refer to PR Notice 91-2). No additional data are required for 61-1 and 62-2 for these products.

The PBI/Gordon 99% T and 85% formulation intermediate (FI) are repackaged from the Uniroyal dichlobenil products; therefore, all product chemistry data requirements for these products, except for individual CSFs (GLNs 61-1 and 62-2), will be satisfied by Uniroyal (formerly Solvay Duphar) data.

Generic and product-specific data remain outstanding for the dichlobenil MPs. Refer to Appendix B for a listing of outstanding product chemistry data requirements.

The product chemistry data are based on currently available information. With respect to the reregistration of dichlobenil, the registrants must submit the chemistry data required for their products and either certify that the suppliers of starting materials and the manufacturing process for the dichlobenil technical products 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 for dichlobenil includes studies performed with dichlobenil and studies performed with 2,6-Dichlorobenzamide (BAM). Since BAM is the major residue in plants treated with dichlobenil, and is consumed in the food supply, it was necessary to perform toxicological studies on BAM. A complete toxicology assessment of BAM follows the toxicology assessment of dichlobenil.

a. Acute Toxicity

The results of the acute toxicity profile of dichlobenil are summarized in the following table:

Table 2: Acute Toxicity Values

GLN	TEST	MRID	RESULT	TOXICITY CATEGORY
81-1 ^a	Oral LD ₅₀ - Rat	00112500	4.25 g (M & F)	III
81-2 ^b	Dermal LD ₅₀ - Rabbit	43250401	> 2 g/kg	III
81-3 ^c	Inhalation LC ₅₀ - Rat	43335703	> 3.3 mg/L	III
81-4 ^c	Primary Eye Irritation - Rabbit	40425403	Not an ocular irritant	IV
81-5 ^c	Primary Dermal Irritation -Rabbit	40425402	Not a dermal irritant	IV
81-6 ^d	Dermal Sensitization - Guinea pig	40548501	Not a skin sensitizer	N/A

- The a.i.% was not specified in the review. However, an acute dermal toxicity study (MRID 00113796) was performed at the same time by the same laboratory. It is assumed that the same concentration (90.7% T) was used for both studies.
- The 98.8% T was used.
- The 85.3% formulation was used.
- The 99.4% T was used.

An acute 4-hour inhalation test was performed using technical dichlobenil (98.8%). However, due to clogging of the apparatus, the highest dose that could be tested was 0.25 mg/L. Therefore, an acute inhalation test was also performed using the 85.3% formulation. An LC₅₀ in rats of > 3.3 mg/L was obtained. This result would normally place dichlobenil in Toxicity Category IV; however, because the respirable particle size was less than optimal (5.5 µm instead of an optimal size of 4 µm), Toxicity Category III was assigned as an added measure of protection.

b. Subchronic Toxicity

The Agency is not requiring a subchronic non-rodent study. The toxicological data requirement for a 90-day feeding study in non-rodents was satisfied by an acceptable two-year dog feeding study (MRID 00067649).

In a 21-day dermal toxicity study, dichlobenil technical (98.8% a.i.) was administered topically to the clipped dorsal region (intact skin) of New Zealand white rabbits (5/sex/dose) at daily dose levels of 0, 100, 300, or 1000 mg/kg/day for 6 hours per day for 3 weeks. Administration of 100, 300 or 1000 mg/kg/day produced no clinical signs or skin irritation. No animals died during the study. There were no treatment-related effects on body-weight, food consumption, hematology, blood chemistry, organ weights, gross or microscopic pathology. The NOEL for dermal irritation and systemic toxicity is equal to or greater than 1000 mg/kg/day, the highest dose tested. The LOEL is greater than 1000 mg/kg/day. (MRID 43879301).

Rats (12/sex/dose) were given dichlobenil in the diet for 13 weeks at doses of 0, 100, 1000, or 3000 ppm (0, 5, 50, 150 mg/kg/day). An additional group of 6 male rats was maintained on a 10,000 ppm diet. Compound-related effects included increased absolute and relative liver and kidney weights at 1000 ppm and higher. There was also hepatic degeneration without significant necrosis at 3000 ppm and higher, and mortality (5 out of 6) and hepatic necrosis at 10,000 ppm. The NOEL was 5 mg/kg/day (100 ppm). The LOEL was set at 50 mg/kg/day (1000 ppm) based on increased absolute and relative liver and kidney weights. This study satisfies the requirement for a 90-day feeding study in rats. (MRID 00107106).

In a 13-week oral toxicity test, mice were given dichlobenil in the diet at concentrations of 0, 25, 125, 625, or 3125 ppm (0, 4, 19, 95, or 473 mg/kg/day). Adverse effects in the liver (specific effects were not reported) were observed in female mice at the 95 mg/kg/day level. (This does not satisfy the data requirements for any guideline study. no MRID)

In a 13-week oral toxicity test, hamsters were given dichlobenil in the diet at concentrations of 0, 41, 209, 1289, or 4648 ppm (0, 3, 16, 79, or 263 mg/kg/day). At the beginning of the study, the high dose was 7500 ppm. However, hamsters could not tolerate a diet of 7500 ppm dichlobenil (395 mg/kg/day); therefore, this dose was lowered to 4648 ppm during week 3. The NOEL for systemic toxicity was 3 mg/kg/day. The LOEL was set at 16 mg/kg/day based on decreased prostate weight and prostatic degeneration and mineralization in males; and increased phospholipids, increased liver weight as well as unspecified adverse liver effects in females. (These data were used as a range-finding study for a carcinogenic hamster study; MRID 40600701)

c. Chronic toxicity

Groups of beagle dogs (4/sex/dose) were given dichlobenil in the diet for 2 years at dosing levels of 0, 20, 50, or 350 ppm (0, 0.5, 1.25, or 8.75 mg/kg/day). The NOEL for systemic toxicity was 1.25 mg/kg/day. The LOEL for systemic toxicity was 8.75 mg/kg/day based on (1) an increase in absolute

and relative liver and thyroid weights in both sexes; (2) an increase in serum alanine aminotransferase in females, and serum alkaline phosphatase in both sexes; (3) an increase in liver enzyme glucose-6-phosphatase and glucose-6-phosphatase dehydrogenase activity in both sexes; and (4) leucocytic infiltration and fibrinoid degeneration around the central hepatic veins of both sexes. (MRID 00067649)

In another chronic study groups of dogs were given dichlobenil by capsule. This study (MRID 43969701) was not required by the Agency; but was required by California. A preliminary review of the study indicates that the results are substantially similar to that of MRID 00067649. This study has not yet been fully reviewed because the study demonstrates substantially similar results, and the RfD for dichlobenil is not used in the risk assessment of this RED.

d. Combined Chronic/Carcinogenicity

Hamsters were selected as a test species based on studies of mice and hamsters indicating that female was the most sensitive sex, and that female hamsters were about six times more sensitive than female mice.

In the first study dichlobenil (technical grade, 99.4%) was given in the diet to groups of 50 male and 50 female hamsters for 80 weeks (females) or 88 weeks (males) weeks at doses of 0, 5, 26, 132, or 675 ppm, (0, 0.35, 1.78, 9.20, or 48.86 mg/kg/day in females and 0, 0.34, 1.69, 9.39, or 45.64 mg/kg/day in males). There were an additional 50 hamsters/sex for the control group. Histopathology was conducted upon completion of treatment.

Administration of dichlobenil did not result in an increase in tumor incidence in any tissue. The incidence of several non-neoplastic endpoints was significantly increased but did not increase with increasing dose.

The NOEL for systemic toxicity was 9.20 mg/kg/day. At 675 ppm in males, the incidences of islet cell hyperplasia of the pancreas, reduced secretion in the prostate and seminal vesicles, and acanthosis of the skin were significantly increased above controls. At 675 ppm in females (1) the incidences of centrilobular hepatocyte enlargement and rarefaction in the liver, (2) cortical hyperplasia of the adrenals, (3) epithelial hyperplasia of the stomach, (4) hyperplasia of bone marrow in the sternum, (5) submucosal inflammatory cells in the stomach, (6) peritonitis, (7) prominent mucous cells in the cecum, (8) luminal dilation of the rectum, and (9) hyperkeratosis of the skin were significantly increased above controls. Thus, the LOEL was set at 45.64 mg/kg/day (MRIDs 41988301, 42015101).

In a second carcinogenicity study, dichlobenil (technical grade, 99.4%) was given in the diet to groups of 50 male and 50 female Bio F1D Alexander Syrian hamsters for seventy-eight weeks (females) or ninety-one weeks (males) at doses of 0, 675, 1500, and 3375 ppm (0, 55, 121, or 277

mg/kg/day for females and 0, 51, 117, or 277 mg/kg/day for males). There were an additional 50 hamsters/sex for the control group. Histopathology was conducted upon completion of treatment.

There was one benign liver tumor in a male dosed at 1500 ppm. In the male hamsters dosed at 3375 ppm, there was a statistically significant increase in benign liver cell tumors. One malignant liver cell tumor was observed in a male dosed at 3375 ppm. At all doses, a significant increase in relative liver weight and a significant decrease in body weight gain in male and female hamsters were observed. Based on this, a systemic toxicity NOEL was not observed in this study. At the 675 ppm dosing level in males, the incidences of centrilobular hepatocyte enlargement and pigmented alveolar macrophages of the lung were significantly increased above controls. Thus, the LOEL was set at 51 mg/kg/day based on decreased body weight gain in both sexes, as well as increased relative liver weight in females.

At the 1500 ppm dosing level, the incidences of centrilobular hepatocyte enlargement, finely vacuolated hepatocytes, and brown pigment in hepatocytes (males) and hepatitis (females) were significantly increased above controls.

At the 3375 ppm dosing level in males, the incidences of centrilobular hepatocyte enlargement, finely vacuolated hepatocytes, hepatitis, pigmented giant cells and sinusoidal cells in the liver, brown pigment in hepatocytes, and eosinophilic hepatocytes were significantly increased above controls. There were incidences of pigmented alveolar macrophages of the lung, pigmented macrophages in the rete testes, and dilated seminiferous tubules which were also significantly increased above controls.

At the 3375 ppm dosing level in females, the incidences of centrilobular hepatocyte enlargement, hepatitis, and pigmented giant cells and sinusoidal cells in the liver were significantly increased above controls. Incidences of hyperplasia of the urothelium of the urinary bladder, microcysts of the pituitary, glandular tissue in the muscularis of the stomach (also with inflammatory cells), and mucosal inflammation of the cecum were also significantly increased above controls. (MRIDs 42221201, 42563601)

Dichlobenil (96.7%) was given in the diet to groups of Fischer 344 rats (50 male and 50 female) at dosing levels of 0 (control), 50, 400 or 3200 ppm for 2 years, (0, 2.3, 18.9, or 173.1 mg/kg/day, respectively). The NOEL for systemic toxicity was 2.3 mg/kg/day. The LOEL for systemic toxicity was set at 18.9 mg/kg/day based on: (1) renal damage in males characterized by increases in water consumption, cholesterol, blood urea nitrogen, creatinine, urinary glucose, urinary bilirubin, nephrosis, parathyroid hyperplasia (with associated osteodystrophy and metastatic calcification), and relative and absolute kidney weight; (2) liver effects including increased relative and absolute liver weights in males and females; and (3) increased cytological alteration (the appearance of nuclear pleomorphism combined with swelling of the liver cells) in females.

There was an increased incidence in hepatocellular tumors at the high dose in both sexes. In female rats there were statistically significant increases by pair wise comparison in adenomas and combined

adenomas/carcinomas. There were also statistically significant positive dose-related trends for adenomas and carcinomas, alone and combined. In male rats there were also statistically significant positive trends for adenomas and carcinomas alone and combined, but there were no statistically significant increases by pairwise comparison in any tumors at any dose. These tumors are considered to be unusual but not rare ($\leq 1\%$) in F344 rats. Tumors did not appear to occur with decreased latency. (MRID 00147438)

e. Developmental Toxicity

Groups of 25 Wistar rats were treated by gavage during gestation days 6 through 15 with 0 (control), 20, 60, or 180 mg/kg/day of dichlobenil. Animals were sacrificed on gestation day 21, and examined for live fetuses and intra-uterine deaths. Fetuses were weighed and examined for external visceral and skeletal alterations. The maternal NOEL was set at 20 mg/kg/day and the LOEL was set at 60 mg/kg/day based on decreased maternal body weight gains, and decreased food consumption. The developmental NOEL and LOEL values were set at 60 mg/kg/day and 180 mg/kg/day, respectively, based on an increase in the incidence of supernumary thoracic ribs that is statistically significant at the 180 mg/kg/day dose level. (MRID 00147437)

New Zealand White rabbits were given dichlobenil by gavage at dosing levels of 0, 15, 45, or 135 mg/kg/day during gestation days 7 through 19. At 135 mg/kg/day, a significant decrease in body weight gain and food consumption was noted in does during the dosing period. Consequently, the maternal NOEL and LOEL values were 45 and 135 mg/kg/day, respectively.

At 135 mg/kg/day, developmental toxicity was manifested as increased incidences of post-implantation loss and late resorptions, and the occurrence of major external (cleft palate, adactyly, and eye anomalies), visceral (anomalies of vascular system), and skeletal (misshapen frontals, enlarged fontanelle and fused sternbrae) defects. Consequently, the developmental NOEL and LOEL values were set at 45 and 135 mg/kg/day, respectively. (MRID 41257302).

f. Reproductive Toxicity

Dichlobenil at dietary levels of 0, 60, 350, and 2000 ppm (0, 3, 17.5, and 100 mg/kg/day) was given to groups of Sprague-Dawley rats (30/sex/dose for F0 and 25/sex/dose for F1) for two generations. The parental NOEL was 17.5 mg/kg/day. The parental LOEL was set at 100 mg/kg/day based on significant decreases in body weight, body weight gain, and food consumption in males and females from both generations. The reproductive NOEL was 3 mg/kg/day. Reduced pup body weights were observed at both the 17.5 and 100 mg/kg/day levels; therefore, the reproductive LOEL was 17.5 mg/kg/day. A significant decrease in birth weight of the F1 pups was observed at 17.5 mg/kg/day. This decreased mean F1 pup weight occurred in the absence of maternal toxicity, but did not present a clear dose response relationship. The effect was not repeated in the second generation. At the same dietary level, the mean body weight of the F2 pups was greater than the mean body weight of the control pups at birth. (MRIDs 41257303, 42239101)

g. Mutagenicity

The following studies did not demonstrate any mutagenic potential for dichlobenil.

In the Ames test, there was no apparent mutagenic potential in Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100 at dosing levels of 0, 40, 200, or 1000 $\mu\text{g}/\text{plate}$, both with and without S-9 activation systems. At 5000 $\mu\text{g}/\text{plate}$, the highest dose tested (HDT) the test compound precipitated. (MRID 00153579)

There was no apparent mutagenic potential up to 5000 $\mu\text{g}/\text{disk}$, HDT, in the B. subtilis H-17 and H-45 strains without activation and up to 5000 $\mu\text{g}/\text{plate}$ in the E. coli (WP2) and S. typhimurium strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100 both with and without S-9 activation systems. (MRID 00153586)

In an in vitro mouse lymphoma (L5178Y TK+/-) test system, there was no apparent mutagenic potential up to 280 $\mu\text{g}/\text{ml}$ without activation and 50 mg/ml with activation. (MRID 00153576)

In an in vitro chromosomal aberrations test with metaphase analysis using human lymphocytes, there was no apparent mutagenic potential up to 1 $\mu\text{g}/\text{ml}$ (the highest soluble concentration) both with and without activation. (MRID 00153577)

An unscheduled DNA synthesis (UDS) in vitro test using human HeLa epithelioid cells assaying for DNA repair in response to DNA damage was performed. There was no apparent mutagenic potential from 0.05 to 102.4 $\mu\text{g}/\text{ml}$ both with and without S-9 activation. (MRID 00153580)

There was no apparent transforming potential up to 7500 $\mu\text{g}/\text{ml}$ with activation in the BALB/3T3 transformation assay. The transforming potential of dichlobenil without activation was not assessed. (MRID 00153581).

Chinese hamster ovary (CHO) cells were exposed to dichlobenil at dosing levels up to 100 $\mu\text{g}/\text{ml}$ both with and without S9 activation. Cultures with the S-9 activation were exposed for 10 or 20 hours. Those without the S-9 activation were exposed for 20 or 30 hours. Dichlobenil was negative for inducing structural chromosome aberrations. (MRID 41319101)

h. Metabolism

These studies collectively provide adequate information on the pharmacokinetics and metabolism of dichlobenil. (MRID 41227404)

Single doses of 5 mg/kg [phenyl- ^{14}C] dichlobenil were given to male and female SD rats by either intravenous (iv) or oral administration. Urine and feces were collected at various intervals after dosing. Seven days after iv administration male rats had excreted 70.7% of the dose in the urine and

25.4% of the dose in the feces. Total recovery was 96%. In females, 65.1% and 30.9% of the dose were excreted in the urine and feces, respectively. Total recovery was also 96%. Similar results were obtained 7 days after oral administration. Males excreted 65.1% and 19.2% of the dose in urine and feces, respectively. Total recovery was 84%. Females excreted 64.9% and 20.7% of the dose in urine and feces, respectively. Total recovery was 86%. Thus, the total recoveries following iv dosing were slightly higher than those following oral dosing. The rate of urinary excretion was rapid; excretion was 95% complete in 24 hours. The similarity in total excretion pattern after either an intravenous or oral dose indicates that dichlobenil at the 5 mg/kg dose is readily absorbed from the gastrointestinal tract.

In addition, three bile duct-cannulated male rats were dosed orally with 5 mg/kg and bile was collected 2, 5, and 24 hours after administration. For these three rats, 78.9% of the administered dose was recovered in the bile and 19.8% in the urine 24 hours after administration. (MRID 41227401)

A similar study using single doses of 2.5 mg/kg [phenyl-U-¹⁴C] dichlobenil given orally was also performed. Radioactive residue levels in various tissues were assayed in two rats/sex at various post-dosing intervals. The results indicate that residue levels decreased with time after dosing. (MRID 41227402)

In another study [phenyl-U-¹⁴C] dichlobenil in single or multiple doses at dosing levels of 3.75, 30, or 240 mg/kg were given orally. The radiolabeled dichlobenil was given as a single dose on day 1 in one study and on day 1 and day 11 in a multiple-dose study, with rats receiving unlabeled test material on days 2 to 10. Rats receiving a single dose of radiolabeled dichlobenil excreted 55% to 69% of the dose in the urine and 15% to 20% in the feces. Total recoveries at the two lower doses were between 89% and 92%. At the highest dose, total recoveries accounted for 77% to 83% of the dose. There were no significant sex-related differences. Similar elimination patterns were noted following the administration of radiolabeled dichlobenil on day 11.

Although some saturation kinetics were noted at the high dose, there were no major differences related to sex or dosing regimens. The great similarities in the percentage excretions for the three dosing levels indicate that dichlobenil administered orally up to the high-dose levels was readily absorbed by the rats. Tissue residue levels were dose-dependent. The highest residue levels were in the liver in the rats receiving the highest dose tested. (MRID 41299401)

The metabolic profiles from the above studies were analyzed, and the metabolites identified. Nine metabolites were found in the urine. Four were found in the feces. The major metabolites found in both urine and feces were 2,6-dichloro-3-hydroxybenzoxitrile and its sulfate conjugate; 6-chloro-3-hydroxy-2-cysteinyl-benzoxitrile; and 6-chloro-2-cysteinyl-benzoxitrile. Based on the metabolites identified, two metabolic pathways were proposed: (1) hydroxylation at the 3 or 4 position of the phenyl moiety followed by sulfation or glucuronidation and (2) conjugation with glutathione through displacement of the chlorine atom. (MRID 41227403)

i. Dichlobenil Toxicological Endpoints of Concern Identified for Use in Human Risk Assessment

Acute

A NOEL for use in calculating an acute (1 day) dietary risk assessment due to consumption of dichlobenil was identified. The NOEL from a rabbit developmental toxicity study (MRID 41257302) was 45 mg/kg/day. The developmental LOEL was set at 135 mg/kg/day based on increased incidences of post-implantation loss and late resorptions, and the occurrence of major external, visceral, and skeletal defects from the rabbit development toxicity study. However, the residue chemistry data indicate that dichlobenil per se is not consumed in food; therefore, use of the dichlobenil acute dietary NOEL in the food source risk assessment would be inappropriate. Data indicate that dichlobenil is found in water therefore, an acute risk assessment for drinking water may be appropriate.

Short term

A short term (1 - 7 days) occupational or residential risk assessment is required based on a rabbit developmental toxicity study. The developmental NOEL is 45 mg/kg/day. The developmental LOEL was set at 135 mg/kg/day based on increased incidences of post-implantation loss and late resorptions, and the occurrence of major external, visceral, and skeletal defects from the rabbit developmental toxicity study.

Intermediate

An intermediate term (1 week - several months) occupational or residential risk assessment is required based on a 2 generation reproduction study of Sprague-Dawley rats. The NOEL is 3 mg/kg/day. The LOEL was set at 17.5 mg/kg/day based on decreased pup body weight. Supporting this selection are a 2-year dog study with a NOEL of 1 mg/kg/day and a 90-day rat study with a NOEL of 5 mg/kg/day.

Chronic

The OPP Cancer Peer Review Committee (CPR) met on March 15, 1995, and determined that the available evidence for dichlobenil constituted only limited evidence for carcinogenicity and classified dichlobenil as a Group C, possible human carcinogen. The CPR Committee also concluded that a quantitative estimation of risk was not appropriate at that time, because the increases in hepatocellular tumors were statistically significant in only one sex (females); the tumors were predominantly benign adenomas, and supporting evidence was weak, at best. Although the tumor type (hepatocellular) is considered unusual for this strain of rat, tumors did not occur to an unusual degree or with an early onset.

The OPP RfD Committee met on March 31, 1994, and determined that the RfD for dichlobenil was 0.013 mg/kg/day. The RfD was based upon a NOEL of 1.25 mg/kg/day from a two-year dog feeding study (MRID 00067649) using an uncertainty factor (UF) of 100 to account for inter-species extrapolation and intra-species variability. The LOEL for systemic toxicity was 8.75 mg/kg/day based on:

- (1) an increase in absolute and relative liver and thyroid weights in both sexes;
- (2) an increase in serum alanine aminotransferase in females, and serum alkaline phosphatase in both sexes;
- (3) an increase in liver enzyme glucose-6-phosphatase and glucose-6-phosphatase dehydrogenase activity in both sexes; and
- (4) leucocytic infiltration and fibrinoid degeneration around the central hepatic veins of both sexes.

The RfD is the traditional endpoint for calculating chronic dietary risk. However, the residue chemistry data indicate that dichlobenil per se is not consumed in food; therefore, use of the dichlobenil RfD in the food source dietary risk assessment would be inappropriate. Data indicate that dichlobenil is found in water therefore a chronic assessment for drinking water may be appropriate.

Dichlobenil has not been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

Toxicity Data for the Dichlobenil Metabolite 2,6-Dichlorobenzamide (BAM)

The BAM metabolite is the major residue detected in plants. It is not an animal metabolite. It was necessary to perform toxicological studies on BAM since it is consumed in the food supply.

j. Acute Toxicity of BAM

The acute oral LD₅₀ of BAM in mice is 1538 and 1144 mg/kg in males and females, respectively, and falls in Category III. (MRID 42940201)

k. Subchronic Toxicity of BAM

BAM was given to Wistar rats (10/sex/dose) for 13 weeks at dietary levels of 0, 50, 180, 600 or 2300 ppm. The NOEL for systemic effects was set at 180 ppm (14 mg/kg/day) and the LOEL was set at 600 ppm (49 mg/kg/day) based on decreased body weight gain and food efficiency, increased blood urea nitrogen, and reduced coagulation times (MRID No. 00067654).

l. Combined Chronic Toxicity/Carcinogenicity Study of BAM

BAM was given to Crl CD rats (35/sex/dose) for 106 weeks at dietary levels of 0, 60, 100, 180 or 500 ppm (0, 2.2, 3.6, 6.5, or 19 mg/kg/day in males; 0, 2.8, 4.7, 8.5, or 25 mg/kg/day in females). The NOEL was 6.5 mg/kg/day. The LOEL was set at 19 mg/kg/day based on a statistically significant decrease in mean body weight gains in both males and females (10% and 20% less than controls, respectively, at week 52); and minimum histologic changes (slightly increased severity of fat deposition) in the livers of females. BAM produced an increased incidence of hepatoma in females

at 500 ppm (14%; vs. 0% at 60 and 100 ppm; 3% at 180 ppm). As part of the Agency's review, clarification of the tumor types and data on the stability/homogeneity of the test compound was requested. This information was submitted. With this additional data from reclassified liver slides, the Agency determined that the high dose female rats demonstrate an increased incidence of adenomas (14%) which was of borderline significance ($p < 0.049$).

Both of the previously identified deficiencies have been satisfied. However, a peer review of the re-read of the liver slides has not been submitted. Therefore, The study was classified as Core Supplementary and therefore does not satisfy the guideline requirement for a chronic toxicity/carcinogenicity study in rats. To upgrade the chronic toxicity/carcinogenicity study to Core-minimum the Agency requests that Uniroyal submit peer review results of the histopathological examination of livers from rats. Before a formal determination can be made on the carcinogenic potential of BAM, peer review results of the histopathological examination of livers from the rats need to be submitted, and these data along with available BAM chronic toxicity/ carcinogenicity need to be evaluated by the Cancer Peer Review Committee (CPRC).

This rat chronic toxicity/carcinogenicity study suggests that the chronic systemic toxicity of BAM in rats does not exceed (and may be lower) than that of its parent compound, dichlobenil. The carcinogenic potential of BAM also appears to be less than or equal to that of dichlobenil. (MRID 00147438, 40401101, 40823801, 42940202, 43747100, 44052901, 44043601). (Dichlobenil has been classified as a group C, possible human carcinogen with a recommendation for quantification using an RfD approach.) This result is also consistent with the chronic toxicity data (MRID 00066983) in beagle dogs.

In a chronic toxicity study in dogs, BAM was fed to beagle dogs 4/sex/dose for two years at dietary levels of 0 (control), 60, 100, 180, or 500 ppm (0, 1.5, 2.5, 4.5, or 12.5 mg/kg/day). The NOEL was 4.5 mg/kg/day. The LOEL was set at 12.5 mg/kg/day based on decreased body weight gain in males (38% less than controls at 2 years) and in females (61% less than controls at 2 years).

The dog study has been classified as Core Supplementary and therefore does not satisfy the guideline requirements for a chronic toxicity study in non-rodents. However, the study is upgradable to Core Minimum upon submission of diet stability and homogeneity data. The registrant has notified OPP of its intent to conduct a retrospective stability /homogeneity study.) Numerous other study deficiencies were noted which would not affect the study's acceptability for regulatory purposes. (MRID 42940203, 43747100)

m. Developmental Toxicity of BAM

Sixteen New Zealand white rabbits per dose group were given BAM at dosing levels of 0, 10, 30, or 90 mg/kg/day by oral gavage on gestational days (GDs) 7 - 19. Maternal toxicity was observed at 30 and 90 mg/kg/day. At 30 mg/kg/day, moribundity increased (2 animals vs 0 in the control). At 90 mg/kg/day, moribundity increased (2 animals vs 0 in the control); body weight decreased nonsignificantly (93%-95% of control) on GDs 13 - 19; weight gain decreased significantly during

the dosing period; food consumption decreased significantly (51% of controls) during the dosing period; and the number of abortions increased (3 animals vs 0 in the control). Compensatory body weight and food consumption increases above controls were noted during the post-dosing period. The maternal NOEL was set at 10 mg/kg/day, and the LOEL was set at 30 mg/kg/day. Developmental toxicity was observed at 90 mg/kg/day. It was manifested as a nonsignificant decrease (94% of controls) in fetal body weight which was outside the historical control range. Consequently, the developmental toxicity NOEL was set at 30 mg/kg/day. The developmental toxicity LOEL was set at 90 mg/kg/day based on decreased fetal body weight and body weight gain. (MRIDs 43003601, 43265201)

n. 3-Generation Reproduction Study of BAM

Results of a reproduction study of rats fed diets containing BAM over three generations (MRID 42940204) were submitted. However, the study was not reviewed. The registrant has been unable to locate the individual animal data requested by the Agency. However, another rat reproduction study has not been required because of the following reasons: (1) cursory review of the results of the submitted 3-generation reproductive study of BAM in rats (MRID 42940204) showed that the reproductive toxicity of BAM at 180 ppm was mainly manifested as a significant decrease in pup body weight (83-86% of the control animals at day 21 only for 1 and 3 generations, but not in 2 generation) (2) Decrease in pup body weight (90-94% of the control animals at days 14 and 21 for both generations) at 350 ppm was also seen in a 2-generation reproductive study of its parent compound, dichlobenil in rats. (3) The toxicity of BAM is not greater than that of its parent compound, dichlobenil, based on the results of chronic toxicity studies of BAM and its parent in rats and dogs.

o. Mutagenicity of BAM

BAM was negative for inducing reverse gene mutation (his- to his+) in TA strains of Salmonella typhimurium exposed, in the absence and presence of mammalian metabolic activation (rat S9 mix), up to 5000 $\mu\text{g}/\text{plate}$ (MRID 43003603).

BAM was negative for inducing repair of DNA damage as measured by unscheduled DNA synthesis (UDS), as determined by net nuclear silver grain count in primary rat hepatocytes, exposed up to cytotoxic doses (1000 $\mu\text{g}/\text{ml}$) (MRID 43003604).

A mouse micronucleus assay using a single dose of BAM (250 mg/kg) was negative. This dose was selected based on a single dose study in which the group of mice treated at 250 mg/kg displayed mild neurotoxic effects (lethargy and ataxia), the group treated at 500 mg/kg were severely affected (becoming comatose), and the groups treated at 1000 mg/kg and higher died in extremis. Thus, the study is consistent with the guideline requirements of dosing animals up to levels producing either clinical toxicity or cytotoxicity in target cells. (MRID 43003602, 43747101)

Taken together, these studies satisfy mutagenicity guideline requirements.

p. BAM Toxicological Endpoints of Concern Identified for Use in Human Dietary Risk Assessment

Acute

For BAM an acute (1 day) dietary risk assessment is not required because the time period in which effects were noted in the rabbit developmental toxicity study exceed a one day dosing period (MRID 43003601, 43265201). The developmental toxicity NOEL is 30 mg/kg/day. The developmental toxicity LOEL is 90 mg/kg/day based on a non-significant decrease in fetal body weight which was outside the historical range. The maternal toxicity NOEL is 10 mg/kg/day. The maternal toxicity LOEL is 30 mg/kg/day based on increased moribundity. However, effects at the 90 mg/kg/day dose level occurred on gestation days (GDs) 13 - 19 which is the second half of the dosing period of GDs 7 - 19. Thus, the Toxicological Endpoint Selection Committee concluded that it would be inappropriate to use these endpoints for an acute assessment.

Short-term and Intermediate

Neither a short term (1 - 7 days) or an intermediate term (1 week - several months) occupational or residential risk assessment is required. As previously stated, BAM is major residue detected in plants. A scenario in which BAM is applied in either an occupational or a residential setting has not been identified. Dichlobenil is the chemical applied by agricultural workers.

Chronic

The OPP RfD Committee met on July 27, 1995, and determined that the RfD for BAM was 0.015 mg/kg/day. The RfD was based upon a NOEL of 4.5 mg/kg/day from a 2 year dog feeding study (MRID 42940203) using an uncertainty factor (UF) of 300 (100 x 3). The 100 is to account for inter-species extrapolation and intra-species variability. The 3 is to compensate for the lack of an acceptable reproduction study. (The LOEL was 12.5 mg/kg/day based on decreased body weight gain in both males and females). The RfD for BAM shall be used in the total dietary (food source and drinking water) risk assessment since plant residue studies indicate that BAM is the major residue detected in plants and environmental fate data indicate BAM has the potential to leach into ground water. BAM is consumed in the food supply and is therefore the chemical of concern.

Although a formal determination has not yet been made regarding the potential carcinogenicity of BAM, a preliminary review of the data indicate that the potential does not exceed (and may be lower) than that of the parent compound (currently classified as an unquantified, Group C, carcinogen).

2. Exposure Assessment

a. Dietary Exposure

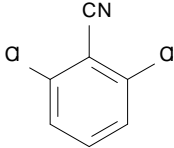
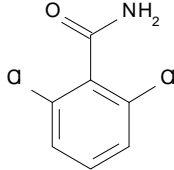
Tolerances for residues of dichlobenil in/on raw agricultural commodities are currently expressed in terms of combined residues of dichlobenil and its metabolite 2,6-dichlorobenzoic acid (2,6-DCBA) per 40CFR180.231. The established tolerances are each 0.15 ppm for plant commodities. No

tolerances have been established for animal commodities and no tolerances for processed food/feed have been established.

On June 8, 1992, the OPP Metabolism Committee met and concluded that 2,6-dichlorobenzamide (BAM) is the major terminal residue of dichlobenil in plants, and should be added to the tolerance expression. Because dichlobenil plant metabolism studies demonstrate that 2,6-DCBA is not a plant metabolite, the Committee has recommended removing 2,6-DCBA from the tolerance expression for dichlobenil. Therefore, residue data for 2,6-DCBA are no longer required. All conclusions specified here regarding the status of residue chemistry data requirements and the adequacy of the established tolerances reflect the Metabolism Committee's determination to add BAM to the tolerance expression and remove 2,6-DCBA from the tolerance expression.

The chemical structures of dichlobenil and its current metabolite of concern, BAM, are depicted in Figure A.

Figure A. The Chemical Structures of Dichlobenil and BAM

Structure Parent: Chemical name	Structure Metabolite: Chemical name
 <p>dichlobenil: 2,6-dichlorobenzonitrile</p>	 <p>BAM: 2,6-dichlorobenzamide</p>

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on acceptable plant metabolism studies on apples and grapes. Both studies indicate that the major residue of concern is BAM; the parent compound, dichlobenil, was not detected in either of the studies. The OPP Metabolism Committee has concluded that the residues to be regulated in plant commodities are dichlobenil and BAM.

In the grape metabolism study, mature grape vines were treated with a single soil application of uniformly benzene-ring labeled [¹⁴C]dichlobenil at a rate equivalent to 1x. HPLC analyses of the organosoluble and acid-hydrolyzed aqueous extracts indicated that BAM was the major residue, amounting to 82.1% of the total radioactive residues (TRR). 4-Hydroxy-BAM was also identified as a residue at 1.9% of the TRR.

In the apple metabolism study, an apple tree was treated with a single soil application of uniformly benzene-ring labeled [¹⁴C]dichlobenil at a rate equivalent to 1x. HPLC analyses of the organosoluble extracts of the apples indicated that BAM was the major residue, amounting to 57% of the TRR. The remaining TRR were insoluble or unidentified soluble fractions, individually accounting for <0.01 ppm.

Animal Metabolism

Dichlobenil poultry and goat metabolism studies which had initially been judged inadequate, due to the failure to account for nonextractable residues and substantial losses of radioactivity prior to HPLC analyses, were later accepted when the plant metabolism studies indicated that dichlobenil is not a significant plant residue. However, BAM, the major terminal residue in plants, was not found as a metabolite or transitory intermediate in the ruminant or poultry studies. Therefore, additional animal metabolism studies in which ruminants and poultry dosed with [¹⁴C]BAM were conducted.

Lactating goats were dosed with [U-phenyl]¹⁴C-BAM at a dose level of 10 ppm for five days. The maximum reasonable dietary burden is 0.5 ppm, based on a diet of 40% wet apple pomace and assuming a 0.5 ppm tolerance for apples, which is the reassessed tolerance. The primary residue found in milk, kidney, fat, and muscle was unchanged BAM. The major residue found in liver was the glutathione conjugate 6-chloro-3-hydroxy-2-mercaptobenzamide. Although, additional information is required to upgrade this study, the available information is sufficient to assess dietary exposure.

Laying hens were dosed with [U-phenyl]¹⁴C-BAM at a dose level of 10 ppm for five days. The primary residue found in all matrices collected was unchanged BAM. As a result of recent revisions to Table 1 in OPPTS Guideline 860.1000 (August, 1996), no significant poultry feed items are treated with dichlobenil. Therefore, secondary residues in poultry are no longer of concern.

Residue Analytical Methods - Plants and Animals

PAM Vol. II, Method A is a GLC/ECD method with a detection limit of 0.05 ppm, which can be used for determination of residues of dichlobenil in/on plant commodities. This method was judged adequate for tolerance enforcement; however, Method A uses benzene as a solvent. The registrant was required to revise the method or develop an alternative method using safer solvents. The revised method (MRID 43805301) is currently under review. However, this method is not adequate and will require additional modification before it can be accepted as a tolerance enforcement method.

The Dichlobenil Guidance Document required development of an analytical method for the detection and quantitation of BAM in plant commodities. The former basic producer, Solvay Duphar, submitted a GLC/ECD method (L 3-53-71) for determination of residues of BAM in/on fruits and nuts. This method has undergone a successful independent laboratory validation and has been validated by the EPA Beltsville Analytical Chemistry Laboratory (ACL). However, a revised method

incorporating ACL's comments must be submitted before the requirements for an analytical method for BAM can be considered fulfilled.

Residue data for dichlobenil that were included in the Residue Chemistry Science Chapter were collected using Method A of PAM, Vol. II or modifications thereof. Dichlobenil residue data reviewed since issuance of the Science Chapter were collected using an adequate GLC/ECD method (L 3-53-64). This method does not involve the use of any hazardous solvents. All BAM residue data submitted in support of dichlobenil reregistration were collected using method L 3-53-71.

Analytical methods for the determination of dichlobenil and BAM in meat, meat by-products, and milk are required. Dichlobenil residues were tentatively identified in goat fat and muscle in the ruminant metabolism study in which the test animals were dosed with the metabolite BAM. Unless additional data are submitted which demonstrate that dichlobenil was misidentified, dichlobenil residue data in livestock commodities will be required. The Agency will use total radioactive residue (TRR) data from the metabolism study so that a worst case risk assessment can be done in the absence of these methods.

The FDA PESTDATA database dated 1/94 (PAM Vol I, Appendix I) indicates that dichlobenil is completely recovered (>80%) using multiresidue methods PAM Vol. I Sections 302 (Luke method) and 304 (Mills fatty food method), and has partial recovery (50-80%) using Section 303 (Mills, Onley, Gaither method). The database also indicates that BAM is completely recovered (>80%) using Section 302, and not recovered using Sections 303 and 304.

Storage Stability

Adequate storage stability data for BAM to support the submitted field residue and processing studies are available. Residues of BAM are stable during frozen storage at $\leq 14^{\circ}\text{C}$ in/on apples for 6 months; grapes, grape wet and dry pomace, and raisin waste for 4 months; apple processed fractions for 3.5 months; cranberries for 3 months; peaches for 2 months; blackberries, plums and raspberries for 1 month; and blueberries for 15 days. BAM residues declined approximately 35% in/on raisins during storage for 79 days. In addition, BAM residues are stable during frozen storage in/on filberts for 1 month but decline 50% after approximately 4 months of storage.

Apple and grape processing studies remain outstanding. Samples from the outstanding processing studies should be analyzed within the interval that BAM residues are known to be stable; alternatively, new supporting storage stability studies should be submitted. In addition, BAM field residue data remain outstanding for cherries. Storage stability data to support this study are required.

Provided that adequate supporting storage stability data for the parent, dichlobenil, are submitted to support the outstanding field residue data for cherries and grapes, and the outstanding processing studies for apples, and grapes, no additional storage stability data will be required for dichlobenil.

Storage stability data for livestock commodities are required to support the outstanding cattle feeding study. Intervals and conditions must reflect those utilized in the feeding study.

Magnitude of the Residue in Plants

All data for magnitude of the residue in plants have been evaluated and deemed adequate to reassess the tolerances for the residues of dichlobenil in/on apples, blackberries, blueberries, cranberries, filberts, pears (translated from apples), and raspberries (translated from blackberries). Adequate data from field trials depicting combined residues of dichlobenil and BAM following treatment according to the maximum registered use pattern have been submitted for apples, blackberries, blueberries, cranberries, and filberts. Additional data are required for residues of dichlobenil and BAM for cherries and dichlobenil only for grapes.

Crops Grown Solely for Seed

The alfalfa and clover grown for seed sites have been cancelled. Therefore, the residue data and tolerance proposals for alfalfa and clover forage and hay that were required in the Dichlobenil Guidance Document, dated 3/23/87, are no longer required.

Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are not fulfilled for any commodity. Processing studies have been submitted for apples, grapes, and plums treated at 1x the maximum seasonal rate. However, these studies were deemed unacceptable because, in the case of apples and plums, the raw agricultural commodity used for processing did not bear detectable residues of dichlobenil or BAM and, in the case of grapes, residues were not determined in the raw agricultural commodity used for processing. In addition, residues of dichlobenil were not determined in the grape and plum processing studies. The grape and plum studies indicate that concentration of BAM residues may occur since detectable residues were detected in the processed commodities.

In a second processing study submitted for apples, no detectable residues of dichlobenil or BAM were detected in apples that were treated at 1x. Consequently, the registrant conducted a processing study with untreated apples that had been spiked with BAM only. Because apples were not spiked with dichlobenil, concentration factors for the combined residues of dichlobenil and BAM could not be determined.

Preliminary data which have been submitted for apples and grapes indicate potential concentration of BAM residues in grape pomace (wet and dry) and raisin waste.

Adequate processing studies depicting the concentration of the combined residues of dichlobenil and BAM in the processed commodities of apples and grapes bearing detectable residues remain outstanding. Exaggerated application rates may be necessary to obtain detectable residues.

There are no registered uses of dichlobenil on citrus fruits, plums or figs. Therefore processing studies are not required to determine the potential for concentration of the combined residues of dichlobenil and BAM in citrus, plums and/or fig processed commodities.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Insufficient data are available to determine if tolerances for ruminant commodities are required. A cattle feeding study must be submitted whereby cattle are dosed with BAM. Total radioactive residue (TRR) values from the ruminant metabolism study (goats fed ¹⁴C BAM) will be used to conduct a worst-case risk assessment in association with this RED. Poultry studies are not required since no significant poultry feed items are treated with dichlobenil.

Magnitude of the Residue in Potable Water, Fish and Irrigated Crops

A dichlobenil DCI issued 11/22/93 detailed the data requirements for these guidelines for aquatic food/feed sites. Subsequently, all aquatic food crop uses for dichlobenil were deleted.

Confined/Field Rotational Crops

Data requirements for these guidelines have been waived based on the results of a hydrolysis study. A restriction against the planting of rotational crops, on which dichlobenil is not registered for use, in treated soil within one year of application has been established. However, rotation of crops is not likely since dichlobenil is only registered for use on domestic orchard crops, grapes, and cane and bush berries. These are commodities which are not grown from seed each year, but are produced from mature plants that remain in place for many years.

b. Dietary Exposure (Water)

Available information indicates that dichlobenil has been detected in surface water and that both dichlobenil and its metabolite BAM have the potential to leach and persist in ground water. Therefore, consumption of drinking water containing residues of dichlobenil and/or BAM is possible.

Very limited ground water monitoring data are available for dichlobenil and BAM; all from non-U.S. sites. While these data are consistent with the Agency's determination that these compounds have the potential to contaminate ground water, they are not sufficient to estimate the levels at which contamination would occur. A drinking water monitoring study is being required through this RED in order to determine the level at which contamination of ground water occurs for both the parent dichlobenil and metabolite BAM. Currently, the Agency does not have adequate data to conduct an exposure assessment for residues of BAM in drinking water.

In order to estimate concentrations of dichlobenil in drinking water, the Agency used GENECC (GENeric Expected Environmental Concentration) modeling. This program estimates expected concentrations from a few basic chemical parameters and pesticide label application information.

GENEEC is a tier one model which uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a ten hectare agricultural field into a one hectare by two meter deep pond. GENECC considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before wash off to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body. GENECC can only estimate a surface water concentration.

It should be noted that GENECC was designed for use in ecological risk assessment. It should be considered as a screen, since GENECC could substantially over-estimate the actual drinking water concentrations. However, preliminary indications are that if the pesticide is not an organophosphate (OP), a carbamate, or a pyrethroid and is not used in repeated applications, that GENECC may be an appropriate screening tool for acute drinking water exposure.

Since dichlobenil is not an OP, a carbamate, or a pyrethroid, and is not used in repeated applications, use of GENECC is appropriate.

The exposure estimates do not take into account reduction of dichlobenil residues at water treatment plants. Treatment of ground water or surface water in a publicly owned water treatment facility would reduce the concentration of any dichlobenil residues that were present and thus reduce the risk to those individuals consuming treated water. Aeration and agitation are used in most public water supply systems to reduce the concentration of volatile compounds in the water. Since parent dichlobenil has a high potential to volatilize, the aeration process will remove some of the dichlobenil in the raw water. It can not be determined if aeration and agitation will be effective in removing BAM from the raw water. Filtration will also help to remove dichlobenil residues from the raw water, with the use of carbon filtration being the most productive filter treatment to help remove dichlobenil residues. The combined use of aeration and filtration treatments should be effective in removing the majority of any dichlobenil residues from public drinking water supplies.

GENEECC was used to estimate both peak surface water concentration and a 56-day surface water concentration for use in a drinking water risk assessment. Assuming an application rate of 8 lb. ai/A which is not incorporated into the soil, the peak concentration was estimated to be 380 ppb and the 56-day concentration to be 27 ppb. It should be noted that if the modeling used a lower application rate or assumed incorporation, these estimates would decrease. See Table 25.

c. Occupational and Residential

An occupational and/or residential exposure assessment is required for dichlobenil based on (1) adverse developmental and reproductive effects and (2) potential exposure to handlers (such as mixers, loaders, and applicators) during use. Due to the absence of a dermal absorption study, 100% dermal absorption is assumed.

Handler (Mixer/Loader/Applicator) Exposure Scenarios

EPA has determined that there is an exposure potential for mixers, loaders, applicators, or other handlers during usual use-patterns associated with dichlobenil. Handler exposure scenarios are as follows:

- # Homeowner application of the two percent G via belly grinder, self-contained shaker can, and other similar hand-held equipment.
- # Application of the four percent G via tractor-drawn or -mounted, rotary or drop-type spreaders, and backpack granular applicators.
- # Application of the 50 percent WP as a prepaving treatment via groundboom equipment.
- # Application of the 50 percent WP (enclosed in water soluble packets) through foam-generating equipment to sewer systems.

The Agency does not have data generated by monitoring mixer/loader/applicator (M/L/A) exposure to dichlobenil; therefore, surrogate data from the Pesticide Handlers Exposure Database (PHED) will be used for this exposure assessment. The occupational exposure assessment will be performed for the short-term (1 - 7 days) scenario only. Available information indicate that exposure based on sewer use can be considered an intermediate scenario. Dichlobenil is routinely applied by sewer maintenance personnel throughout the root growing season. However, there are no data to perform an assessment. Once, the Agency receives exposure data for the sewer use scenario, then an intermediate term assessment will be performed. For all other scenarios, the annual usage data available to the Agency does not seem to support either an intermediate-term or a chronic exposure scenario. If, in the future, the annual usage data confirm that an intermediate-term (or chronic scenario) exists, then another exposure assessment for an intermediate term scenario will be performed. See Table 3 for exposure values and assumptions.

Table 3: Exposure Values for Handlers Using Dichlobenil

Exposure Scenario	Clothing Parameters	Dermal Exposure (mg/lb ai)	Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Daily Amt. Treated	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)	Combined Daily Dermal and Inhalation Exposure (mg/kg/day)
Mixer/Loader Exposure								
Wettable Powder-Open Bag/Box (Sewer Treatment)	Long-sleeved shirt, long pants, gloves	0.1737	0.0037	10 lb ai	--	0.029	0.0006	0.03
Wettable Powder-Water Soluble Packet (Sewer Treatment)	Long-sleeved shirt, long pants, gloves	0.01	--	10 lb ai	--	0.0016	--	0.002
Wettable Powders-Open Bag (Asphalt Treatment)	Long-sleeved shirt, long pants, gloves	0.1737	0.0037	10-12 lb ai/A	5 acres	0.145 - 0.174	0.003 - 0.004	0.15 - 0.18
Granular Formulations - (Asphalt Treatment)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	10-12 lb ai/A	5 acres	0.0053 - 0.0063	0.0014 - 0.0017	0.007 - 0.008
Granular Formulations - (Agricultural Treatments)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	4-6 lb ai/A	30 acres	0.0126 - 0.0189	0.0034 - 0.0051	0.016 - 0.024
Granular Formulations - (Shelterbelt, Woody Ornamental Treatments)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	4-8 lb ai/A	30 acres	0.0126 - 0.0252	0.0034 - 0.0068	0.016 - 0.032
Granular Formulations - (Ornamental Linerstock Treatments for Nutsedge Control)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	10-20 lb ai/A	5 acres	0.0525 - 0.105	0.0014 - 0.0028	0.054 - 0.108
Granular Formulations - (Industrial, Non-Crop, Rights of Way Treatments)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	12-20 lb ai/A	30 acres	0.0378 - 0.063	0.01 - 0.017	0.048 - 0.08
Granular Formulations (Aerial Application)	Long-sleeved shirt, long pants, gloves	0.0063	0.0017	1.4-2 lb ai/A	100 acres	0.0147 - 0.021	0.004 - 0.006	0.019 - 0.027
Applicator Exposure								
Aerial Application (Granular Formulation) - Dichondra	Long-sleeved shirt, long pants, no gloves	0.009	--	1.4-2 lb ai/A	100 acres	0.021 - 0.03	--	0.021 - 0.03
Groundboom Application, Open Cab (Asphalt)	Long-sleeved shirt, long pants, no gloves	0.017	--	10-12 lb ai/A	5 acres	0.0142 - 0.017	--	0.014 - 0.017
Tractor-Drawn or-Mounted Granular Spreader (Agricultural Treatments)	Long-sleeved shirt, long pants, no gloves	0.013	0.0012	4-6 lb ai/A	30 acres	0.026 - 0.039	0.0024 - 0.0036	0.028 - 0.043
Tractor-Drawn or-Mounted Granular Spreader (Shelterbelt, Woody Ornamental Treatments)	Long-sleeved shirt, long pants, no gloves	0.013	0.0012	4-8 lb ai/A	30 acres	0.026 - 0.052	0.0024 - 0.0048	0.028 - 0.057
Tractor-Drawn or-Mounted Granular Spreader (Ornamental Linerstock Treatments for Nutsedge Control)	Long-sleeved shirt, long pants, no gloves	0.013	0.0012	10-20 lb ai/A	5 acres	0.011 - 0.022	0.001 - 0.002	0.012 - 0.024

Exposure Scenario	Clothing Parameters	Dermal Exposure (mg/lb ai)	Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Daily Amt. Treated	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)	Combined Daily Dermal and Inhalation Exposure (mg/kg/day)
Tractor-Drawn or-Mounted Granular Spreader (Industrial, Non-Crop, Rights of Way Treatments)	Long-sleeved shirt, long pants, no gloves	0.013	0.0012	12-20 lb ai/A	30 acres	0.078 - 0.13	0.0072 - 0.012	0.085 - 0.142
Tractor-Drawn or-Mounted Granular Spreader (Dichondra)	Long-sleeved shirt, long pants, no gloves	0.013	0.0012	1.4-2 lb ai/A	30 acres	0.0091 - 0.013	0.0008 - 0.0012	0.01 - 0.014
Sewer Treatment Using Foam Generating Equipment	Long-sleeved shirt, long pants, gloves	no data	no data	10 lb ai	10 lb ai/day	--	--	--
Mixer/Loader/Applicator								
Homeowner Shaker-Container (Using a Hand Dispersal of Granular Bait Surrogate)	Total deposition (assumes no protection from clothing)	77.5	0.468	0.0009 lb ai/10 sq ft	Entire contents of the container (0.025 lb ai)	0.032	0.0002	0.032
Homeowner Belly Grinder, Granular Spreader	Total deposition (assumes no protection from clothing)	211	0.0618	0.0009 lb ai/10 sq ft	1000 sq ft (0.09 lb ai)	0.32	0.0001	0.32
Commercial Belly Grinder, Granular Spreader	Long-sleeved shirt, long pants, no gloves	12.9	0.0618	0.0009 lb ai/10 sq ft	10000 sq ft (0.9 lb ai)	0.194	0.001	0.195
Commercial Granular Backpack Applicator (Landscape Treatment)	No Data	--	--	--	--	--	--	--
Homeowner Sewer Treatment - Toilet Bowl Method, Open bag/jar (from the open-bag wettable powder M/L surrogate)	Total deposition (assumes no protection from clothing)	15.8	0.037	0.011 lb ai for a 4" sewer pipe	0.011 lb ai per day	0.0029	--	0.003

Since the toxicological endpoint is from a developmental study the default body weight for a woman (60 kg) was used.

The daily exposure is calculated using the following formula:

$$\text{Daily exposure (mg ai/kg bw/day)} = \frac{\text{unit exp. (mg ai/lb ai handled)} \times \text{lb ai/A} \times \text{daily acres treated}}{\text{body weight (60 kg)}}$$

Post-Application Exposures

There are no data available to address post-application exposure for persons reentering areas treated with dichlobenil.

Occupational Post-Application Exposures

The potential for dermal exposure following applications of dichlobenil appears to be limited. Many agricultural and horticultural applications are made to the soil early in the season and may be followed by shallow incorporation or irrigation. Therefore, workers would not ordinarily be in direct contact with dichlobenil, unless their task involved activities in which the surface of the soil was disturbed. For agricultural and horticultural situations, applications are usually made to established plants or transplants established for at least four weeks in orchards or groves thus, limiting the potential for worker activities requiring substantial contact with treated soil. The granular formulation is not likely to leave a significant deposit on foliage surfaces and use-directions indicate that deposit on foliar surfaces is to be avoided. In addition, applications are also made when temperatures are below 70° F, before weed seeds are germinating, and when harvesting and other usual hand-labor tasks are less likely. For raspberries and blackberries applications are prohibited during shoot emergence, a time when some postapplication tasks may take place.

However, the Agency has concerns about potential post-application dermal exposures in the following situations: (1) uses in dichondra-producing establishments which could involve substantial contact with the soil subsurface, and (2) uses in nursery settings just prior to placement of ornamental stock in liners. In nursery settings, workers are likely to place ornamental stock in liners on the treated area soon after application is complete.

There is concern about post-application inhalation exposures for various horticultural and nursery uses based on dichlobenil's moderate vapor pressure and the uncertainties of whether the various use-scenarios should be considered to be short-term or intermediate-term. These concerns are for the horticultural uses. For enclosed or confined horticultural uses, if dichlobenil is not soil-incorporated the possibility for vaporization and resulting build-up of vapors exists.

Residential Post-Application Exposures

Homeowners may be engaged in hand-weeding or hand-mulching in treated areas which could involve substantial contact with the soil subsurface.

3. Risk Assessment

a. Acute Dietary

(1) Dichlobenil

The NOEL of 45 mg/kg/day from rabbit developmental study is used to assess acute dietary risk of dichlobenil.

(a) Food

Residues of dichlobenil are not found on food. Therefore, a risk assessment is not needed.

(b) Water

Since the NOEL for dichlobenil is taken from a developmental toxicity study the subpopulation of interest for this risk assessment will be pregnant females (age 13+). As discussed earlier, a concentration of 380 ppb dichlobenil was used as estimated by GENECC.

Exposure for this subpopulation is calculated using the following formula:

Exposure (mg/kg/day) = (ppb in water consumed) (10^{-6}) (upper 95 percentile drinking water intake)

The 10^{-6} conversion factor is necessary to achieve the final units of mg/kg/day and is derived as follows:

$$\frac{(L) (ml H_2O) (mg)}{(10^3 ml) (g H_2O) (10^3 \mu g)}$$

The upper percentile drinking water intake estimates were derived from USDA's 1977-1978 nationwide Food Consumption Survey.

A MOE (Margin of Exposure) approach is used for estimating acute dietary risk. The MOE is a measure of how closely the estimated high end exposure comes to the NOEL. The MOE is calculated by:

$$MOE = NOEL/exposure$$

$$MOE = 45/0.015 = 3000 \text{ (rounded to 2 significant figures.)}$$

The estimated MOE greatly exceeds 100, which is the level of concern when the NOEL is taken from an animal study. Thus, this screening assessment raises no concerns for acute dietary risk from consumption of surface water-derived drinking water containing residues of dichlobenil.

If, the dichlobenil were to be incorporated, then GENEEC modeling indicated that the surface water concentration would decrease to 190 ppb. Thus, the MOE would be even larger.

(2) BAM

There was no toxicological endpoint of concern from acute exposure to BAM. Therefore, an acute dietary risk assessment is not needed.

Even though data are not currently available to determine levels of dichlobenil in ground water, concentrations could be 30 times higher than the 380 ppb level derived using GENEEC for surface water and still have an adequate MOE 100. The Agency does not believe that levels in ground water will be of that magnitude.

b. Chronic Dietary

(1) Dichlobenil

The RfD for dichlobenil is based on a NOEL of 1.25 mg/kg/day from a 2-year dog feeding study with a 100-fold safety factor applied.

(a) Food

Residues of dichlobenil are not found on food. Therefore, a risk assessment is not needed.

(b) Water

Using the 56-day surface concentration of 27 ppb estimated by GENEEC, exposure for the general population is calculated using the formula:

Exposure (mg/kg/day) = (ppb in water consumed) (10^{-6}) (upper 95 percentile drinking water intake)

$$\text{Exposure} = (27) (10^{-6}) (50) = 0.001350 \text{ mg/kg/day}$$

$$\% \text{RfD} = 0.001350 / 0.013 = 10\% \text{ (rounded to 1 significant figure)}$$

Exposure for the subpopulation, non-nursing infants, assuming a 10 kg child, is calculated using the formula:

$$\text{Exposure (mg/kg/day)} = (27) (10^{-6}) (126.5) = 0.003415 \text{ mg/kg/day}$$

$$\% \text{RfD} = 0.003415 / 0.013 = 26\% \text{ (rounded to 2 significant figures)}$$

Generally, the Agency has no concerns when less than 100% of the RfD has been used.

As stated previously, GENECC can substantially over-estimate the actual drinking water concentration, which could mean that these risk estimates may also be over-estimated.

Even though there are no data for ground water with which to estimate exposure from drinking water from that source, and given that only 26% of the RfD is utilized from high-end estimates for surface water, the Agency has no risk concerns from exposure to drinking water from contaminated ground water. Data are being required through this RED to confirm this determination.

(2) BAM

The RfD is based on a NOEL of 1.25 mg/kg/day from a 2 year dog feeding study with a 300-fold safety factor applied.

(a) Food

As previously stated, the residue detected in the food supply is BAM. Chronic dietary (food source) risk for BAM was estimated using the BAM RfD of 0.015 mg/kg/day (MRID 42940203) for the general U.S. population and 22 population sub-groups. Tolerance level residues and 100 % crop treated (CT) were assumed. Two DRES (Dietary Risk Evaluation System) runs using tolerance level residues were performed. The first DRES run was performed using all the established tolerances per 40 CFR 180.231. Even commodities for which revocation was proposed were included since as long as the tolerance exists commodities containing BAM residues could be imported.

Using All Established Tolerances

<u>Subgroup</u>	<u>Exposure(mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.000612	4%
Nursing Infants (< 1 yr old)	0.001729	12%
Non-Nursing Infants (< 1 yr old)	0.002739	18%
Children (1-6 yrs old)	0.001710	11%

All other sub-groups are less than 6% of the RfD.

For the second DRES run, it was necessary to estimate residues of BAM in meat (ruminant tissues) and milk. As previously stated TRR data were used. The estimated residues are 0.0012 ppm in fat, 0.060 ppm in kidney, 0.47 ppm in liver, 0.012 ppm in muscle, and 0.0025 ppm in milk.

The second DRES run was performed using these estimated residues, the reassessed tolerances in Section IV, Table 33 as well as tolerances proposed for revocation. It should be noted that it was necessary to increase the tolerances for apples and pears, which are high consumption commodities for infants and children. As explained in Table 33, this is due to the change of the tolerance expression to include the BAM metabolite. It was also necessary to use the established tolerances for grapes, and

the stone fruits group (peaches, plums, cherries, apricots, and nectarines) since additional data are necessary to assess the adequacy of the established tolerances.

Using Reassessed Tolerances and Estimated Residues for Meat and Milk

<u>Subgroup</u>	<u>Exposure(mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.000701	5%
Nursing Infants (< 1 yr old)	0.001790	11%
Non-Nursing Infants (< 1 yr old)	0.002959	20%
Children (1-6 yrs old)	0.001914	13%

All other sub-groups are less than 7% of the RfD.

These % RfDs can be considered to be over-estimates since DRES runs were performed using tolerance level residues. It is likely that actual residues in the food supply are much lower. It is also unlikely that 100% of a commodity has been treated with dichlobenil. Thus, there are no chronic dietary concerns for consumption of the dichlobenil metabolite BAM.

(b) Water

Adequate data to conduct a chronic drinking water assessment for BAM are not available to the Agency.

c. Short-Term Nondietary

Risk values from short-term exposure from occupational and homeowner uses of dichlobenil are presented in Table 4.

As previously stated, the toxicological endpoint of concern for a short-term occupational and residential exposure is from a developmental toxicity study (MRID 41257302). The NOEL is 45 mg/kg/day. The Margin of Exposure (MOE) is a measure of how closely the estimated exposure comes to the NOEL. An MOE of 100 is considered to be acceptable when based on animal studies. The MOE for short-term occupational and residential exposure for dichlobenil is:

$$\text{Short-Term Exposure MOE} = \frac{45 \text{ mg/kg/day}}{\text{daily exposure (mg/kg/day)}}$$

Table 4: Summary of Risk for Handlers Using Dichlobenil

Exposure Scenario	Combined Daily Dermal and Inhalation Exposure (mg/kg/day)	Short-Term Margin of Exposure
Mixer/Loader Exposure		
Wettable Powder-Open Bag/Box (Sewer Treatment)	0.03	1500
Wettable Powder-Water Soluble Packet (Sewer Treatment)	0.002	>20,000
Wettable Powders-Open Bag (Asphalt Treatment)	0.15 - 0.18	250 - 300
Granular Formulations - (Asphalt Treatment)	0.007 - 0.008	5625 - 6429
Granular Formulations - (Agricultural Treatments)	0.016 - 0.024	1875 - 2813
Granular Formulations - (Shelterbelt, Woody Ornamental Treatments)	0.016 - 0.032	1406 - 2813
Granular Formulations - (Ornamental Linerstock Treatments for Nutsedge Control)	0.054 - 0.108	417 - 833
Granular Formulations - (Industrial, Non-Crop, Rights of Way Treatments)	0.048 - 0.08	563 - 938
Granular Formulations (Aerial Application)	0.019 - 0.027	1667 - 2368
Applicator Exposure		
Aerial Application (Granular Formulation) - Dichondra	0.021 - 0.03	1500 - 2143
Groundboom Application, Open Cab (Asphalt)	0.014 - 0.017	2647 - 3214
Tractor-Drawn or-Mounted Granular Spreader (Agricultural Treatments)	0.028 - 0.043	1047 - 1607
Tractor-Drawn or-Mounted Granular Spreader (Shelterbelt, Woody Ornamental Treatments)	0.028 - 0.057	789 - 1607
Tractor-Drawn or-Mounted Granular Spreader (Ornamental Linerstock Treatments for Nutsedge Control)	0.012 - 0.024	1875 - 3750
Tractor-Drawn or-Mounted Granular Spreader (Industrial, Non-Crop, Rights of Way Treatments)	0.085 - 0.142	317 - 529
Tractor-Drawn or-Mounted Granular Spreader (Dichondra)	0.01 - 0.014	3214 - 4500
Sewer Treatment Using Foam Generating Equipment ^a	No Data	--
Mixer/Loader/Applicator		
Homeowner Shaker-Container (Using a Hand Dispersal of Granular Bait Surrogate)	0.032	1406
Homeowner- Belly Grinder, Granular Spreader	0.32	141
Commercial- Belly Grinder, Granular Spreader	0.195	231
Commercial Granular Backpack Applicator (Landscape Treatment)	--	--
Homeowner Sewer Treatment - Toilet Bowl Method, Open bag/jar (from the open-bag wettable powder M/L surrogate)	0.003	>15000

^a This is the only scenario for which the Agency can verify the need for an intermediate-term occupational scenario.

Risk Estimates From Handler Exposures

All short-term MOEs are greater than 100 for all handler exposure scenarios for which there are data. As previously explained, the estimates taken from PHED were based on studies of mixers and loaders wearing long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves; and applicators wearing long-sleeved shirt, long pants, shoes, socks, and no gloves. Thus, there are no occupational concerns for the short-term exposure scenarios for M/L/As attired as described in Table 3, or concerns for any of the residential scenarios.

There are two data gaps: exposure data from the use of a backpack granular applicator and applications to sewer pipes. It can be stated that the use of backpack applicators for liquids usually results in high exposures. However, it is likely that exposure from a granular backpack applicator would be less since leaks are common with liquid backpack sprayers and the user is in close proximity to the spray. On the other hand, granular backpack applicators can cover greater areas, since applications can be made with swath widths of 20 feet. Granular backpack applicators are likely to be used by occupational users; therefore, it is likely that larger areas can be treated with more days of exposure than could be expected for liquid backpack applications, which are likely to be used by homeowners. These data shall be required.

The other scenario for which there are no data is the application of dichlobenil to sewer pipes. Available information indicates that exposure based on sewer use can be considered to be an intermediate exposure. These data shall be required.

Risk From Post-Application Exposures

As previously stated there are no data available to address postapplication exposure (occupational or residential) for persons reentering areas treated with dichlobenil. Therefore, the risk could not be quantitated. However, all short term MOEs for application are greater than 100. It is assumed that post-application exposure is less than exposure during application due to dissipation and degradation. Thus, generally speaking any post-application MOEs (both occupational and residential) should be even larger than application MOEs. When postapplication data are not available, interim REIs are usually based on acute toxicity categories, as well as an evaluation of the entire toxicological database. The acute toxicity categories for dichlobenil are III/IV.

There are a number of other reasons exposure to home owners should be minimal. Dichlobenil is used to treat areas where all vegetation is to be killed (such as around established trees and shrubs or around buildings, fences, and other structures) rather than lawns or other areas where children's play or similar activities would be expected. The 2G formulation label specifies that dichlobenil should be applied "in early spring before weeds emerge" or "between late fall (after a killing frost) and mid-winter". The cool temperatures would minimize vaporization. In early spring and late fall, children playing outside are bundled up with sweaters and coats, and are wearing shoes and long

pants. Thus, exposure is minimized by the clothing as well as by considering that a child spends less time outdoors in the early spring versus the summer. Therefore, this cannot be considered a summer scenario of children playing outdoors for long periods of time wearing shorts, short-sleeve tops, and sandals or barefoot. As an additional mitigation measure the label recommends that after application of dichlobenil the soil be moistened and applicators avoid disturbing the soil. Both of these measures would lock the dichlobenil beneath the soil surface, thereby minimizing exposure to granules.

The Agency notes dichlobenil is moderately volatile (vapor pressure of 5.5×10^{-4} mm Hg). Thus, there are concerns for horticultural/ nursery workers and homeowners during treatments in confined areas due to dichlobenil vapors.

Additionally, there may be concerns for horticultural workers during activities that disturb the soil. The MOEs previously calculated were for application of dichlobenil. BAM is a soil metabolite. It is assumed that nursery workers could be exposed to BAM during their routine activities. The Agency toxicological database for BAM is not as complete as that of dichlobenil.

Confirmatory post-application exposure data for both dichlobenil and BAM for applications to ornamentals are required.

4. FQPA Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCFA 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) also provide for an additional safety factor of up to 10-fold in situations where **available data** indicate **increased sensitivity of 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 for the general population and major subgroups of the population.

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

a. Assessment of Additional Sensitivity to Infants and Children

For dichlobenil, an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits, have been submitted to the Agency, meeting the basic data requirements, as defined for a food-use chemical by 40 CFR Part 158.

Prenatal sensitivity:

In both the prenatal developmental toxicity studies in rats and rabbits, the NOELs for developmental effects were greater than or equal to the NOELs for maternal toxicity. The prenatal developmental toxicity study in New Zealand White rabbits demonstrated decreased body weight gain and food consumption in the maternal animals at a gavage dose of 135 mg/kg/day; at the same dose level, there was an increased incidence of postimplantation loss and the occurrence of major external, visceral, and skeletal anomalies in fetuses. The maternal and developmental NOELs and LOELs in this study were equivalent at 45 and 135 mg/kg/day, respectively. In Wistar rats, decreased maternal body weight gain and food consumption were observed at the LOEL of 60 mg/kg/day (NOEL = 20 mg/kg/day), while an increase in supernumerary ribs was observed in fetuses at the LOEL of 180 mg/kg/day (NOEL = 60 mg/kg/day). In the two-generation reproduction study in Sprague-Dawley rats, a significant decrease in the birth weight of F1 pups was observed at a dietary dose level of 350 ppm (17.5 mg/kg/day). This decreased pup weight occurred without maternal toxicity. Nevertheless, the effect was not repeated in the second generation (at the same dietary level, the F2 pups weighed more than control pups), and a clear dose response relationship was not present in the pup weight decreases of the first generation. Based upon these data, the Agency concludes that there is no evidence of increased sensitivity of rats or rabbits to prenatal exposure to dichlobenil. This conclusion is also supported by the findings of the prenatal developmental toxicity study in New Zealand White rabbits with BAM, the dichlobenil plant metabolite which is the primary residue of concern for dietary exposure. In that study, the maternal NOEL (10 mg/kg/day), based upon moribundity at 30 mg/kg/day, was lower than the developmental NOEL of 30 mg/kg/day, based upon nonsignificantly decreased fetal body weight at 90 mg/kg/day.

Postnatal sensitivity:

In the two-generation reproduction study in Sprague-Dawley rats, the offspring NOEL was established at 60 ppm (3 mg/kg/day), based upon pup weight decreases observed at the LOEL of 350 ppm (17 mg/kg/day). The parental toxicity NOEL was 350 ppm (17 mg/kg/day) and the LOEL was 2000 ppm (100 mg/kg/day), based upon decreased body weight gain and food consumption. A lower NOEL in offspring than adults is suggestive of increased sensitivity to the offspring following exposure to dichlobenil. In the evaluation of this possibility, the following additional information was considered:

- As previously addressed, the birth weight decrease was discounted as evidence of prenatal sensitivity to dichlobenil, due to lack of consistency between generations and the absence of a clear dose response.

- A significant decrease in pup weight on postnatal day 4 also only occurs in first generation pups which had been of low birth weight.
- Significantly decreased pup weight on postnatal days 14 and 21 occurred in both generations (F1 and F2 pups) in a dose-response relationship. It was noted by the Agency that the pups were consuming treated feed, as well as receiving the dichlobenil in the maternal milk during this time period. Therefore, it is noted that the actual dose to the pups was likely to be exceptionally high on a mg/kg basis, although exact estimates of the difference in test substance intake between adults and offspring cannot be made.
- For the first generation (F1) pups, significant differences in mean body weight that are observed at weaning (postnatal day 21) in the 350 ppm (17.5 mg/kg/day) dose group are absent in the first week of the preweaning period (approximately 3 to 5 weeks of age). At 2000 ppm (100 mg/kg/day) significantly decreased F1 weight gain is still demonstrated at this point in time.
- A cursory review of the limited and inadequate data from the 3-generation reproduction study in rats with BAM, the primary metabolite of concern, by an *ad hoc* committee, had previously indicated that an inconsistent pattern of decreased pup body weights on postnatal day 21 was the only offspring toxicity noted in this study at the HDT of 180 ppm (approximately 9 mg/kg/day), and that no issues of additional sensitivity following postnatal exposure to BAM were identified.

Based on the above, only minimal confidence could be placed in the pup body weight data that appeared to suggest an increase in sensitivity to the offspring of rats following postnatal exposure to dichlobenil.

Other Factors Considered :

The RfD value for dichlobenil was calculated to be 0.013 mg/kg/day, based upon a NOEL of 1.25 mg/kg/day from the chronic study in dogs. It was noted that the offspring NOEL for the two-generation reproduction study in rats was 3 mg/kg/day, based upon body weight decrements in pups. If estimating an approximate doubling or tripling of feed intake between young and old rats on the reproduction study, the NOEL on the reproduction study would be nearly 6 to 9 times that of the NOEL from the chronic canine study.

Based upon the use patterns for dichlobenil, it is considered unlikely that infants and children will be exposed to this chemical. Dietary exposure to the plant metabolite, BAM, is more likely to occur. The assessment of the available data for BAM identified a data gap for the prenatal developmental toxicity study in rodents, and due to the lack of these data, an additional 3-fold uncertainty factor was included in the risk assessment for BAM. For BAM, the developmental NOEL (30 mg/kg/day) was 6.7-fold greater than the NOEL used to determine the RfD (4.5 mg/kg/day, from the chronic toxicity study in dogs).

Based upon the information discussed above, the Agency is confident that adequate protection of infants and children would be ensured by the use of an uncertainty factor of 100 (10X for interspecies variability and 10X for intraspecies variability) in the risk assessment for dichlobenil.

b. Aggregate (Multi-Pathway) Exposure and Resultant Risk

An aggregate risk assessment resulting from combining exposures from residential uses of dichlobenil with exposures from drinking water consumption could be performed. When comparing exposures from the homeowner application scenarios and adult consumption of dichlobenil contaminated drinking water, the exposure value for consumption of drinking water is orders of magnitude lower than that of a homeowner applicator. Therefore, the risk is essentially that of residential exposure alone since the contribution from drinking water is insignificant in comparison. Note that the Agency has no information to indicate that this type of exposure is likely to occur.

Only one scenario exists where aggregating exposures and calculating risk is appropriate. This is presented below.

BAM

Exposure to BAM can occur from exposure to food and from drinking contaminated water. As no acute toxicity endpoint was identified, only a chronic risk assessment is appropriate.

Chronic dietary risks for BAM from food sources are summarized below. These risks can be considered to be overestimated since tolerance level residues and 100% crop treated are assumed. Actual risks will be much lower.

<u>Subgroup</u>	<u>% Reference Dose</u>
U.S. population	5%
Nursing infants (<1 yr old)	11%
Non-nursing infants (<1 yr old)	20%
Children (1-6 yrs old)	13%

Water:

At this time, the Agency does not have adequate data to perform a quantitative chronic drinking water risk assessment for BAM. The most highly exposed subpopulation from food containing residues of BAM is non nursing infants which utilizes 20% of the RfD. Thus, the drinking water risk from BAM could be as high as 80 percent of the RfD and still be protective of the public health. Data are being required through this RED to confirm the Agency's conclusion that the aggregate risk does not exceed 100 percent of the BAM RfD.

c. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency 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 scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although 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 methodologies to resolve the complex scientific issues concerning common mechanisms 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 increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which common mechanism issues can be resolved. For example, pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Bromoxynil is the only compound found to have structural similarities to dichlobenil. Note that the BAM metabolite is not a benzonitrile, but a benzamide.

Structurally, both dichlobenil and bromoxynil are halogenated benzonitrile compounds. However, dichlobenil is di-chlorinated, while bromoxynil is di-brominated (in different positions relative to the nitrile group); and bromoxynil is hydroxylated para to the nitrile moiety.

While the compounds have some similar toxic effects, there are many differences in their toxicities. Similarities include some liver effects (both cause liver tumors and other liver effects), but dichlobenil causes numerous other toxic effects not seen with bromoxynil including effects on the prostate, pancreas, thyroid and adrenal glands.

Therefore, while some similarities exist between the two chemicals, there is insufficient information available at this time to conclude that they do or do not have a common mode of action with regard to human toxicity. The likelihood of exposure to both bromoxynil and dichlobenil (parent) is small. Bromoxynil has not been detected in water and has no residential uses. Dichlobenil is not detected

in the food supply. A cumulative exposure assessment resulting from use of these chemicals has not been performed.

In the case of dichlobenil, EPA does not have at this time, available data to determine whether dichlobenil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, dichlobenil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that dichlobenil has a common mechanism of toxicity with other substances.

C. Environmental Assessment

The environmental assessment consists of four sections: the first section reports ecological toxicity data from laboratory studies; the second section describes the environmental fate and transport data from field and laboratory studies, analyzes the impact to water resources, and details the environmental fate assessment; the third section estimates ecological exposure and assesses the effects to non-target terrestrial and aquatic organisms; the fourth section, the environmental risk characterization section, integrates the exposure and effects assessment to determine the extent and potential for risk to the environment.

The ecological risk characterization was limited to anticipated exposures from the use of the granular formulations. Non-granular formulations, such as the wettable powder and foam formulations, are only used to treat pre-pavement areas and sewage systems, and are not expected to result in exposure to non-target organisms.

1. Ecological Toxicity Data

The Agency has adequate data to assess the acute hazards of dichlobenil to nontarget terrestrial animals but does not have data to assess the chronic hazards of dichlobenil to nontarget birds. Adequate data to assess the acute and chronic hazards of dichlobenil to nontarget aquatic animals are available. Adequate data are available to assess the hazards of dichlobenil to non-target plants from runoff, however, the Agency does not have adequate data to assess the hazards to non-target terrestrial plants from dichlobenil volatilization.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

The basic avian studies required for all pesticides (using the technical grade material) are one avian single-dose oral (LD₅₀) study on one species (preferably mallard or bobwhite quail) and two subacute dietary studies (LC₅₀) on one species of waterfowl (preferably the mallard duck) and one species of upland game birds (preferably bobwhite quail).

Table 5 Avian Acute Oral Toxicity Findings

Species	% A.I.	LD ₅₀ mg/kg	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	98.8	683	43469801	Johnson, 1994	slightly toxic	Yes
Mallard Duck	98.7	>2000	00160000	Hudson, 1984	practically non-toxic	Yes
Mallard Duck	99.4	>50	40600601	Roberts, 1988	n/a	No, Supplemental
Ring-necked Pheasant	98.9	1189	00160000	Hudson, 1984	slightly toxic	Yes

Table 6 Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC ₅₀ ppm	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	99.4	5200	40600603	Roberts, 1988	practically non-toxic	Yes
Japanese Quail	96.4	>5000 ¹	00022923	Hill, 1975	practically non-toxic	No, Supplemental
Ring-necked Pheasant	96.4	1500	00022923	Hill, 1975	slightly toxic	Yes
Mallard	99.4	>5200	40600602	Roberts, 1988	practically non-toxic	Yes

¹ At 5000 ppm dose level, 19% of the birds died.

These results indicate dichlobenil is slightly to practically non-toxic to avian species on an acute oral and subacute dietary basis.

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications; or if mammalian reproduction tests indicate a reproductive hazard. In the 2-generation rat reproduction study (MRIDs 41257303, 42239101), the reproductive NOEL was 3 mg/kg/day (60 ppm) for dichlobenil and dichlobenil may be persistent. Two avian reproduction studies are required on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). Currently no avian reproduction data are available. Therefore, this guideline has not been satisfied. A chronic risk assessment for birds can not be performed.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD₅₀ from the OPP's Health Effects Division (HED) is used to determine toxicity to mammals. This LD₅₀ is reported below.

Table 7 Mammalian Acute Toxicity Findings for Dichlobenil

Species	LD ₅₀ mg ai/kg	Toxicity Type	MRID
Rabbit (mammal surrogate)	> 2 g/kg	Dermal	43250401
Rat (small mammal surrogate)	4250	Oral	00112500

The available mammalian data indicate that dichlobenil is slightly to practically non-toxic to small mammals on an acute oral basis.

Table 8 Mammalian Acute Toxicity Findings for Degradate 2,6-dichlorobenzamide (BAM)

Species	LD ₅₀ mg ai/kg	Toxicity Type	MRID
Mice (small mammal surrogate)	1538 (M) 1144 (F)	Oral	42940201
Rat (small mammal surrogate)	1470 (M) 2330 (F)	Oral	00111402

The available mammalian data indicate that the dichlobenil degradate BAM is slightly toxic to small mammals on an acute oral basis. Although mice appear to be the most sensitive mammal and are used in the human health assessment, the rat LD₅₀ was used in the mammalian toxicity assessment because it is the standard species used in eco-toxicity assessments.

Table 9 Mammalian Sub-Acute Toxicity Findings for Dichlobenil

Species	NOEL / LOEL	Study Type	MRID
Rabbit (mammal surrogate) tested on 2,6 dichlorobenzamide (BAM)	10 / 30 mg/kg/day ¹	developmental toxicity - Endpoint affected is mortality (6 day exposure)	43003601 43265201
Rabbit (mammal surrogate)	45 / 135 mg/kg/day ¹	developmental toxicity - occurrence of major external, visceral, and skeletal defects. (12 day exposure)	41257302
Rat (small mammal surrogate)	20 / 60 mg/kg/day ¹	developmental toxicity - decreased weight gain, food consumption, and food efficiency from maternal. (10 day exposure)	00147437
Rat (small mammal surrogate) ²	3 / 15 mg/kg/day (60 / 350 ppm)	2-generation reproduction - reduced pup weight. No other endpoints affected. Highest dose is 2000 ppm (100 mg/kg/day)	41257303 42239101

¹ Doses were done by gavage.

² Study report indicates dichlobenil made the feed unpalatable and affected the endpoints.

According to these studies, the lowest NOEL for subacute and reproductive effects to mammals is 60 ppm. At 350 ppm, dichlobenil reduced pup weight.

(4) Insects

A honey bee acute contact LD₅₀ study is required if the use will result in honey bee exposure. The use of granular pesticides results in minimal exposure to honey bees.

Table 10 Nontarget Insect Acute Contact Toxicity Findings

Species	% AI	LD ₅₀ µg a.i./bee	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	technical	>120	0001884 2	Atkins, 1969	practically non-toxic	Yes

There is sufficient information to characterize dichlobenil as practically non-toxic to bees.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

The basic fish studies required for all pesticides (using the technical grade material) are two freshwater fish toxicity studies. One study should use a cold water species (preferably the rainbow trout), and the other should use a warm water species (preferably the bluegill sunfish).

Table 11 Freshwater Fish Acute Toxicity Findings for Dichlobenil

Species	% A.I.	LC ₅₀ ppm a.i.	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
Rainbow Trout	98.9	6.26	40098001	Mayer, 1986	moderately toxic	Yes
Rainbow Trout	98.9	4.93 ¹	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Bluegill Sunfish	98.9	6.72 ¹	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Bluegill Sunfish	98.9	8.31	40098001	Mayer, 1986	moderately toxic	Yes
Fathead Minnow	98.9	6.00	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Fathead Minnow	98.9	7.12 ¹	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Goldfish	98.9	7.83	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Goldfish	98.9	7.68 ¹	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Green Sunfish	98.9	5.7	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Green Sunfish	98.9	12.6 ¹	40098001	Mayer, 1986	moderately toxic	No, Supplemental
Rainbow Trout	99.5	7.6	43846901	McCann, 1975	moderately toxic	Yes

¹The test was conducted in hard water with 272 mg/L of CaCO₃. Guideline studies are conducted in water with hardness of 40-48 mg/L CaCO₃ for bluegill and trout.

The results of the 96-hour acute toxicity studies indicate that dichlobenil is moderately toxic to fish.

Table 12 Freshwater Fish Acute Toxicity Findings for 2,6 dichlorobenzamide (BAM)

Species	% A.I.	LC ₅₀ ppm a.i.	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	97.0	235	00156312	Van Leeuwen, 1985	practically non-toxic	No, Supplemental
Rainbow trout	100	140	40098001	Mayer, 1986	practically non-toxic	Yes
Bluegill Sunfish	100	120	40098001	Mayer, 1986	practically non-toxic	Yes
<i>Poecilia reticulata</i>	97.0	275	00156312	Van Leeuwen, 1985	practically non-toxic	No, Supplemental

The results of the 96-hour acute toxicity studies indicate that BAM is practically non-toxic to fish.

Data from fish early life-stage tests are required if the product is applied directly to water or expected to be transported to water from the intended use site, and if the pesticide's acute LC₅₀ or EC₅₀ is greater than 1 mg/L or studies of other organisms indicate the reproductive physiology of fish may be affected or the half-life of the aerobic aquatic metabolism half-life is greater than 4 days. This study is not required at this time since dichlobenil is no longer directly applied to water, nor does it meet the other criteria. However, the registrant submitted data that were used in the risk assessment (see table below).

Table 13 Fish Early Life-Stage Toxicity Findings

Species	% A.I.	NOEL ppm	LOEL ppm	MATC ppm	MRID	Author/Year	Endpoint Affected	Fulfills Guideline Requirement
Rainbow trout	97.0 ¹	10.0	18.0	13.4	00156312	Van Leeuwen, 1985	60-day survival, length, weight	No, Supplemental
Rainbow trout	99.4	0.66 <0.33	1.2 0.33	0.89 0.33	40825101 ² 42224202 ²	McAllister, 1988 Dykstra, 1992	mortality length	Yes

¹ The chemical tested is the metabolite BAM

² MRIDs 40825101 and 42224202 are from the same study

The results indicate that dichlobenil may chronically affect fish at levels as low as 0.33 ppm.

Field studies can be required when the pesticide is applied directly to water as in aquatic weed control. Dichlobenil was previously registered for aquatic weed control and the field study was provided. Although these data are no longer required because dichlobenil is no longer directly applied to water, the Agency has included them in the risk assessment.

Table 14 Aquatic Field Studies Findings

Species	% A. I.	MRID Author/Year	Findings	Fulfills Guideline Requirement?
Green Sunfish Largemouth Bass Bluegill Sunfish	50.0	00113752 Cope, 1968	Mortality of bluegill fingerlings more likely due to subacute affects at concentrations as low as 5 ppm ai (lowest measured concentration).	No, supplemental

(2) Freshwater Invertebrates

The basic freshwater invertebrate study required for all pesticides (using the technical grade material) is freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Table 15 Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC ₅₀ ppm	MRID	Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Simocephalus serrulatus</i> (daphnid)	50.0	5.8	4009460 2	Johnson,1980	moderately toxic	No, Supplemental
<i>Pteronarcys californica</i> (stonefly)	50.0	7.0	4009460 2	Johnson,1980	moderately toxic	No, Supplemental
<i>Gammarus lacustris</i> (scud)	50.0	5.8	4009460 2	Johnson,1980	moderately toxic	No, Supplemental
<i>Asellus brevicaudus</i> (sowbug)	50.0	35.0	4009460 2	Johnson, 1980	slightly toxic	No, Supplemental
<i>Daphnia pulex</i> (daphnid)	50.0	3.7	4009460 2	Johnson, 1980	moderately toxic	No, Supplemental
<i>Gammarus fasciatus</i> (scud)	tech.	18.0	0500149 7	Sanders, 1970	slightly toxic	No, Supplemental
<i>Asellus brevicaudus</i> (sowbug)	tech.	34.0	0500149 7	Sanders ,1970	slightly toxic	No, Supplemental
<i>Daphnia magna</i> (daphnid)	tech.	10.0	0500149 7	Sanders, 1970	moderately toxic	No, Supplemental
<i>Palacmonetes kadiakensis</i> (glass shrimp)	tech.	9.0	0500149 7	Sanders, 1970	moderately toxic	No, Supplemental
<i>Cypridopsis vidua</i> (seed shrimp)	tech.	7.8	0500149 7	Sanders, 1970	moderately toxic	No, Supplemental
<i>Daphnia magna</i> (daphnid)	99.0	6.2	4077500 1	Burgess, 1987	moderately toxic	Yes

There is sufficient information to characterize dichlobenil as slightly to moderately toxic to aquatic invertebrates.

Table 16 Freshwater Invertebrate Toxicity Findings 2,6 dichlorobenzamide (BAM)

Species	% A.I.	EC ₅₀ ppm	MRID Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Daphnia magna</i> (daphnid)	97.0	856	00156312 Van Leeuwen, 1985	practically non-toxic	No, Supplemental

There is sufficient information to characterize BAM as practically non-toxic to aquatic invertebrates.

Data from aquatic invertebrate life cycle studies are required if the product is applied directly to water or expected to be transported to water from the intended use site, and if the pesticide's acute LC₅₀ or EC₅₀ is greater than 1 mg/L or studies of other organisms indicate that reproduction of aquatic invertebrates may be affected or the pesticide's aerobic aquatic metabolism half-life is more than 4 days.

Table 17 Aquatic Invertebrate Life-Cycle Toxicity Findings

Species	% A.I.	NOEL ppm	LOEL ppm	MATC (unit)	MRID	Author/Year	Endpoint Affected	Fulfills Guideline Requirement
<i>Daphnia magna</i>	97.0 ¹	>320	N/A	N/A	00156312	Van Leeuwen, 1985	reproduction and 21-day survival	No, supplemental
<i>Daphnia magna</i>	99.0	0.56	1.0	0.75	40775002, 42224201	Forbis, 1988, 1992	delayed reproduction	Yes

¹ The chemical tested is 2,6-dichlorobenzamide (BAM)

The results indicate that dichlobenil may chronically affect aquatic invertebrates at concentrations as low as 0.75 ppm.

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required because the terrestrial non-food, cranberry and turf use of dichlobenil may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC₅₀ for an estuarine fish, a 96-hour LC₅₀ for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Table 18 Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC ₅₀ /EC ₅₀ (ppm)	MRID Author/Year	Toxicity Category	Fulfills Guideline Requirement
Eastern Oyster embryo larvae	98.9	2.5	40228401 Mayer,1986	moderately toxic	Yes
Pink Shrimp	98.9	>1.0	40228401 Mayer,1986	N/A	No, supplemental
Mysid Shrimp	98.8	2.35	43905405 Durham,1995	moderately toxic	Yes
Sheepshead Minnow	98.8	12.7	43905403 Durham,1995	moderately toxic	Yes
Eastern Oyster shell growth	98.8	1.63	43905404 Durham,1995	moderately toxic	Yes
Sheepshead Minnow	98.9	14.0	40228401 Mayer,1986	slightly toxic	Yes

There is sufficient information to characterize dichlobenil as slightly to moderately toxic to estuarine organisms.

c. Toxicity to Plants

(1) Terrestrial

Tier II toxicity data on the technical material for the most sensitive species are listed below:

Table 19 Terrestrial Plant Toxicity

Study Type	Species	NOEC or EC ₀₅ (lb ai/A)	EC ₂₅ (lb ai/A)	MRID	Author, Year	Fulfills Guideline Requirements
Seedling Emergence	dicot - lettuce	0.011	0.023	41280801	Eussen, 1989	Yes
	monocot - oat	0.084	0.120			

The results indicate that non-target terrestrial plants may be affected from runoff if the runoff exceeds 0.023 lb ai/A. The guideline requirements are fulfilled for seedling emergence. Seed germination requirements have been waived because the seedling emergence study is a more sensitive measurement. The vegetative vigor portion of the study was reviewed and found to be invalid. At this time, the Agency is not requiring a new vegetative vigor study.

(2) Aquatic

Tier II aquatic plant studies are required for all herbicides. The following species should be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. Tier II toxicity data on the technical material are listed below:

Table 20 Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	NOEC (ppm)	EC ₅₀ ppm ai	MRID	Author/year	Fulfills Guideline Requirement
<i>Navicula pelliculosa</i> (Freshwater diatom)	99.0	0.31	1.000	40758204	Giddings, 1988	Yes
<i>Lemna gibba</i> (duckweed)	99.0	0.006	0.030	40758203	Giddings, 1988	Yes
<i>Selenastrum capricornutum</i> (green algae)	99.0	0.16	1.500	40758201	Giddings, 1988	Yes
<i>Skeletonema costatum</i> (marine diatom)	99.0	0.63	2.100	40758205	Giddings, 1988	Yes
<i>Anabaena flos-aquae</i> (blue-green algae)	99.0	2.5	2.900	40758202	Giddings, 1988	Yes
<i>Isochrysis galbana</i> (estuarine algae)	98.9	no data	60.0	40228401	Mayer, 1986	No, Supplemental
<i>Phaeodactylum tricorutum</i> (estuarine algae)	98.9	no data	25.0	40228401	Mayer, 1986	No, Supplemental
<i>Dunaliella tertiolecta</i> (estuarine algae)	98.9	no data	60.0	40228401	Mayer, 1986	No, Supplemental
<i>Chlorella pyreoidosa</i> (estuarine algae)	97.0 ¹	no data	100.0	00156312	Van Leeuwen, 1985	No, Supplemental
<i>Chlorococcum</i> sp. (estuarine algae)	98.9	no data	60.0	40228401	Mayer, 1986	No, Supplemental

¹ The chemical tested is the degradate BAM.

The results indicate that dichlobenil is toxic to an aquatic macrophyte (duckweed).

2. Environmental Fate

Acceptable and supplemental information from environmental fate studies with respect to the persistence and mobility of dichlobenil under laboratory and field conditions has been reviewed and the environmental data base for dichlobenil is essentially complete.

a. Environmental Fate and Transport

(1) Degradation

Hydrolysis

Dichlobenil is stable to degradation by hydrolysis. The calculated half-life, extrapolated from a 30 day study, is >150 days in sterilized buffers at pH 5, 7 and 9. This guideline requirement is fulfilled. (MRID 40548502).

Photodegradation in Water

Uniformly ring-labeled [¹⁴C] dichlobenil (radiochemical purity 99.3%) at 5.749 mg/L, degraded with a calculated half-life of 15.1 days at pH 7. A major degradate was 4-chloro-2(3H)benzoxazolone (BZZ) present at 17% of total [¹⁴C] at 21 days. Additional degradates, found at low levels, identified in the irradiated samples at 21 days were 2-hydroxybenzotrile (4% of total [¹⁴C]), 2,6-dichlorobenzoic acid (3% of total [¹⁴C]), 2-chlorobenzotrile (2% of total [¹⁴C]), 2,6-dichlorobenzamide (1% of total [¹⁴C]), and 4-hydroxy-2,6-dichlorobenzotrile (1% of total [¹⁴C]). Up to 5% of the applied were lost to volatility by day 21. This guideline requirement is fulfilled. (MRID 41709801).

Photodegradation on Soil

Dichlobenil is persistent in soil photodegradation studies. Dichlobenil did not photodegrade under the conditions of the soil photolysis experiment (i.e. continuously irradiated with a xenon arc lamp at 25 C for 30 days). However, dichlobenil dissipated with a half-life of 4.7 days in the dark control. The study authors attributed this to the volatilization of the compound, lack of trapping efficiency, and lack of water jacket surrounding the dark control. No degradates were identified in the irradiated or dark control soil samples. This guideline requirement is fulfilled. (MRIDs 41119001; 43006801).

Aerobic Soil Metabolism

Dichlobenil is persistent to metabolism in soil under aerobic conditions. Dichlobenil degraded from sandy loam soil with a calculated half-life of 13 weeks; most of the dissipation was due to volatilization of dichlobenil. Of the 61.0% of total ^{14}C trapped, 56.8% was dichlobenil and 2.3% was CO_2 . When correcting for the volatilization, the calculated half-life of dichlobenil was 46.3 weeks. One degradate identified, 2,6-dichlorobenzamide (BAM), was 13.1% (maximum concentration) at 50 weeks. The guideline requirement (162-1) is fulfilled. (MRIDs 41340601; 43006803).

Anaerobic Aquatic Metabolism

Dichlobenil is persistent to metabolism under anaerobic aquatic conditions. Dichlobenil exhibited a half-life of 2.8 years in lake water:sediment slurries incubated under anaerobic conditions for 370 days. The guideline requirement is fulfilled. (MRID 41306001).

Aerobic Aquatic Metabolism

Dichlobenil exhibited a half-life of 2.4 days in sediment:lake water systems; the major route of dissipation was due to volatilization; > 97% of the applied 1 ppm dichlobenil was found in the traps as the base catalyzed hydrolysis product 2,6-dichlorobenzamide. No degradates were identified and no correction in half-life was calculated. The guideline requirement is fulfilled. (MRID 41149501).

(2) Mobility

Adsorption/Desorption Studies

Acceptable and supplemental studies indicated mobility is related to the soil organic matter (OM) content ranging from mobile with low OM soils to relatively immobile with high OM soils. Freundlich K_{ads} values of 0.295, $K_{\text{oc}} = 49$, silt loam 0.6% OM; $K_{\text{ads}} = 2.098$, $K_{\text{oc}} = 110$, silty loam 1.9% OM; $K_{\text{ads}} = 3.197$, $K_{\text{oc}} = 114$, aquatic sediment 2.8% OM; $K_{\text{ads}} = 6.141$, $K_{\text{oc}} = 205$, loam 3.0% OM; $K_{\text{ads}} = 5.576$, $K_{\text{oc}} = 116$, sand 4.8% OM. (MRIDs 40600604; 43006800).

In an additional study, adsorption was also correlated with organic matter content of the soils. Freundlich K_{ads} values of 0.3 for the sand soil (0.28% OM), 4.2 for the hydrosol (2.24% OM), 7.4 for the silt loam (4.7% OM), 9.6 for the clay soil (12.4% OM), and 10.5 for the sandy loam (6.9% OM); respective K_{oc} values were 195, 323, 272, 133, 262. Adsorption was correlated with the organic matter content of the soils (correlation coefficients were 0.992-0.999). (MRID 43611101).

Supplemental studies indicated that dichlobenil at 0.5-10 ppm adsorbed to sandy clay loam, sandy loam, and sand soils with Freundlich K_{ads} values of 4.80, 4.23, and 2.71, respectively. Adsorption appeared to be correlated with soil organic matter content. (MRID 00049725).

Soil Column Leaching

Dichlobenil (at 22.5 kg/ha) was slightly mobile in sand (5% OM) and loam soil (3.2% OM columns (30 cm) with 84.9% and 87% of the applied, respectively, detected in the 0-12 cm depth. Dichlobenil was mobile in silt loam (1.8% OM) soil columns with 68.7% of applied detected in the 0-12 cm depth. The amount of radioactivity detected in the leachate from the sand, loam, and silt loam soils was 0, 0.55 and 16.0% of the applied, respectively. After aerobic aging (30 days) of the treated silt loam soil, 85.65% of the applied was detected in the 0-12 cm depth, and 0.3% in the leachate. The degradate 2,6-dichlorobenzamide (BAM) was detected in the 25-30 cm column segment at 28% of applied. Adsorption appeared to be correlated with organic matter content. Soil Column Leaching (parent/unaged); (MRID 00151561).

Based on column leaching studies aged (31 days) dichlobenil residues were determined to be mobile (3% of applied was found in leachate) in a column of sandy loam (1.5% OM) treated with 73.8 mg [¹⁴C] dichlobenil equivalence of residues and leached with 52 cm of deionized water. Following leaching, approximately 10.7% (7.93 mg) of the radioactivity applied to the column remained in the treated soil layer, approximately 12-15 mg (approximately 17.5% of the applied) were in each of the top three 2-cm soil segments (totaling 52.6% in the 1 to 7 cm column depth); 12.6 mg were in the 7 to 9 cm depth; <7.2 mg were in the 9 to 11 cm depth; and <1.1 mg were in the 11 to 13 cm depth (28.4% in the 7 to 13 cm depth). Total residues in the remainder of the column were <1% of the applied. In the entire column (including the treated soil layer), extractable and unextracted [¹⁴C]residues comprised 85.9% (63.41 mg) and ≤7.0% (≤5.2 mg) of the applied, respectively. In the treated layer plus upper 10 cm of the soil column, [¹⁴C]dichlobenil comprised 87-92% of the applied and the degradate 2,6-dichlorobenzamide comprised <1.8-3.7%; deeper soil segments were not analyzed for specific compounds. The material balance for the column was 93% of the applied. (MRID 41709802). The guideline requirement is fulfilled. (MRIDs 0004925; 40600604; 43006800; 43611101; 00151561; 41709802).

Laboratory Volatility

Dichlobenil (4G) rapidly volatilized in a sandy soil with the highest concentration measured 24 hours posttreatment (313 µg/m³ in tube A). By 96 hours posttreatment the concentration in tube A decreased to 49 µg/m³. The volatility rate decreased from 0.15 to 0.05 µg/cm²/hr during the test period of 96 hours. By 4 days posttreatment, an average of 35% of applied dichlobenil had been volatilized. This guideline requirement is fulfilled. (MRID 43754001).

Field Volatility

This guideline requirement was waived in the Registration Standard 10/22/86.

(3) Accumulation

Bioaccumulation in fish

Bluegill sunfish exposed to 0.14 mg/l dichlobenil for 28 days showed maximum bioconcentration factors of 32X, 63X and 110X for fillet, whole fish and viscera respectively, within 1 day depuration of the 14 day depuration period, there was a 89% loss of radioactivity in the fillet, 85% in the whole fish, and 87% in the viscera. The data requirement is fulfilled. (MRIDs 40465801; 40465802).

Bioaccumulation in aquatic non-target organisms

Dichlobenil accumulated in edible (fillet) and nonedible (viscera) tissues of rainbow trout, largemouth bass, and brown bullhead catfish that were exposed to dichlobenil (10% G) applied at 15 lb ai/A to a pond in Oregon. Maximum bioconcentration factors for edible, nonedible, and whole fish tissues were 12X, 35X, and 27X for rainbow trout; 10X, 17X, and 15X for largemouth bass; and 14X, 21X, and 17X, respectively, for brown bullhead catfish. The degradate, 2,6-dichlorobenzamide, was detected in largemouth bass nonedible and whole fish tissues at maximum concentrations of 0.028 and 0.021 ppm, respectively, and was not detected (<0.01 ppm) in edible tissues. In brown bullhead catfish, 2,6-dichlorobenzamide was detected at day 0 only at 0.015 and 0.013 ppm in nonedible and whole fish tissues, respectively, and was not detected (<0.01 ppm) in edible tissues. In rainbow trout, the degradate was not detected in edible tissues (<0.01 ppm) or nonedible tissues (<0.05 ppm). (MRID 41877301)

Dichlobenil accumulated in edible (fillet) and nonedible (viscera) tissues of bluegill sunfish, channel catfish, and largemouth bass that were exposed to dichlobenil (10% G) applied at 15 lb ai/A to a pond in Florida. Maximum bioconcentration factors for edible, nonedible, and whole fish tissues were 22X, 55X, and 40X for largemouth bass; 20X, 28X, and 22X for channel catfish; and, 13X, 29X, and 22X for bluegill sunfish. The degradate, 2,6-dichlorobenzamide, was not detected in any of the fish tissues. (MRID 41780601). The data requirement is fulfilled. MRIDs 40465801; 40465802.

(4) Field Dissipation

Terrestrial Field Dissipation

Dichlobenil (4G) dissipated with a calculated half-life of 3.7 months from the upper 3 inches of a loamy sand soil in an established commercial apple orchard located in the Town of Huron, New York; the orchard was treated with dichlobenil (Norosac, 4% G) at 6 lb ai/A on May 18, 1987. Dichlobenil was detected to a 12-inch depth in the treated plots. The degradate 2,6-dichlorobenzamide (BAM) was detected to a depth of 72 inches. The soil was not sampled deep enough to determine the extent of leaching of BAM. (MRIDs 41170801; 43006800).

Dichlobenil (4G) dissipated with a calculated half-life of 16 days from the upper 3 inches of Hanford sandy loam soil located in Madera, California. A loss of 80% of the applied dichlobenil was not accounted for after a 7-day period and was attributed to volatilization. Dichlobenil was detected at a 6-inch soil depth in the treated plots. The degradate 2,6-dichlorobenzamide was consistently detected to a 48-inch soil depth. (MRIDs 41149502; 412808023; 43006800).

Dichlobenil (4G) dissipated with a calculated half-life of 241 days from the upper 3 inches of silt loam soil in field plots that were planted to arborvitae in Hillsboro, Oregon. The average dichlobenil concentrations from the deeper soil layers were ≤ 0.024 ppm at all sampling intervals except for 0.084 ppm in the 48 inch to 58 inch depth. There were dichlobenil detections at 36-48, 48-50, and 50-60 inches. The detections at 50-60 inches were attributed to contamination. The degradate 2,6-dichlorobenzamide, was detected to a depth of 96 inches (deepest sampled). (MRID 41385601). This guideline requirement is fulfilled for the (4G) formulation. (MRIDs 41170801; 43006800; 41149502; 41280802; 43006800 and 41385601).

The terrestrial field dissipation data requirement for dichlobenil 50% WP formulation has been waived due to the use pattern of the formulation being limited to prepaving under asphalt and sewer lines.

Aquatic Field Dissipation

Dichlobenil (10G) dissipated from pond water with a calculated half-life of 15 days following a surface application (15 lbs ai/A) to a pond located near Bascom, Florida. Average dichlobenil concentrations in water samples taken 1-2 feet from the pond bottom were 0.11 ppm immediately post-treatment, 0.19 ppm at 7 days, 0.093 ppm at 21 days and were not detected by 84 days post-treatment. Dichlobenil was detected to the 6- to 12-inch depth. The degradate, 2,6-dichlorobenzamide, was not detected in the water or sediment (detection limit is 0.01 ppm). (MRIDs 41780601; 42191401).

Dichlobenil (10G) dissipated from pond water with a calculated half-life of 69 days following a surface application of dichlobenil at 15 lb ai/A to a pond located near Philomath, Oregon. Average dichlobenil concentration in water samples taken 1-2 feet from the pond bottom were <0.01 ppm (not detected) immediately posttreatment, 0.16 ppm at 14 days, 0.043 ppm at 59 days, 0.084 ppm at 84 days, and 0.011 ppm at 182 days posttreatment. The degradate 2,6-dichlorobenzamide was not detected in any of the water samples (detection limit is 0.01 ppm). In the sediment fraction, dichlobenil dissipated with a calculated half-life of 39 days. Dichlobenil and the degradate, 2,6-dichlorobenzamide, were detected to a depth of 12 inches. (MRIDs 41877301; 42191401).

Forestry Dissipation

A risk assessment for the use of dichlobenil on hybrid cottonwood-poplars in pulpwood production areas in this RED was performed on the assumption that the use was limited to the pulpwood production areas of the eastern Oregon-Washington desert which is defined as 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and

Morrow in Oregon. The cultivation of cottonwood-poplar hybrids grown at these sites is not considered a forestry use because the trees are grown as a row crop with drip irrigation in a desert setting on land previously used to cultivate row crops. However, the registration on cottonwood hybrid poplars has recently been expanded under section 3 of FIFRA to include regions outside of this limited area.

The forestry dissipation study is required to enable the Agency to assess the risks from the use of dichlobenil in all hybrid cottonwood-poplar pulpwood production areas. Alternatively, registrants may waive this data requirement if they limit the use of dichlobenil on hybrid cottonwood-poplar plantations to the areas in Oregon and Washington as defined above.

The other registered use sites, including shelterbelts were not considered forestry use. The cottonwood-poplar hybrid plantations and shelterbelt use sites were not considered forestry use.

(5) Spray Drift

The droplet size spectrum/drift field evaluation studies have been waived due to the minimal spray drift of the aerial application of the large mesh size dry 4G granules.

b. Water Resources

(1) Ground Water

The Office of Pesticide Programs (OPP) evaluates the persistence and mobility of each pesticide for ground water concerns. If the data indicate that the parent and/or degradates are persistent and mobile, then a small-scale prospective ground water study may be requested. The basic triggering criteria include: weight of the evidence from laboratory and field dissipation studies indicating that the pesticide has properties and characteristics similar to pesticides that are known to leach or have been detected in ground water; movement of the parent or degradates 75-90 centimeters through the soil profile or plow layer in a field dissipation study; reports of detections in ground water from other monitoring studies and information about toxicity. In addition, use patterns, application rates, timing of application, potential acreage treated, depth to ground water, soil types, hydraulic gradient, and climate are also evaluated as part of the triggering criteria. Persistence, mobility, and detections in ground water are also used to evaluate a chemical to determine whether its use should be restricted for ground water concerns. A pesticide may be recommended as a candidate for Restricted Use if it exceeds one or more characteristic for each of the three factors (persistence, mobility and detections).

Persistence and Mobility

Dichlobenil was evaluated for persistence and mobility in relation to its potential to leach to ground water. Below is a summary of that evaluation.

Table 21 Mobility and Persistence of Dichlobenil Relative to Restricted Use Criteria

FACTOR	CHARACTERISTIC	RESTRICTED USE CRITERIA	REPORTED VALUE(S)
PERSISTENCE	Field dissipation half-life	> 3 weeks or	2.3, 14.8, 34 weeks
	Lab-derived aerobic soil metabolism half-life	> 3 weeks or	46.3 weeks (calculated)
	Hydrolysis half-life	< 10% in 30 days or	stable (calculated 50% in >150 days)
	Photolysis half-life (soil)	< 10% in 30 days and	stable
MOBILITY	Soil adsorption: K_d	≤ 5 ml/g or	0.3, 2.1 - 10.5 ml/g
	Soil adsorption: K_{oc}	≤ 500 ml/g or	49, 114-323 ml/g
	Depth of leaching in field dissipation study	75 cm	152 cm (60 inches)



Shaded value indicates that parameter exceeds trigger

* Does not include degradate data.

Depth of leaching in field dissipation study

In one field dissipation study, the maximum reported depth of dichlobenil residues was reported to be in the 50-60 inch sampling depth (60 inches = 152 cm). The registrant attributed these detections to contamination, however there were also detections at the 36-48", and 48-50" depth. Other studies found the parent dichlobenil at the 12" depth and 6" soil depth. These studies also sampled for the degradate BAM and residues were detected at depths of 48", 72", and 96" in three studies. The study detecting residues at 72" did not sample deep enough to determine the extent of leaching of BAM. The study detecting residues at 96" was the deepest sample taken for analysis, and this supports conclusions that the degradate BAM is more mobile than the parent.

Volatilization

OPP has concluded that volatilization may be a significant dissipation pathway. Volatilization of dichlobenil appears to be controlled by soil moisture content and temperature. Inadequate soil moisture, or the lower temperatures associated with northern use areas will allow more of the compound to remain in the soil and be available for leaching. The mobility of the parent dichlobenil is correlated with the organic matter content of the soils. OPP concludes that under some conditions, inadequate soil moisture, low temperatures, or low soil organic matter, dichlobenil or its degradate BAM, are likely to leach to ground water.

Ground Water Detections

To date, there has been extremely limited monitoring for dichlobenil in ground water in the United States. The "Pesticides in Ground Water Database" (Hoheisel et al., 1992) reports sampling for dichlobenil in only one well in California in 1987. No residues were detected in this one well, but no

MCL or HA was established and no information is available about the details of the monitoring. A summary of this is presented below.

Table 22 Summary of Ground Water Detections

CRITERION	CHARACTERISTIC	RESTRICTED USE CRITERIA	REPORTED DETECTIONS
DETECTIONS	Number of wells per state with detections	25 wells in 4 or more states or	No Data
	Number of counties with detections > 10% of reference point	3 counties at >10% of MCL or HAL	No MCL or HA Established

shaded value indicates parameter exceeds trigger

In 1994, the previous dichlobenil basic producer requested that the label advisory and prospective ground-water monitoring study be waived. To support their claim that these regulatory measures were not needed, a document summarizing monitoring information for dichlobenil in The Netherlands and lysimeter studies in Germany were submitted.

The monitoring information for The Netherlands is summarized below:

Table 23 Netherlands Monitoring Information

Type of Sample/Date	Dichlobenil Concentration	BAM Concentration
Surface Water, 1987	<0.01-0.097 ppb	not analyzed
Tap Water, 1987	No detections	not analyzed
Tap Water (Ground Water), 1989-1990		No detections
Ground-Water Pumping Stations, 1991		up to 0.30 ppb
Ground Water, 1988-1990	up to 0.12 ppb	up to 180 ppb

As seen above, residues of dichlobenil and BAM have both been detected in ground water and dichlobenil has been detected in surface water in the Netherlands. Residues of BAM have been detected up to 180 ppb in an area of shallow ground water (approximately 5 feet).

In 1990, three undisturbed sandy soil cores were removed from a field and installed in Schmallenberg, Germany. These soil core "lysimeters" were monitored for two years, after which they were sectioned and analyzed. Parent dichlobenil did not occur in any of the leachate above the limit of quantification of 0.047 ppb. BAM was found in the leachate of all three lysimeters with average concentrations of 14.2 ppb (2.7 kg/ha application rate), 51.7 ppb (4.0 kg/ha application rate), and 80.4 ppb (8.1 kg/ha application rate). BAM was also detected in nearly all soil layers. The report states that "results demonstrate that the metabolite 2,6-dichlorobenzamide (BAM) has a higher potential to reach groundwater than the parent compound."

Considering the widespread use of dichlobenil, its chemical and physical parameters, and the wide range of use conditions, OPP believes that dichlobenil will be detected in ground water if more monitoring is conducted.

Dichlobenil meets all the persistence and mobility triggers for recommending Restricted Use classification based on ground-water concerns. At the present time, dichlobenil is not a candidate for Restricted Use classification because insufficient monitoring information is available in the United States. Considering the wide spread use of dichlobenil and the wide range of use conditions, we believe that more monitoring data will find more detections of dichlobenil and/or BAM in the ground water. OPP has concluded that dichlobenil probably would exceed the detections trigger for Restricted Use classification with additional monitoring data.

Ground-Water Concerns

Based on the limited data available, OPP concludes that dichlobenil and BAM have the potential to exceed levels of concern for ground water quality. However, the available monitoring data in the United States is insufficient at this time.

GROUND-WATER QUALITY. OPP is concerned about the potential degradation of ground-water quality that may occur in areas where dichlobenil is used. Dichlobenil is registered for a variety of terrestrial uses and considering the persistence and mobility of both dichlobenil and BAM, these chemicals are likely to leach to ground water in vulnerable areas. In addition, after reaching ground water it can persist because of its resistance to abiotic degradation and its resistance to microbiological degradation coupled with the low microbiological activity of most groundwater.

HUMAN EXPOSURE. Dichlobenil and BAM are extremely mobile and persistent under anaerobic conditions. Considering the wide spread use of dichlobenil and the wide range of use conditions, we believe that more monitoring data will find more detections in ground water.

Because OPP's ground water concerns are focused on the potential occurrence of BAM in drinking water and the resulting possible human exposure, OPP is requiring a drinking water monitoring study.

The proposed drinking water monitoring study should have samples from existing drinking water wells. The samples should be from drinking water wells in dichlobenil use areas and taken as close as possible to treated fields. Samples should be analyzed for both the parent and the degradate BAM. When possible, sampling should include, but not be limited to, wells near cranberry fields, nurseries, and several non-ag uses such as rights-of way, hedge/fence row treatment and home owner use, however not sewers and "under asphalt." All studies must use protocols that have been reviewed and approved by all parties. The drinking water study results will be used to determine if any additional ground water mitigation measures or prospective ground water studies are needed.

OPP has evaluated the potential for dichlobenil to reach groundwater in the proposed hybrid poplar pulpwood production sites in the eastern Oregon-Washington desert which is defined as 15 miles

from the Columbia river in the counties of Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon and has concluded that risk to ground water is relatively low in these areas. The registration of cottonwood hybrid poplars has recently been expanded under section 3 of FIFRA to include regions outside of this limited area. The Agency is concerned about expanding dichlobenil use to areas considered vulnerable to ground water contamination. If the use of dichlobenil for pulpwood production is extended beyond the above defined production areas in Oregon and Washington, then one or more small-scale prospective groundwater studies need to be conducted. Alternatively, the registrant may limit the use of dichlobenil on hybrid poplar pulpwood production sites to the desert areas of eastern Oregon and Washington as defined above.

(2) Surface Water

Dichlobenil and its metabolite BAM have the potential to contaminate surface water from runoff or spray drift associated with ground application. There are insufficient data for BAM to determine presence in surface water. However, results of two aquatic field dissipation studies conducted in Bascom, Florida and Philomath, Oregon indicate dichlobenil is slightly to moderately persistent (DT_{50s} of 15-69 days) in surface waters. Using the results from the aquatic field studies and integrating the laboratory data, dichlobenil dissipates from surface waters primarily by volatilization with limited sorption to sediment and slow microbial biotransformation to BAM or DCBA. Minimal binding to sediment was found; dichlobenil or the degradate BAM were detected in sediment samples to the 12-inch depth. However, dichlobenil should not bioaccumulate, as shown in a bioaccumulation in fish study and from the $\log K_{ow}$ of 2.90.

Transport of dichlobenil in the dissolved phase during surface runoff events which occur soon after application should not be substantial because of its high potential to volatilize. Dichlobenil was not persistent in the laboratory aerobic aquatic environment (half-life of 2.4 days). In anaerobic environments such as sediments in stream and lake bottoms, dichlobenil is persistent (anaerobic aquatic metabolism half-life = 2.85 years). The low to intermediate soil/water partitioning coefficients for dichlobenil (K_{ds} of 0.3-10.5 ml/g; K_{oc} of 49-323) indicate that granular released dichlobenil in surface runoff would occur primarily dissolved in the runoff as opposed to that adsorbed onto eroding soil or entrained in sediment. Volatilization of dichlobenil from surface waters is considered the most important route of dissipation based on the acceptable study results and its vapor pressure (5.5×10^{-4} mm Hg at 25° C) and Henry's Law constant (6.6×10^{-6} atm-m³/mol, estimated). From the findings of the bioaccumulation in fish study, and supported by its low octanol/water partitioning coefficient ($\log K_{ow} = 2.90$), dichlobenil should not bioaccumulate.

To model BAM in surface water, additional data on BAM's vapor pressure and solubility are required. If these data demonstrate that the Henry's constant for BAM is less than 10^{-5} , it indicates that BAM does not volatilize from surface water and additional environmental fate data will be required including guidelines:

161-2 Photodegradation in water

162-1 Aerobic soil metabolism

162-4 Aerobic aquatic metabolism
 163-1 Adsorption/desorption

If Henry's constant does not exceed 10^{-5} these additional data would not be required because that would indicate that BAM will volatilize from surface water.

Dichlobenil is not currently regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) is not established. Public water supply systems are not required to sample and analyze for dichlobenil. Dichlobenil is classified in Toxicity Category III for Oral Acute Toxicity and has been classified as a Group C - possible human carcinogen by the OPP Carcinogenicity Peer Review Committee (document dated 8/30/91). A RfD of 0.013 mg/kg/day for dichlobenil was established earlier from a 2-year dog feeding study; however, the degradate BAM (also a major residue detected in plants) is the appropriate material for dietary exposure. The RfD of 0.015 mg/kg/day was established for BAM was established from the 2 year dog feeding study.

Although dichlobenil has the potential to contaminate surface water from runoff and spray drift, limited surface water monitoring information is available at this time.

A summary of the dichlobenil detections in the STORET database are listed in Table 24. The maximum concentration of dichlobenil was $0.32 \mu\text{g/L}$ (ppb) for a filtered surface water sample collected on the South Platte River in Colorado. In filtered surface water samples, 5 detections were reported for 36 samples with the concentrations of dichlobenil ranging from 0.04 to $0.32 \mu\text{g/L}$.

TABLE 24 Summary of Dichlobenil Detections in Storet Database

SITE NAME	MONITORING PERIOD	DETECTIONS/ SAMPLES	DETECTION LIMIT ($\mu\text{g/L}$)	RANGE OF CONCENTRATIONS -- $\mu\text{g/L}$ -
Fanno Creek, OR	4/12/93 - 8/10/95	4/21	0.03	0.04 - 0.3
South Platte River, CO	12/13/93 - 8/10/94	1/15	0.05	0.32

EPA used GENEEC, a computer program model, to calculate generic EECs based on runoff from a 10 hectare field to a 1 hectare water body, 2 meters deep. This model is designed based on the assumption that off site drift is minimal from granular formulations. These generic EECs also take into account degradation in the field prior to a rain event.

The estimated results of the Tier 1 Aquatic EEC modeling with GENEEC are listed in Table 25. For the simulations without soil-incorporation of dichlobenil, the range of aquatic EECs was $95 \mu\text{g/L}$ for 2 lbs ai/A to a maximum of $951 \mu\text{g/L}$ at 20 lbs ai/A, and the peak EEC varied by a factor of 47.5 $\mu\text{g/L}$ for each pound increase in dichlobenil. For the model results with soil-incorporation to 2 inch depth, the maximum EEC was estimated to be $476 \mu\text{g/L}$, and the peak EEC changed by 23.8 $\mu\text{g/L/lb-ai/A}$ for each pound of dichlobenil applied. Comparison of the simulation results between unincorporated and soil-incorporated to 2 inches suggests aquatic EECs for dichlobenil are lowered

by approximately one-half following soil incorporation. It is important to note that the GENEEC program does not directly incorporate volatilization into the model. Although the laboratory metabolism half-lives used in GENEEC partially reflect losses due to volatilization, they do not completely account for volatilization. Dichlobenil dissipates primarily by volatilization; therefore, the aquatic EECs reported for dichlobenil would be considered as maximum values because dissipation by volatilization was not completely reflected in the input to the model. Also, assumptions made in GENEEC concerning losses due to runoff are very conservative. The amount in surface water will probably be lower and dependent on climate and environmental conditions.

The following data were used for the GENEEC program:

- K_{OC} for silt loam soil with 0.6% organic matter = 49
- Solubility = 25 ppm
- Aerobic aquatic metabolism half-life = 2.4 days
- Aerobic soil metabolism half-life = 322 days in sandy loam.
- Photolysis half-life = 15 days
- Soil incorporation = 2 inches

TABLE 25. GENEEC Aquatic Estimated Environmental Concentrations for Dichlobenil

<i>NOT SOIL-INCORPORATED</i>				
RATE (lbs ai/A)	PEAK EEC	DAY 4 EEC --- $\mu\text{g/L}$ ---	DAY 21 EEC	DAY 56 EEC
2	95	65	18	7
4	190	129	36	14
6	285	194	54	20
8	380	259	72	27
20	951	648	180	67
<i>SOIL-INCORPORATED TO 2 INCHES</i>				
RATE (lbs ai/A)	PEAK EEC	DAY 4 EEC --- $\mu\text{g/L}$ ---	DAY 21 EEC	DAY 56 EEC
2	47	32	9	3
4	95	65	18	7
6	141	96	27	9
8	190	130	36	14
20	476	324	90	34

Soil incorporation reduces aquatic exposure by approximately one half. In addition, dichlobenil exhibits high volatility in water and volatility is not a parameter of GENEEC. Therefore, it is

expected that the 4-, 21-, and 56-day average exposure values are lower than those calculated in the table above.

c. Environmental Fate Assessment

Dichlobenil dissipates in the environment (on soil and in surface water) principally by volatilization. However, it is persistent under field conditions that reduce the potential for volatilization (i.e. cooler climates). When degradation proceeds through aerobic soil metabolism, 2,6-dichlorobenzamide (BAM) is generated (13.1% at 50 weeks). Under conditions where dichlobenil does not volatilize there is potential for both dichlobenil and BAM to move to ground water in coarse-textured soils low in organic matter.

Generally, any dissipation that took place in both laboratory and field studies was a result of volatilization of parent compound. This is consistent with a vapor pressure of 5×10^{-4} mm Hg at 25°C and a Henry's Law constant of 6.6×10^{-6} atm-m³/mol, and the relatively low soil/water partitioning. Dichlobenil was stable to hydrolysis, photodegradation in soil and metabolic degradative processes. Dichlobenil was very persistent in the aerobic soil metabolism (half-life of 46.3 weeks) and the anaerobic aquatic metabolism (half-life of 2.8 years) studies.

Adsorption/desorption studies indicated that dichlobenil can be mobile with K_{ads} ranging from 0.2 to 10.5. Dichlobenil has a moderate water solubility of 25 ppm at 20°C. Adsorption was correlated with the organic matter content of the soils. Soil column leaching studies indicated that dichlobenil was mobile in silt loam and sandy loam and slightly mobile in sand and loam soil.

Bioaccumulation in fish testing indicated that dichlobenil has a low potential to bioaccumulate (maximum BCF 32X, 63X and 110X for fillet, whole fish and viscera, respectively) and a high rate of depuration (within 1 day of the 14 day depuration period, there was a 89% loss of radioactivity in the fillet, 85% in the whole fish, and 87% in the viscera).

Studies in the field were consistent with lab study results with volatilization occurring more readily in warmer climates. A field dissipation study conducted in California yielded a dissipation time for 50% of dichlobenil (DT_{50}) of 16 days. When dichlobenil is used under similar conditions (limited amount of rainfall expected) it would not pose a threat to ground water. However, in warmer climates where a large amount of the compound would dissipate through volatilization, dichlobenil may drift off-site.

When conditions are not conducive to volatilization, i.e., cooler temperatures, as was encountered during the terrestrial field dissipation study conducted in Oregon, (half-life of 241 days) dichlobenil when applied to sandy soils of low organic matter could be persistent and mobile enough to migrate to lower soil depths where the compound is stable (anaerobic aquatic metabolism half-life of 2.8 years). Use of dichlobenil under these conditions could potentially cause ground water contamination. After reaching ground water it could persist because of its resistance to abiotic degradation and its

resistance to microbiological degradation coupled with the low microbiological activity of most groundwater.

The main aerobic soil metabolism degradate (BAM) was consistently detected at the lowest soil depths sampled in the terrestrial field dissipation study (up to 96 inches, which in that field study was the deepest sampling depth). The soils in the terrestrial field dissipation study were only analyzed for dichlobenil and BAM. In two previously reviewed aerobic soil metabolism studies the major degradate was also BAM. However, BAM did not concentrate on the surface of the soil. Two other degradates, 2-6-dichlorobenzoic acid (DCBA) and an unidentified compound, were isolated. DCBA is another highly mobile compound that is a degradation product of dichlobenil.

Dichlobenil and its major degradate (BAM) exhibit many of the properties and characteristics associated with chemicals that have been detected in ground water. Dichlobenil can be extremely mobile and moderately to highly persistent under aerobic conditions. Under anaerobic conditions, the half-life for parent dichlobenil is 2.8 years, indicating that it will persist for extremely long periods of time once it reaches ground water. BAM appears to be more mobile than the parent compound. Dichlobenil was detected in a field dissipation study to a depth of 60 inches. BAM was detected in the same study, to a depth of 96 inches, the maximum sampling depth (USEPA, 1993). For these reasons, dichlobenil use is likely to have a significant impact on ground-water quality in certain areas.

Dichlobenil is slightly- to moderately-persistent in surface waters (aquatic field dissipation half-lives in water ranging from 15-69 days) since it is stable to degradation from abiotic hydrolysis and aqueous photolysis. Limited microbial-mediated metabolism of parent dichlobenil and the degradate BAM occurs in aerobic soil environments. Dichlobenil may slowly transform by microbial-mediated metabolism or possibly alkaline hydrolysis to the degradate BAM (2,6-dichlorobenzamide). The compound BAM may be transformed to the degradate DCBA (2,6-dichlorobenzoic acid). Based on the Freundlich adsorption coefficients, dichlobenil does not adsorb significantly to soil particles and runoff to surface water may be primarily by way of dissolution of dichlobenil in runoff water. However, soil/water partition coefficients > 1 suggest that the concentration of dichlobenil adsorbed to suspended and bottom sediment will be greater than that dissolved in the water column. Both major transformation products, BAM and DCBA, are less strongly adsorbed to soil or sediment than dichlobenil. Consequently, their runoff is also primarily by way of dissolution in runoff water as opposed to adsorption to eroding soil. Dichlobenil has the potential to contaminate surface water from runoff or spray drift associated with ground spray application. In surface waters, dichlobenil dissipates principally by volatilization with some biotransformation and binding to sediments. Limited monitoring data for surface waters are summarized in Table 24. The modeling results for aquatic EECs from GENEEC Tier 1 aquatic EEC modeling are briefly discussed in the Surface Water Assessment of the Environmental Fate and Transport section.

3. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC):

Levels of Concern are criteria used to indicate potential risk to nontarget organisms. Exceeding the criteria indicates that a pesticide, when used as directed, has the potential to cause undesirable effects to nontarget organisms. Two general categories of LOC (acute and chronic) exist: one for each of the four nontarget faunal groups and one category for each of two nontarget floral groups. To determine if an LOC has been exceeded, a risk quotient is derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC₅₀.

The acute effect levels are:

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

The chronic effect levels are:

- NOEC (avian and mammalian reproduction studies)
- NOEC or MATC for aquatic species.

The effects levels for plants are:

- EC₂₅ (terrestrial and semi-aquatic plants)
- EC₅₀ (aquatic plants)
- NOEL or EC₀₅ (for endangered plants)

When the RQ exceeds the LOC for a particular category, risk is presumed. Risk presumptions, along with the corresponding LOCs, are identified below.

Levels of Concern (LOC) and Associated Risk Presumption

Birds and Mammals

IF THE	LOC	PRESUMPTION
Acute RQ>	0.5	Potentially High Acute Risk
Acute RQ>	0.2	Restricted Use Candidate
Acute RQ>	0.1	May Effect Endangered Species
Chronic RQ>	1	Chronic Risk, May Affect Endangered Species

Fish and Aquatic Invertebrates

IF THE	LOC	PRESUMPTION
Acute RQ>	0.5	Potentially High Acute Risk
Acute RQ>	0.1	Restricted Use Candidate
Acute RQ>	0.05	May Effect Endangered Species
Chronic RQ>	1	Chronic Risk, May Affect Endangered Species

Terrestrial and Semi-aquatic Plants

IF THE	LOC	PRESUMPTION
EEC/EC ₂₅ >	1	Potentially High Risk
EEC/NOEL or EEC/EC ₀₅ >	1	May Effect Endangered Species

Aquatic Plants

IF THE	LOC	PRESUMPTION
EEC/EC ₅₀ >	1	Potentially High Risk
EEC/NOEL or EEC/EC ₀₅ >	1	May Effect Endangered Species

At this time, OPP does not require data which would allow quantitative assessment for reproductive risk to plants, or acute or chronic risks to nontarget insects. Chronic risk to mammals from granular dichlobenil was evaluated qualitatively.

Dichlobenil Use Patterns Addressed in Risk Assessment

Application rates, and the associated use sites, used in estimating RQs are identified below:

- 2 lb ai/A is used on turf (dichondra).
- 4 lb ai/A is used on blackberry, raspberry, cranberry (spring application), and cottonwood hybrids (pulp).
- 6 lb ai/A is used on cranberry (fall application), blueberry, cherry, apple, grape, filbert, and pear.
- 8 lb ai/A is used on ornamental/shade tree, ornamental woody shrubs and vines, and shelterbelt planting.
- 20 lb ai/A is used on landscaping rights-of-way, fencerow, hedgerow, residential and commercial landscaping, cemeteries, and in industrial and recreational areas.

These granular formulations are expected to result in exposure to nontarget organisms. Dichlobenil is formulated into three granule sizes; Two of which are 4% ai and one is 10% ai. According to the registrant, the smaller granule of the 4% granule formula (4G) (16/30 size), contains approximately 0.0216 mg ai/granule; the larger granule of the 4G (8/30 size), contains approximately 0.1528 mg ai/granule. According to information provided by Uniroyal and PBI Gordon, the large granule of the 4G is applied by air, the smaller granule of the 4G is applied by ground equipment or air. The 10% ai granule (10G) is 8/16 mesh size and contains approximately 0.3276 mg ai/granule.

Non-granular formulations, used to treat under pavement and in sewage systems, are not expected to result in exposure to non-target organisms.

a. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

Birds may be exposed to granular pesticides by intentionally or inadvertently ingesting granules when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules. The risk quotient for birds for granular pesticides is calculated by dividing the mg ai/ft² by the LD50 in mg ai/bird. Risk quotients are calculated for a 180-gram bird (e.g., quail).

Table 26 Avian Acute Risk Quotients for Granular Applications of Dichlobenil, both Broadcast (Unincorporated) and Incorporated

Lbs ai/A	Risk Quotients Based on Bobwhite LD50 of 683 mg/kg (122 mg for a 180 gram bird)			
	Unincorporated		Incorporated ^a	
	EEC ^b mg/sq ft	RQ based on LD50 of 122 mg per bird	EEC ^b mg/sq ft	RQ based on LD50 of 122 mg per bird
2	21	0.2*	3	<0.1
4	42	0.3*	6	<0.1
6	63	0.5**	9	<0.1
8	83	0.7***	12	<0.1
10	104	0.85***	16	0.13*
20	208	1.7***	31	0.3**

^a It is assumed that only 15% of the applied ai is exposed after incorporation. This assumption is based on dichlobenil being lightly incorporated into the soils.

^b mg/sq ft = lbs ai/A X (453590 mg per lb / 43560 ft² per acre).

* Exceeds Endangered Species LOC

** Exceeds Restricted Use LOC

*** Exceeds High Acute Risk LOC

Based on LD50s/ft², unincorporated application at 2 lbs ai/A and higher exceeds the LOCs for effects to endangered bird species feeding on the ground. The LOC for restricted use and potentially high acute risk to birds is exceeded at application rates equal to or above 6 lb ai/A and 8 lb ai/A, respectively. The RQ for soil incorporated applications at 10 lbs ai/A exceed the LOC for effect to endangered species and at 20 lbs ai/A exceed the LOC for restricted use.

However, likelihood of hazardous exposure to birds also depends on how many granules it would take to exceed the LOC. Two granular formulations were assessed (4G and 10G) for potential risk to birds.

Avian Assessment of 4G Granulars

According to the registrant, the 4G formulation comes in two sizes, a smaller granule (16/30 size) which contains approximately 0.0216 mg ai/granule; and the larger granule (8/30 size) which contains approximately 0.1528 mg ai/granule. The larger granule is still small enough to be easily swallowed by a small bird.

Using the bobwhite LD₅₀ of 683 mg/kg, the estimated LD₅₀ for a 20 gram bird the size of a sparrow (Dunning, 1984) would be 13.66 mg/bird (683 X 0.02 = 13.66). To take in enough active ingredient to equal the LOC (0.5 x LD₅₀) for potential high risk, a sparrow would have to ingest 45 large granules (0.5 x 13.66/0.1528) or 316 small granules (0.5 x 13.66/0.0216) in one day. Since the granules are not considered a food source, ingestion would occur inadvertently as grit. **It is considered unlikely that a sparrow sized bird would ingest 45 granules, therefore high risk to birds is considered unlikely at any use rate (Best, 1992).**

To exceed the endangered species LOC, the same sized bird would have to ingest approximately 9 large granules or 63 small granules of the 4G dichlobenil formulation. It is considered unlikely that a bird would consume 63 granules in the process of gathering grit, however, it is considered possible that 9 granules could be ingested in one day. **Therefore, the larger granules of the 4G formulation may affect endangered birds at a 2 lb ai/A or higher unincorporated application rate and at 10 lb ai/A or higher incorporated rate. The smaller granules, regardless of the use rate, are not expected to have an acute affect to endangered birds.**

Avian Assessment of the 10G Granulars

The 10G granule (8/16 size), contains approximately 0.3276 mg ai/granule. This size granule is still large enough to be easily swallowed by a small bird.

Using the bobwhite LD₅₀ of 683 mg/kg, the estimated LD₅₀ for a 20 gram bird the size of a sparrow (Dunning, 1984) would be 13.66 mg/bird (683 X 0.02 = 13.66). To take in enough active ingredient to equal the LOC (0.5 x LD₅₀) for potential high acute risk, a sparrow would have to ingest 20 to 21 large 10G granules (0.5 x 13.66/0.3276) in one day. Since the granules are not considered a food source, ingestion would occur inadvertently as grit. It is considered reasonable and likely that a sparrow sized bird would ingest up to 21 granules (Best, 1992). Therefore, the high potential of acute risk to birds is considered likely at 6 lb ai/A or higher when using the 10G formulation.

The trigger for classifying dichlobenil as a restricted use candidates has been exceeded at all unincorporated application rates.

To exceed the endangered species LOC, the same sized bird would have to ingest approximately 4 granules of the 10G formulation. It is considered likely that a bird would consume the granules in the process of gathering grit in one day. Therefore, the 10G granules may affect endangered birds at all unincorporated rates of application and at the 10 lb ai/A or higher incorporated application rates.

Birds, Chronic

No avian reproduction data are available.

Bird Summary

The relatively low exceedances means the overall acute risk of dichlobenil to birds is low. However, ground-feeding endangered birds may be affected at all use rates if these birds ingest the larger granules, especially the 10G formulations.

(2) Mammals

Mammalian species may be exposed to granular pesticides by inadvertently ingesting granules. They also may be exposed by other routes, such as by walking on exposed granules and drinking water contaminated by granules. The number of LD₅₀s that are available within one square foot immediately after application is used as a risk quotient (LD₅₀s/ft²) for the various types of exposure to granular pesticides. Risk quotients are calculated for a 200 gram mammal (e.g. rat).

Risk quotients are presented below.

Table 27: Mammalian Risk Quotients for Granular Applications of Dichlobenil, both Broadcast (Unincorporated) and Incorporated

Lbs ai/A	Risk Quotients Based on Rat LD ₅₀ of 4250 mg/kg (850 mg per 200 gram rat)			
	Unincorporated		Incorporated ^a	
	EEC ^b mg/sq ft	200 gram mammal LD ₅₀ 850 mg	EEC ^b mg/sq ft	200 gram mammal LD ₅₀ 850 mg
2	21	<0.1	3	<0.1
4	42	<0.1	6	<0.1
6	63	<0.1	9	<0.1
8	83	<0.1	12	<0.1
20	208	0.2	31	<0.1

^aIt is assumed that only 15% of the applied ai is exposed after incorporation. This assumption is based on dichlobenil being lightly incorporated into the soils.

^b mg/sq ft = lbs ai/A X (453590 mg per lb / 43560 ft² per acre).

No LOCs are exceeded if dichlobenil is soil incorporated.

With unincorporated application, the LOC for effects to small endangered mammals are exceeded at a use rate of 20 lbs ai/A. However, several factors are considered that may result in less exposure of dichlobenil to mammals:

- Mammals do not intentionally ingest grit and soil. Exposure would occur from dichlobenil that is attached to food items or fur.
- The use sites for 20 lbs ai/A applications are nurseries, homeowner and landscaping sites. Endangered mammals are not expected to inhabit these areas.
- The 2-generation rat reproduction study indicated that dichlobenil makes the food items unpalatable for the rats. This suggests that the presence of dichlobenil may discourage mammals from feeding in the treated area.

Therefore, it is concluded that dichlobenil is unlikely to affect endangered mammals.

The major degradate of dichlobenil, BAM, is similar in toxicity to mammals to parent dichlobenil. The rat LD₅₀ of BAM is 1,470 mg/kg (MRID 00112500) compared to an LD₅₀ of 4,250 mg/kg for dichlobenil. It is not known precisely how much of dichlobenil transforms to BAM, and of that, how much remains exposed on the soil surface. However, BAM is formed slowly as a result of aerobic soil metabolism, and therefore would not be expected to be concentrated on the soil surface. Therefore, exposure to mammals from BAM is expected to be minimal.

Mammals, Chronic

Currently, EPA does not have a formal process for determining chronic risk to mammals from granular formulations. However, since chronic mammalian toxicity data for dichlobenil technical are available, an attempt was made to estimate if a chronic impact was possible. It is assumed that if exposure in the field exceeds NOELs from chronic lab studies, mammals may be chronically affected. The NOELs range from 3 to 45 mg/kg/day or 60 to 900 ppm.

NOEL (ppm) = NOEL (mg/kg/day) / 0.05 (daily food consumption)

At some point after application, it is assumed that the dichlobenil is released from the clay granule into the surrounding soil. Since mammals do not intentionally consume clay granules or soil, exposure to mammals would only occur if the granules or soil containing dichlobenil attached to a mammalian food item or if dichlobenil is dissolved in surface water puddles. If the applied dichlobenil is mixed with the top 3 inches of soil, the concentration in the soil would be approximately 0.73 ppm for each pound applied per acre (Ecological Risk Assessment SEP, 1986). Therefore, soil concentrations would range from 2 to 15 ppm. It is assumed the concentrations in food items to which the soil was attached, or the water covering the treated soil would not exceed the concentration in the soil. A minimal likelihood of chronic effects to mammals is suggested since 2 to 15 ppm of dichlobenil in the soil is substantially lower than the NOELs of 60 to 900 ppm.

The overall risk of dichlobenil to mammals including endangered species is low.

(3) Insects

At this time, EPA has no quantitative procedure for assessing risk to nontarget insects. Because dichlobenil is practically non-toxic to honey bees, and is applied only as a granular, exposure and risk is expected to be minimal. Because dichlobenil is practically non-toxic to honey bees, no label restrictions are required.

(4) Exposure and Risk to Nontarget Aquatic Animals

The EECs for aquatic exposure are provided in Table 25.

(a) **Freshwater Fish**

Table 28: Fish Acute Risk Quotients for Granular Applications of Dichlobenil, both Broadcast (Unincorporated) and Incorporated

Lbs ai/A	Risk Quotients					
	Unincorporated			Incorporated		
	Initial EEC ppb	RQ trout LC ₅₀ 6260 ppb	RQ bluegill LC ₅₀ 8310 ppb	Initial EEC ppb	RQ trout LC ₅₀ 6260 ppb	RQ bluegill LC ₅₀ 8310 ppb
2	95	0.02	0.01	47	0.01	<0.01
4	190	0.03	0.02	95	0.02	0.01
6	285	0.04	0.03	141	0.02	0.02
8	380	0.06	0.04	190	0.03	0.02
20	951	0.15*	0.1*	476	0.08	0.06

* Exceeds Endangered Species LOC
 ** Exceeds Restricted Use LOC
 *** Exceeds High Acute Risk LOC

Dichlobenil volatilizes rapidly in water. The generic EECs did not fully account for this route of rapid dissipation. EPA concludes that a level of concern for endangered species at the 8 lb ai/A for unincorporated and at 20 lb ai/A for incorporated applications would not be triggered.

RQs for unincorporated applications at 20 lbs ai/A exceed the LOC for effects to endangered fish. The LOCs for restricted use and potentially high risk are not exceeded. Incorporated applications do not exceed any LOCs.

Long-term exposure levels (56-day average EECs) range from 3 to 67 ppb. Comparing these values to the trout early life stage 56-day MATC of 330 ppb indicates minimal likelihood of chronic risk to fish.

The dichlobenil degradate BAM is practically non-toxic to aquatic organisms with a LC₅₀ for bluegill and trout at 120 and 140 ppm, respectively. BAM represents minimal risk to fish.

(b) Freshwater Invertebrates

Table 29: Aquatic Invertebrate Acute Risk Quotients for Granular Applications of Dichlobenil, Both Unincorporated and Incorporated

Lbs ai/A	Risk Quotients					
	Unincorporated			Incorporated		
	Initial EEC ppb	RQ Oyster EC ₅₀ 1630 ppb	RQ <i>D. magna</i> EC ₅₀ 6200 ppb	Initial EEC ppb	RQ Oyster EC ₅₀ 1630 ppb	RQ <i>D. magna</i> EC ₅₀ 6200 ppb
2	95	0.05	0.01	47	0.02	<0.01
4	190	0.11*	0.03	95	0.06	0.01
6	285	0.17**	0.04	141	0.09*	0.02
8	380	0.23**	0.06	190	0.12*	0.03
20	951	0.58***	0.15*	476	0.29*	0.08

* Exceeds Endangered Species LOC
 ** Exceeds Restricted Use LOC
 *** Exceeds High Acute Risk LOC

Dichlobenil volatilizes rapidly in water. Generic EECs do not fully account for this route of rapid dissipation. The Agency therefore concludes that a level of concern for endangered species of freshwater aquatic invertebrates at the 8 lb ai/A for unincorporated and at 20 lb ai/A for incorporated applications would not be triggered. EPA also concludes that a level of concern for endangered species would not be triggered for mollusks from incorporated applications at 4 lb ai/A and restricted use would not be triggered for mollusks from unincorporated applications at 4 lb ai/A.

Freshwater Mollusks

When a estuarine mollusk species (oyster) EC₅₀ is available, it is used as an indicator species for freshwater mollusk species.

The LOC for potentially high acute risk to mollusks is exceeded for unincorporated applications at 20 lb ai/A. The restricted use LOC is exceeded by unincorporated applications at 6 lbs ai/A, and incorporated applications at 20 lbs ai/A. Unincorporated applications at 4 lbs ai/A and higher and incorporated applications at 6 lbs ai/A and higher are considered to exceed the endangered mollusks species LOC.

Aquatic Invertebrates

Unincorporated applications at 20 lbs ai/A exceed the LOC for effects to endangered aquatic invertebrates. The LOCs for restricted use and potentially high acute risk are not exceeded. Incorporated applications do not exceed any LOCs.

Long-term exposure levels (21-day average EECs) range from 9 to 180 ppb. Comparing these values to the *Daphnia magna* life cycle 21-day MATC of 750 ppb indicates minimal likelihood of chronic risk to aquatic invertebrates.

The dichlobenil degradate BAM is practically non-toxic to aquatic organisms with an EC_{50} of 856 ppm for daphnids. BAM represents minimal risk to aquatic invertebrates.

(c) Estuarine and Marine Animals

Since the EC_{50} for shrimp (2.35 ppm) and oysters (1.63 ppm) are lower than that of freshwater organisms (6.2 ppm for daphnids), there is a greater potential for risk for estuarine organisms. However, there are factors that may lessen this presumed risk. The use sites that may result in exposure to estuarine and marine environments are blueberries, apples, pears, cranberries and turf. Based on data provided by registrants and other public sources, blueberry, apple and pear use sites where dichlobenil is applied are not close to estuaries (Data from the National Center for Food and Agriculture Policy) with the exception of apples in Rhode Island and blueberries in Maine. Dichlobenil used on apples and blueberries at these two locations could runoff into estuaries. Minimal exposure to estuaries from cranberry use sites are expected for the following reasons: flooding only occurs at harvest time and levees hold any rainfall; application times are only early in the season or at fall after harvest; and the granular formulation results in minimal drift to estuarine habitats. The turf use sites are limited to spot treatment on grass lawns and to dichondra lawns which are limited to the south eastern part of the U.S. Limited amounts of dichlobenil are used in this area. Therefore, dichlobenil is not generally expected to represent a high risk to estuarine and marine organisms except from the use of apples in Rhode Island and blueberries in Maine.

There are no estuarine invertebrates or mollusks on the endangered species list. However, there are endangered estuarine fish species. Effects to endangered estuarine fish are not expected based on the low toxicity ($LC_{50}=12,700$ ppb) of dichlobenil to fish relative to exposure potential.

(5) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

The Agency does separate risk assessments for nontarget terrestrial and semi-aquatic plants. Nontarget terrestrial plants inhabit non-aquatic areas which are generally well drained. Nontarget semi-aquatic plants inhabit low-lying areas that are usually wet, although they may be dry during certain times of the year. Semi-aquatic plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. Both the terrestrial and semi-aquatic plants are exposed to pesticides from runoff. They differ, however, in that terrestrial plants are assumed to be exposed via sheet runoff, whereas semi-aquatic plants are assumed to be exposed via channelized runoff. Calculating runoff exposure is done using a simple model which assumes that a certain percentage of that which is applied transports with run off. The percentage is based on solubility. Based on the solubility of 25 ppm, it is assumed that approximately 2% of the applied dichlobenil runs off the site

of application. Since dichlobenil is used as a granular at all use sites except for under the pavement and sewer system treatment, drift is assumed to be negligible. Volatilization is also a potential route of exposure to nontarget plants. However, vegetative vigor data are not available to determine risk from this exposure.

The EECs for terrestrial and semi-aquatic plants are calculated using the following formulae:

Unincorporated Application

Terrestrial plants EEC (lb ai/A) = appl rate (lb ai/A) X 1 acre X 0.02 (percent runoff)

Semi-aquatic plants EEC (lb ai/A) = appl rate (lb ai/A) X 10 acres X 0.02 (percent runoff)

Incorporated Application

Terrestrial plants EEC (lb ai/A) = appl rate (lb ai/A) X 1 acre X 0.02 (percent runoff) ÷ 5 cm depth

Semi-aquatic plants EEC (lb ai/A) = appl rate (lb ai/A) X 10 acres X 0.02 (percent runoff) ÷ 5 cm depth

Table 30 EECs and Risk Quotients for Terrestrial and Semi-aquatic Plants (EC₂₅=0.023 lb ai/A)

Application Rate (lb ai/A)	Type of Plant	Incorporated Application		Unincorporated Application	
		EEC (lb ai/A)	Risk Quotient EEC/EC ₂₅	EEC (lb ai/A)	Risk Quotient EEC/EC ₂₅
2	Terrestrial	0.01	<1	0.04	1.7
	Semi-aquatic	0.08	3.5	0.40	17.4
4	Terrestrial	0.02	<1	0.08	3.5
	Semi-aquatic	0.16	7.0	0.80	34.8
6	Terrestrial	0.02	<1	0.12	5.2
	Semi-aquatic	0.24	10.4	1.20	52.2
8	Terrestrial	0.03	1.3	0.16	7.0
	Semi-aquatic	0.32	13.9	1.60	69.6
20	Terrestrial	0.08	3.5	0.40	17.4
	Semi-aquatic	0.80	34.8	4.00	173.9

Shaded area indicates that parameter exceeds LOC.

Table 30 above describes the risk quotients and EECs for terrestrial and semi-aquatic plants. The LOC for potentially high risk for non-target semi-aquatic plants has been exceeded at all rates of application. The LOC for non-target terrestrial plants has been exceeded at 8 lb ai/A or higher rates

when incorporated. The LOC for potentially high risk for non-target terrestrial plants has been exceeded at all rates of application when dichlobenil is not incorporated. At the higher rates, the margins of exceedance are relatively high. It should be noted that the method of estimating exposure did not fully take into account that during runoff events, dichlobenil moving with surface water will likely volatilize relatively quickly, reducing potential exposure and impact.

Dichlobenil is also expected to affect endangered species of terrestrial and semi-aquatic plants.

(b) Aquatic

Exposure to non-target aquatic plants may occur through runoff from terrestrial sites or from volatilization. As with terrestrial plants, exposure from volatilization cannot be estimated with available data. The EECs are derived from the GENEEC program as described in Table 25. Duckweed, *Lemna gibba*, is used as the surrogate for aquatic vascular plants. The diatom *Navicula pelliculosa* is the most sensitive algae or diatom species tested and is used to assess risk to algae and diatoms.

Table 31 EECs and Risk Quotients for Aquatic Plants

Application Rate (lb ai/A)	Type of Plant	Incorporated Application		Unincorporated Application	
		EEC (ppb)	Risk Quotient EEC/EC ₅₀	EEC (ppb)	Risk Quotient EEC/EC ₅₀
2	Vascular (<i>Lemna gibba</i>) ¹	47	2	95	3
	Algae and diatom ²		<1		<1
4	Vascular	95	3	190	6
	Algae and diatom		<1		<1
6	Vascular	141	5	285	10
	Algae and diatom		<1		<1
8	Vascular	190	6	380	13
	Algae and diatom		<1		<1
20	Vascular	476	16	951	32
	Algae and diatom		<1		<1

Shaded area indicates that parameter exceeds LOC.

¹ EC₅₀ of 30 ppb is used for *Lemna gibba*.

² EC₅₀ of 1,000 ppb is used for *Navicula pelliculosa*.

Table 31 above shows the risk quotients and EECs for aquatic plants. The LOC for diatoms and algae is not exceeded. The LOC for risk to non-target aquatic vascular plants from runoff has been

exceeded at all application rates. Even though soil incorporation reduces the aquatic EEC by about one half, all use rates would still represent a risk to aquatic vascular plants including endangered species of aquatic vascular plants. Dichlobenil volatilizes rapidly in water. The generic EECs did not fully account for this route of rapid dissipation. The risk may not be as high as indicated in the tables.

(6) Endangered Species

Dichlobenil may affect endangered species of birds, fish, aquatic invertebrates, freshwater mollusks and plants.

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

4. Environmental Risk Characterization

a. Overview of the Chemical

Dichlobenil is a non-selective herbicide registered for use on terrestrial food crops and non-food crops including residential, industrial and agricultural non-crop sites. Dichlobenil is an inhibitor of cell wall biosynthesis. Dichlobenil acts by thinning the cell wall which eventually causes cellular collapse of the seedling. It is soil applied and is activated by moisture. Formulations include the wettable powder (used for sewage lines and under pavement) and the 4% granular. Application rates range from 2 lb ai/A to 20 lb ai/A. Total dichlobenil use is estimated to be under 300,000 lbs active ingredients annually, with the largest acreage on cottonwood hybrids, cranberries, turf, apple and cherry orchards, non-crop sites and ornamental. Most of dichlobenil is formulated as granulars. GIS mapping interpretations were used to help assess areas impacted by dichlobenil use.

b. Overview of the Findings

(1) General Conclusions for Environmental Fate and Transport

- Dichlobenil dissipates in the environment (on soil and in surface water) principally by volatilization. However, it is persistent under field conditions that reduce the potential for volatilization (ie. cooler climates). When transformation proceeds through aerobic soil metabolism, the metabolite, 2,6-dichlorobenzamide (BAM) is generated (13.1% at 50 weeks).

Under conditions where dichlobenil does not volatilize there is potential for both dichlobenil and BAM to move to ground water in coarse-textured soils low in organic matter.

- Dichlobenil is stable to hydrolysis, photodegradation in soil and metabolic degradative processes. Dichlobenil is very persistent to aerobic soil metabolism (half-life of 46.3 weeks) and anaerobic aquatic metabolism (half-life of 2.8 years).
- Terrestrial field dissipation study results were consistent with lab study results with volatilization occurring more readily in warmer climates.
- Both dichlobenil and BAM can be extremely mobile and persistent under anaerobic conditions. Dichlobenil and BAM exceed levels of concern for ground-water quality.
- Dichlobenil is predicted to volatilize from most surface waters; therefore, its persistence in the surface water environment will depend primarily on the environmental factors which control volatility rates (temperature, wind speed, humidity, etc.).

Acceptable and supplemental information from environmental fate studies with respect to the persistence and mobility of dichlobenil under laboratory and field conditions has been reviewed and the environmental data base for dichlobenil is essentially complete.

(2) General Conclusions for Ecological Effects

Except for the acute effects to freshwater mollusks and non-target plants, the concentrations of dichlobenil granules in the environment are not expected to cause either potentially high acute or chronic levels of risk to non-target organisms.

Restricted use triggers have been exceeded for birds and freshwater mollusks.

Endangered species of birds, mollusks, fish and plants may be affected from the use of dichlobenil.

(a) Acute Risk

The following exceedances have been identified from the risk assessment section of this document. A qualitative discussion of risks to estuarine organisms is provided.

Table 32 Acute Risk Predicted with Dichlobenil¹

lbs ai/A	Terrestrial Animals		Freshwater Animals			Plants	
	Birds ²	Mammal	Fish	Aquatic Invertebrate	Mollusk	Aquatic Plants	Terrestrial Plants
2	E,	none	none	none	none	E, A, IE, IA	E, A, IE, IA
4	E, R	none	none	none	E	E, A, IE, IA	E, A, IE, IA
6	E, R	none	none	none	E, R,IE	E, A, IE, IA	E, A, IE, IA
8	E, R, A	none	none	none	E, R,IE	E, A, IE, IA	E, A, IE, IA
20	E, R, A, IE	none	E	E	E, R, A, IE, IR	E, A, IE, IA	E, A, IE, IA

¹ The codes in the table are as follows:

- For unincorporated application: E= endangered species, R= restricted candidate, A= potentially high acute risk.
- For incorporated application: IE= endangered species, IR= restricted candidate, IA= potentially high acute risk.

² It is estimated that there is minimal potential for adverse affects to birds from exposure to the smaller granules. The effects to birds are a result of exposure to the large size granules only.

- The 10G formulation poses a high potential for acute risk to birds at the 6 lb ai/A or greater application rate when dichlobenil is not incorporated.
- Endangered species of birds may be affected by applications of the large 4G granules and 10G granules at all rates when unincorporated and at the 10 lb ai/A or greater application rate when granules are incorporated.
- There is minimal likelihood of acute effects to mammals.
- At 20 lbs ai/A, aquatic organisms are not at potentially high risk from dichlobenil except for freshwater mollusks. As shown on the table, endangered fish (20 lb ai/A), aquatic invertebrates (20 lb ia/A) and mollusks (4 lbs ai/A or higher) may be affected. The restricted use LOC is exceeded for freshwater mollusk (6 lbs ai/A or higher).
- Exposure to estuarine invertebrates is expected to be minimal except from the uses of dichlobenil on apples in Rhode Island and blueberries in Maine. Estuarine exposure from these use patterns is not known, therefore, while estuarine invertebrates are more sensitive to dichlobenil than freshwater organisms, the risk is uncertain.
- Acute risk to honey bees is minimal.
- The degradate, BAM, poses minimal risk to aquatic and terrestrial organisms.
- Risks to non-target organisms from the wettable powder used for under the pavement and the sewage lines applications are considered to result in minimal exposure to the environment and therefore minimal risk to non-target organisms.

Discussion of risk estimate for granular formulations and birds

In order to determine the risk to birds from granulars, the Agency used the method as described in the "Comparative Analysis of Acute Avian Risk From Granular Pesticides" as published by the Office of Pesticide Programs USEPA, March, 1992.

The following considerations were taken into account in assessing the acute risk to birds from the use of dichlobenil:

- Although birds are known to ingest pesticide granulars, the amount consumed is not known because the mechanisms of bird attraction, avoidance, and/or selection are not yet completely understood. The size of granulars overlap, at least to some extent, with the size of the grit the birds select (Best, 1992). "Characteristics of Corn Rootworm Insecticide Granules and the Grit Used by Cornfield Birds: Evaluating Potential Avian Risks; Louis B Best Am. Midl. Nat. 128:126-138. 1992.
- Only direct oral ingestion was considered for this assessment. Birds may also be exposed to granular pesticides through routes other than direct oral ingestion of granulars; for example, drinking contaminated water after rainfall, preening contaminated feathers, contacting eyes with contaminated water while bathing, walking on contaminated soil and breathing fumes of dichlobenil. Consideration of additive exposures would result in higher risk than had been predicted in this analysis.
- The length of time the granular remains intact in a size that can be consumed by birds as grit is unknown.

The Agency considered dichlobenil in the report, *Comparative Analysis of Acute Avian Risk From Granular Pesticides*. (OPP/USEPA, 1992) Dichlobenil was not included in the comparative analysis because it was not highly toxic to birds.

(b) Chronic Risk

- Chronic risk to birds can not be assessed due to lack of avian reproduction data. These studies are requested.
- There is minimal likelihood of chronic effects to mammals.
- There is minimal likelihood of chronic effects to fish and aquatic invertebrates
- The BAM degradate poses minimal chronic risk to aquatic and terrestrial organisms because exposure is unlikely to occur to aquatic organisms at levels that exceed the LOC.

(3) General Conclusions for Ground Water Quality

OPP is concerned about the potential degradation of ground-water quality that may occur in dichlobenil use areas. The mobility of dichlobenil is correlated with organic matter content of the soils. Dichlobenil is very mobile in low organic matter soils. The principal degradate BAM, is more mobile than its parent. It is likely that use of dichlobenil on low organic matter soils will result in leaching through the soils and may reach ground-water. Both dichlobenil and BAM are extremely mobile and persistent under anaerobic conditions.

Dichlobenil and its degradates exceed levels of concern for Ground-Water Quality. Dichlobenil exceeded all the triggers for mobility and persistence used to recommend restricted use, but not the ground-water detection trigger at this time.

With only one well sampled for dichlobenil in the United States to date, there has been extremely limited monitoring for dichlobenil and BAM in ground-water. (Hoheisel, et al., 1992). Information provided by the registrant demonstrates that dichlobenil can leach to ground-water in some environments. Residues of dichlobenil and BAM were reported in surface and ground-water studies in Europe.

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 ingredients 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 dichlobenil active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of most products containing dichlobenil under the conditions specified in this Reregistration Eligibility Document (RED). A decision on the eligibility of products applied to sewers or applied with a granular backpack can not be made at this time. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of dichlobenil, and lists the submitted studies that the Agency found acceptable.

The Agency therefore finds that all products containing dichlobenil as the active ingredients are eligible for reregistration under the conditions specified in this RED except for those registered for application to sewers or granular backpack application. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target 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 most uses of dichlobenil identified in Appendix A are eligible for reregistration under the conditions specified in this RED, it should be understood that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing dichlobenil, 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 ingredients dichlobenil, the Agency has sufficient information on the health effects of dichlobenil and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that dichlobenil products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment with the exception of sewer and granular backpack application use sites. Therefore, the Agency concludes that products containing dichlobenil for the remaining uses are eligible for reregistration under the conditions specified in this RED.

2. Eligible and Ineligible Uses

The Agency has determined that all uses except sewer treatment and granular backpack application of dichlobenil are eligible for reregistration provided application rates are modified and other precautions as noted in this RED are followed. The Agency can not make a decision at this time as to the eligibility of sewer treatment and granular backpack application of dichlobenil usage sites at this time because additional data are needed to evaluate exposure of mixer/loader/applicators at these sites.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

Determination of safety includes consideration of special sensitivity to children, potential cumulative effects with pesticides that have a common mode of toxicity, and aggregate risks resulting from exposure to dietary residues, drinking water, and residential sources.

Although the available toxicological database for dichlobenil appears to suggest a sensitivity for infants and children to dichlobenil, the Agency has determined that there is no need for an additional

safety factor. This decision is based on findings of the two generation reproduction and developmental toxicity studies. These studies indicate that there is no evidence of increased sensitivity of the test animals to prenatal exposure to dichlobenil. The NOELs for developmental effects are equal to or greater than the NOELs for maternal effects, thus not indicating a unique sensitivity for prenatal exposure. A lower NOEL in offspring than adults in the two generation reproduction data appeared to suggest an increase in offspring sensitivity. In that study, it was noted that low pup birth weights were only in the first generation, not the second generation. Thus, the effect is not reproducible. It was concluded that only minimal confidence could be placed in the pup body weight data that appeared to suggest an increase in sensitivity to the offspring of rats following postnatal exposure to dichlobenil.

For BAM there does not appear to be any unique sensitivity from prenatal exposure. However, as previously stated, the BAM toxicological database is incomplete. However, dietary risk estimates utilizing the BAM reference dose (which was calculated using an additional 3X factor to account for the incomplete database) should sufficiently account for any special sensitivities of infants or children that are unknown due to the lack of a rat developmental study and the unacceptable reproductive study.

It is also noted that there is no post-natal dietary (food source) exposure to dichlobenil, and possible exposure in drinking water is not considered to be a major route of exposure.

The use of an uncertainty factor of 100 (10X for interspecies variability, and 10X for intraspecies variability) in the risk assessment for dichlobenil provides adequate protection of infants and children.

The Agency has determined that insufficient data are available to conclude that other pesticides either have or do not have a common mode of toxicity with dichlobenil.

An aggregate risk assessment resulting from combining exposures from residential uses of dichlobenil with exposures from drinking water consumption could be performed. When comparing exposures from the homeowner application scenarios and adult consumption of dichlobenil contaminated drinking water, the exposure value for consumption of drinking water is orders of magnitude lower than that of a homeowner applicator. Therefore, the risk is essentially that of residential exposure alone since the contribution from drinking water is insignificant in comparison. Note that the Agency has no information to indicate that this type of exposure is likely to occur.

There are no **chronic** homeowner exposure scenarios; therefore, the aggregate chronic risk would include only dietary exposure from consumption of the BAM metabolite and drinking water contributions. Although there are insufficient data to estimate chronic drinking water exposure for BAM, a combined food source and drinking water assessment cannot be performed. Since the toxicity endpoints for use in chronic risk assessment are different for dichlobenil and BAM, aggregation of risks would be appropriate only for residues of BAM from food and drinking water. The most highly exposed subpopulation from food containing residues of BAM was estimated to utilize 20 percent

of the RfD. Consequently the drinking water risk from BAM could be as high as 80 percent of the RfD and still be protective of the public health. Monitoring data for both dichlobenil and BAM residues in drinking water are required to confirm the Agency's conclusion that the public health is protected.

2. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect . . ." The Agency is currently working with interested stake holders, including other government agencies, public interest groups, industry, and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At this time, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects.

3. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.231:

The tolerances listed under 40 CFR §180.231 are for the combined negligible residues of the herbicide dichlobenil (2,6-dichlorobenzonitrile) and its metabolite 2,6-dichlorobenzoic acid (2,6-DCBA). The HED Metabolism Committee has determined that the metabolite 2,6-Dichlorobenzamide (BAM) should be added to the tolerance expression and the metabolite 2,6-DCBA should be deleted from the tolerance expression. Therefore, 40 CFR §180.231 should be modified to state: "Tolerances are established for the combined residues of the herbicide dichlobenil (2,6-dichlorobenzonitrile) and its metabolite 2,6-dichlorobenzamide in or on the following raw agricultural commodities: ..."

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.231 for the following commodities: apples, blackberries, blueberries, cranberries, filberts, pears, and raspberries.

The available data indicate that the established tolerances for apples and pears are too low and that increased tolerances are necessary. The available data also indicate that the established tolerances for blackberries, cranberries, and raspberries are too high and that tolerances of 0.1 ppm would be more appropriate. A separate tolerance for filberts will be proposed at 0.1 ppm.

Additional field residue data are required for grapes before a complete tolerance reassessment can be made. Processing studies for apples and grapes remain outstanding. Following receipt of the requested data on animal metabolism, and the magnitude of residues, the need for and expression of tolerances for residues in animal commodities will be determined.

Table 33: Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.231			
Almond hulls	0.15	Revoke	The tolerance should be revoked because no registered uses exist for almonds.
Apples	0.15	0.5	The available data indicate that the established tolerance is too low, due to the addition of the BAM metabolite to the tolerance expression. These data indicate the need to increase the tolerance for the combined residues of dichlobenil and BAM.
Avocados	0.15	Revoke	The tolerance should be revoked because no registered uses exist for avocados.
Blackberries	0.15	0.1	The available data indicate that the established tolerance is too high and that the tolerance for the combined residues of dichlobenil and BAM can be decreased.
Blueberries	0.15	0.15	
Citrus	0.15	Revoke	The tolerance should be revoked because no registered uses exist for citrus.
Cranberries	0.15	0.1	The available data indicate that the established tolerance is too high and that the tolerance for the combined residues of dichlobenil and BAM can be decreased.
Figs	0.15	Revoke	The tolerance should be revoked because no registered uses exist for figs.
Grapes	0.15	TBD ¹	Adequate BAM data have been submitted, however data for residues of dichlobenil remain outstanding.
Mangoes	0.15	Revoke	The tolerance should be revoked because no registered uses exist for mangoes.
Nuts	0.15	Revoke	The established nuts tolerance should be revoked <u>concomitant</u> with the establishment of a separate tolerance for filberts since the use of dichlobenil on all other nuts has been cancelled.
Pears	0.15	0.5	Residue data were translated from apples. The available data indicate that the established tolerance is too low, due to the addition of the BAM metabolite to the tolerance expression. These data indicate the need to increase the tolerance for the combined residues of dichlobenil and BAM.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Raspberries	0.15	0.1	Residue data were translated from blackberries. The available data indicate that the established tolerance is too high and that the tolerance for the combined residues of dichlobenil and BAM can be decreased.
Stone fruits	0.15	Revoke	The established stone fruit tolerance should be revoked <u>concomitant</u> with the establishment of a separate tolerance for cherries, since the use of dichlobenil on all other stone fruits has been dropped.
Tolerances to be established under 40 CFR §180.231			
Cherries	(0.15- stone fruits)	TBD ¹	A separate tolerance should be established for cherries since other stone fruit uses are not being supported. A value of 0.15 should be used for residues of dichlobenil and BAM in/on sweet and sour cherries until the new residue data submissions are evaluated by the Agency.
Filberts	(0.15 - nuts)	0.1	A separate tolerance should be established for filberts since no other tree nut uses are being supported by Uniroyal Chemical.

1. TBD = To be determined. Reassessment of tolerance(s) cannot be determined at this time because additional data are required.

CODEX HARMONIZATION

No Codex MRLs have been established for residues of dichlobenil. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

4. Tolerance Revocations and Import Tolerances

During EPA's process of preparing the reregistration eligibility document for dichlobenil several food/feed uses were voluntarily cancelled. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance generally is no longer needed. It is EPA's policy to propose revocation of a tolerance, following the deletion of a related food use from a registration, or **following** the cancellation of a related food-use registration. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance on the grounds that the Agency cannot conclude that the tolerance is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and

toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing dichlobenil tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances, so that the Agency may determine whether maintenance of the tolerance would be protective of the public health.

a. Human Health

(1) Dietary

Acute Dietary

The Agency has not evaluated the acute (1 day) dietary (food source) risk associated with the use of dichlobenil because a scenario in which consumption of dichlobenil per se residues occurred was not identified. BAM is the major residue detected in food/feed items treated with dichlobenil. However, an acute drinking water risk assessment for consumption of dichlobenil was performed. The level of concern was not exceeded.

Although a scenario for consumption of BAM exists, no acute assessment was performed because no endpoint of concern for use in this assessment was identified. The endpoints observed in the BAM developmental study were inappropriate for an acute dietary assessment.

Chronic Dietary

Dichlobenil was classified as a nonquantifiable group C (possible human) carcinogen, therefore the RfD approach was used to evaluate chronic dietary risk. The Agency has evaluated the chronic dietary risk associated with the consumption of the dichlobenil metabolite BAM based on tolerance level residues, 100% crop treated data and estimated BAM residue values for meat and milk. The RfD for BAM was determined to be 0.015 mg/kg/day based upon the NOEL from a chronic toxicity study in dogs and an uncertainty factor of 300 (100 x 3). The uncertainty factor of 100 accounts for the inter-species extrapolation and intra-species variability. The uncertainty factor of 3 is to compensate for the lack of an acceptable BAM reproduction study. The highest chronic dietary exposure, for non-nursing infants < 1 year, was 20% of the RfD. Most of the sub-group exposures were less than 7%.

A chronic drinking water risk was assessed for dichlobenil. The RfD for dichlobenil was determined to be 0.013 mg/kg/day based upon a NOEL of 1.25 mg/kg/day from a two-year dog feeding study and an uncertainty factor of 100. The chronic dietary exposure of non-nursing infants (< 1 year) to dichlobenil from drinking water was 26% of the RfD. While the dietary exposure to the general population was 10% of the RfD. The Agency considers exposures which utilize 100% or less of the RfD to be adequately protective.

(2) Occupational and Residential

Short-Term (1-7 days)

The Agency has determined that there is a potential for dermal and inhalation exposure to pesticide handlers. The endpoint used for the short-term assessment is a developmental toxicity study based on a NOEL of 45 mg/kg/day. The MOEs for short-term occupational exposure resulting in subchronic systemic effects to dichlobenil are greater than 100 for all the exposure scenarios considered. PPE as specified in the description of the exposure scenarios, long-sleeved shirt, long pants, shoes, socks and chemical resistant gloves for mixers and loaders; long-sleeved shirt, long pants, shoes, socks and no gloves for applicators, will be required.

Intermediate (1 week to several months)

The usage data available to the Agency do not support either intermediate-term or chronic exposure for most scenarios. However available information indicate that exposure based on sewer use can be considered an intermediate scenario. However, there are no exposure data to perform an assessment. Therefore, exposure data will be required for sites identified as having potential intermediate exposure: granular backpack application and application to sewer pipes. The NOEL (3 mg/kg/day) that will be used in the intermediate-term assessment is from a 2-generation reproduction study.

Post-Application

There are no data available to address post-application exposures to dichlobenil for persons re-entering areas treated with dichlobenil. For most scenarios, the potential for dermal exposure following applications of dichlobenil appears to be limited since dichlobenil applications are made to the soil early in the season and may be followed by shallow incorporation or irrigation. Generally if the MOEs at the time of application are greater than 100, then post-application MOEs should be even larger.

However, there are concerns about the use of dichlobenil in some horticultural/nursery scenarios. Therefore, post-application exposure studies for applications of dichlobenil to ornamentals are required.

A 12-hour restricted-entry interval (REI) for all uses of dichlobenil except horticultural/nursery uses within the scope of the WPS was established.

A 24-hour restricted-entry interval for all horticultural/nursery uses of dichlobenil within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) was established due to concerns about inhalation exposure of nursery workers to dichlobenil vapors, as well as, the uncertainties for exposure to the soil metabolite BAM. As previously stated, the toxicological database for BAM is not as complete as that for dichlobenil. If the dichlobenil is not incorporated (physically or by watering in), then due to dichlobenil's moderate vapor pressure there is the potential for vaporization at ambient temperatures. The 24-hour REI would allow time for the dispersement of dichlobenil vapors generated by vaporization. During the 24 hours the dichlobenil should be activated by soil moisture, thus enabling the dichlobenil to "flow" to the subsurface. Once the application has been correctly incorporated through watering-in and the treated surface is dry, workers may enter the treated area during the REI without PPE if they are performing tasks that do not involve contact with the soil subsurface. Thus, the 24 hour REI can be effectively shortened by watering in.

Due to concerns about inhalation exposures from sewer treatments, ventilation (open window or exhaust fan) must be supplied for all treatment uses in connection with inhabited buildings, such as residences, offices, and hospitals. This measure should adequately prevent inhalation exposure to occupants of buildings where the sewer lines are being treated because only a small amount of dichlobenil is used in sewer treatment and plumbing systems have water traps that trap gas to prevent its entry into buildings.

b. Environmental

The exposure estimates (EECs) used for assessing the ecological risks to wildlife were produced with a GENEEC model. The model does not account for the dissipation of dichlobenil by volatilization, so the risks in some instances may be significantly less.

(1) Avian

Acute

The overall acute risk to birds is low. However, the acute risk for birds from different dichlobenil granule formulations vary with granule size and concentration of dichlobenil per granule. The 4G formulation (both 16/30 and 8/30 granule size) is not expected to pose a potential for acute risk. The 10G formulation poses a potential for acute risk to birds at the 6 lb. ai/A or greater application rate when dichlobenil is not incorporated. Due to these risk estimates, the registrant has agreed to lower the maximum application rate from 20 lb ai/A to 10 lb ai/A. Further the Agency is requiring that the label for the 10G formulation impose soil incorporation. The small granules (16/30 size) of the 4G formulation are not expected to have an acute effect to endangered birds. Endangered species of birds may be affected by applications of the larger 4G and 10G dichlobenil granules at all unincorporated rates and at the 10 lb ai/A or higher incorporated rates. The Agency is developing a program to mitigate risks to endangered species. Dichlobenil will be included in that program.

Chronic

Chronic risk can not be assessed due to lack of avian reproduction studies. These studies are required.

(2) Mammals

Acute

No levels of concern were exceeded. There is minimal likelihood of acute effects to mammals.

Chronic

The likelihood of chronic effects to mammals is minimal since they do not intentionally ingest clay granules or soil.

(3) Insects

Dichlobenil is practically non-toxic to honeybees. Therefore, insects are not likely to be adversely affected by the use of dichlobenil.

(4) Freshwater Fish

The acute LOC for unincorporated application of dichlobenil at a 20 lb ai/A rate exceed the LOC for effects to endangered fish. However the chronic risk to fish was determined to be minimal.

(5) Aquatic invertebrates

The LOC for potentially high acute risk to mollusks is exceeded for unincorporated applications at 20 lb ai/A. The restricted use LOC is exceeded by unincorporated applications at or above 6 lbs ai/A, and incorporated applications at 20 lbs ai/A. Unincorporated applications at or above 4 lbs ai/A and incorporated applications at or above 6 lbs ai/A exceed the endangered mollusks species LOC.

Unincorporated applications at 20 lbs ai/A exceed the LOC for effects to endangered aquatic invertebrates. The LOCs for restricted use and potentially high acute risk are not exceeded. Incorporated applications do not exceed any LOCs.

(6) Estuarine and Marine Organisms

Exposure to estuarine invertebrates is expected to be minimal except from the uses of dichlobenil on apples in Rhode Island and blueberries in Maine. Estuarine exposure from these use patterns is not known; therefore, while estuarine invertebrates are more sensitive to dichlobenil than freshwater organisms, the risk is uncertain.

(7) Nontarget Plants (Terrestrial, Semi-Aquatic, and Aquatic)

The Agency has evaluated data which indicate that high acute risk LOCs are exceeded for all vascular terrestrial, semi-aquatic, and aquatic plants at application rates as low as 2 lbs ai/A. Therefore, use of dichlobenil on all sites may adversely affect nontarget terrestrial and semi-aquatic plants, including endangered species. This evaluation does not take into account the dissipation of dichlobenil from volatilization, so the risk may be significantly less.

(8) Forestry

The registration of hybrid cottonwood-poplar plantation use has recently expanded under section 3 of FIFRA to regions beyond the Oregon- Washington desert sites evaluated. Use of dichlobenil at hybrid cottonwood-poplar plantation sites in the eastern Oregon-Washington desert region which is defined as 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon was not considered a forestry use. The Agency does not have sufficient forestry dissipation data to evaluate use of dichlobenil at hybrid cottonwood-poplar hybrid sites beyond the evaluated area.

(9) Endangered Species

The Agency has concerns about the exposure of threatened and endangered plant, bird, and mollusk species to dichlobenil as discussed above in the Section III. 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 limitations to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from existing or 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.

(10) Surface Water

Although dichlobenil has the potential to contaminate surface water from run-off and spray drift, limited surface water monitoring information is available at this time. There is not a significant concern for dichlobenil contaminating surface water because dichlobenil has a high potential to volatilize from surface waters.

There is insufficient data to determine the potential of the BAM metabolite to contaminate surface water. Data on the vapor pressure and solubility of BAM are required in order to calculate Henry's constant and model BAM's fate in surface water. Additional environmental fate studies on BAM may be required to determine its potential to contaminate surface water, if the Henry's constant for BAM is less than 10^{-5} . If Henry's constant is less than 10^{-5} , it indicates that BAM does not volatilize from surface water, and aerobic soil metabolism, aerobic aquatic metabolism, adsorption/desorption and photodegradation in water studies are required on BAM.

(11) Ground Water

Dichlobenil and its metabolite BAM exhibit some of the properties and characteristics of chemicals that have been detected in ground water. Environmental fate data suggest that dichlobenil and BAM leach to ground water as a result of normal agricultural use.

To date, there has been extremely limited monitoring for dichlobenil and BAM in ground water in the United States with one well sampled for dichlobenil. (Hoheisel, et al., 1992). Information provided by the registrant demonstrates that dichlobenil can leach to ground water in some environments. Residues of dichlobenil and BAM were reported in surface and ground water studies in Europe.

Uniroyal, the basic producer has already placed a ground water advisory on product labels. All dichlobenil product labels must bear the ground water advisory presented in chapter V.

Because OPP's ground water concerns are focused on the potential occurrence of BAM in drinking water and the resulting possible human exposure, OPP is requiring a drinking water monitoring study. The drinking water study results will be used to determine if any additional ground water mitigation measures or additional prospective ground water studies are needed.

A small scale prospective ground water study is being required at this time only to support hybrid cottonwood poplar sites outside the desert areas of the Pacific northwest defined as 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon. These data are needed because of the potential for the expansion of the use of dichlobenil for hybrid cottonwood poplar tree to areas vulnerable to ground water contamination.

A small scale prospective ground water study was not required at other sites based on the available dichlobenil usage information which indicate annual production of dichlobenil is less than 300,000 lbs. If the use of dichlobenil for cottonwood-poplar pulpwood production is expanded to areas considered vulnerable, one or more small-scale prospective ground water studies would need to be conducted. An alternative to generating this data for a small scale prospective ground water study for hybrid cottonwood sites is for the registrant(s) to limit to the use of dichlobenil at hybrid cottonwood poplar production sites to desert areas of the Pacific northwest which is defined as 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon.

5. Restricted Use Classification

Dichlobenil is not classified as restricted use. However, many dichlobenil products for treating sewers contain metam sodium and are therefore classified as restricted use.

6. 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 restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time in the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Occupational/Residential Labeling Rationale

Even though data to address post-application exposure are not available, there are several post-application exposure scenarios, involving both dermal and inhalation exposures, for which some risk-mitigation measures are prudent.

Due to concerns about inhalation exposure from vaporization of dichlobenil in enclosed areas, soon after application, the Agency is establishing a 24-hour restricted-entry interval for all horticultural/nursery uses of dichlobenil within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). These uses include uses on woody agricultural (orchards and bramble) and ornamental (shrubs and trees) crops and the Special Local Need (SLN) use on dichondra. Due to the inhalation (off-gassing) exposure concerns, the Agency is requiring that the application be thoroughly incorporated into the soil (or other target surface) through watering-in. The Agency notes that once the product has been correctly incorporated through watering-in and the treated surface is dry, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

Due to concerns about dermal and inhalation exposures from soil and soil-subsurface contact soon after application, the Agency recommends thorough incorporation through watering-in for all products primarily intended for homeowner use. Entry would be restricted until the soil is dry following the watering-in.

Due to concerns about inhalation exposures from sewer treatments, EPA is establishing a requirement for all uses in connection with inhabited buildings (residences, offices, hospitals, etc.) specifying that windows must be open or an exhaust fan must be operating during the application.

Scope of the Worker Protection Standard (WPS)

The 1992 Worker Protection Standard for Agriculture Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within the scope include not only uses on plants, but also uses to the soil or planting medium the plants are (or will be) grown in.

Some of the registered uses of dichlobenil are within the scope of the Worker Protection Standard and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on 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;
- in a manner 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, sewer treatments, and treatments under asphalt and swimming pool liners.

a. Personal Protective Equipment/Engineering Controls for Handlers for Occupational-Use Products (WPS and NonWPS Uses)

The PPE requirements will pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS 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 determines that no regulatory action must be taken as a result of 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 determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED for that active ingredient, EPA may establish minimum or "baseline handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient."
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

(1) **Wettable Powder Formulations**

For the **wettable powder** formulations, the MOEs for **short-term** exposures were calculated as being acceptable for mixers and loaders when chemical resistant gloves were worn with long-sleeve shirts, long pants, shoes, and socks. Therefore, such clothing and PPE will be required for persons mixing and loading WP formulations. Because acceptable MOEs were calculated for groundboom applicators (pre-asphalt use) wearing long-sleeve shirts and long pants, shoes, and socks, but no gloves, no minimum (baseline) PPE will be established for such handlers. For the sewer uses however, a requirement for chemical-resistant gloves is being established for applicators and other handlers (in addition to mixers and loaders) based on the uncertainties regarding the potential exposure of the use. For the sewer use, dichlobenil is often used with metam sodium. Since the PPE requirements for metam sodium are likely to be more stringent than for dichlobenil, the metam sodium requirements will be retained.

(2) **Granular Formulations**

For the **granular** formulations, the MOEs for **short-term** occupational exposures were calculated as being acceptable for mixers and loaders when wearing chemical-resistant gloves, long-sleeve shirts, long pants, shoes, and socks. Therefore, such clothing and PPE will be required for persons mixing and loading granular formulations. Since the MOEs for **short-term** occupational exposure for applicators of the granular formulations are greater than 100 when wearing long-sleeved shirt, long pants, shoes, socks, and no gloves, no minimum (baseline) PPE will be established for such handlers. The PPE for these handlers can be set on the toxicity of the end-use product.

b. PPE/ Engineering Controls for Homeowner-Use Products

The MOEs for products intended primarily for homeowner use were calculated as being acceptable for mixing, loading, and applying without assuming any specific clothing or equipment being worn. Therefore, no minimum (baseline) clothing or equipment requirements are being established. However, directions specifying ventilation during application are being required for homeowner products for use as a sewer treatment. This is based on dichlobenil's moderate vapor pressure.

c. Post-Application/Entry Restrictions

(1) 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 REI 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 dichlobenil as an active ingredient, the Agency is setting a restricted-entry interval at 24 hours for all horticultural/nursery uses of the product that is within the scope of the Worker Protection Standard (WPS). In addition, due to dermal and inhalation concerns, as well as the uncertainties of whether the use-scenarios should be considered to be short-term or intermediate-term for uses on dichondra and sites where ornamental stock will be placed in liners, the Agency is also establishing a requirement for thorough incorporation into the soil (or other treated surface) through watering-in. The Agency notes that the WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. The Agency believes that these existing WPS restrictions are sufficient to mitigate post-application exposures of workers who contact surfaces treated with dichlobenil.

The REI remains 12 hours for all other use sites under WPS.

The WPS interim REI in effect until now was 12 hours (based on early data that indicated that dichlobenil was classified as category III for acute dermal toxicity.) 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 interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.
2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

There are no data to evaluate the post-application risk to this chemical. However, the Agency is taking steps to reduce post-application inhalation exposures by establishing a 24-hour restricted entry interval and requiring thorough incorporation through watering-in after application to horticultural and nursery uses. In conjunction with these protective measures, the Agency is establishing PPE for dermal protection based on the acute toxicity of the active ingredient. Dichlobenil is classified as toxicity category III for acute dermal toxicity and toxicity category IV for skin irritation potential. Since dichlobenil is classified as category IV for eye irritation potential, protective eyewear is not required.

(2) Occupational-Use Products (NonWPS Uses)

The Agency is establishing entry restrictions for some nonWPS occupational uses of dichlobenil end-use products. Due to concerns about inhalation exposures from sewer treatments, the Agency is establishing a requirement for all uses in connection with inhabited buildings (residences, offices, hospitals, etc.) specifying that windows must be open or an exhaust fan must be operating during the application. For specific language, refer to Section V of this document.

(3) Homeowner-Use Products

Due to concerns about possible dermal and inhalation exposures from soil contact soon after application, the Agency is recommending thorough incorporation through watering-in for all soil uses (around established ornamental trees and shrubs, and outdoor non-crop areas such as buildings, fences, and other structures) on products primarily intended for homeowner use. Entry would be restricted until the soil is dry following the watering-in.

8. Ground-Water Advisory

As explained above dichlobenil and its principal metabolite BAM have the potential to leach into groundwater. Therefore, a groundwater advisory is required for all dichlobenil products.

9. Application Rate Reduction

Because of risk concerns for birds, fish, aquatic invertebrates, mollusks, and non-target plants at the 20 lb. ai/A application rate, the Agency is requiring that the maximum application rate for dichlobenil not exceed 10 lb. ai/A. Sites with maximum application rates at 20 lb. ai/A include drainage systems, rights-of-way, fencerow, hedgerow, cemeteries, and on industrial, recreational, and uncultivated areas. The application rates at these use sites must be **reduced** to a maximum application rate \leq 10 lb. ai/A.

10. 10G Soil Incorporation Requirements

Because of a potential risk to birds from unincorporated applications of the 10G formulation, soil incorporation or watering-in is required for all use sites on the 10G labels other than pre-paving. Exposure to birds to the 10G formulation applied at pre-paving sites is expected to be limited provided the applicator follows the manufacturer's recommendation to cover the treated area as soon as possible with asphalt.

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 dichlobenil for the above eligible uses has been reviewed and determined to be substantially complete. However, the following additional data are outstanding and are now required.

a. Requirements for Handler (Mixer/Loader/Applicator) Exposure Studies

A dermal exposure study (Guideline 231) and an inhalation exposure study (Guideline 232) are required for the following mixer, loader, and applicator scenarios:

- use of backpack applications of granular formulations for landscape treatment.
- all application of dichlobenil to sewer pipes except formulations applied by flushing down toilet bowl.

These studies should be conducted concurrently, i.e., dermal and inhalation samples should be collected from the same handler and at the same site during each trial.

b. Requirements for Post-Application Studies

Post-application exposure studies for applications to ornamentals are required at this time. Guidelines 132-1(a) Foliar residue dissipation, 132-1 (b) Soil residue dissipation, 133-3 Dermal passive dosimetry exposure, 133-4 Inhalation passive dosimetry exposure are required for dichlobenil.

Guideline 132-1b is required for both dichlobenil and BAM. These studies should be conducted concurrently, i.e., dermal and inhalation samples should be collected from the same worker and at the same site during each trial.

c. Requirements for BAM Chemistry and Environmental Fate Studies

Guidelines 63-8 Solubility and 63-9 Vapor pressure are required for BAM. If it is determined that the Henry's constant for BAM is less than 10^{-5} , then the following environmental fate data are also required for BAM: 161-2 photodegradation in water, 162-1 Aerobic soil metabolism, 162-4 Aerobic aquatic metabolism, and 163-1 Adsorption/desorption.

d. Requirements for Drinking-Water Monitoring Studies

The drinking water monitoring study should have samples from existing drinking water wells. The samples should be from drinking water wells in dichlobenil use areas and taken as close as possible to treated fields. Sampling should analyze for both the parent and the degradate BAM. When possible, sampling should include, but not limited to, wells near cranberry fields, nurseries, turf sites, and several non-agricultural uses such as rights-of way, hedge/fence row treatment and home owner use, however not sewers and "under asphalt." All studies must use protocols that have been reviewed and approved by OPP. The drinking water study results will be used to determining if any additional ground water mitigation measures or prospective groundwater studies are needed.

e. Requirements for Prospective Groundwater Monitoring Studies

At this time the groundwater monitoring studies are only required to support hybrid cottonwood-poplar plantation use sites. One or more small-scale prospective ground water studies need to be conducted to support hybrid cottonwood poplar production sites in areas outside the eastern desert areas of Oregon and Washington. Alternatively, registrants may modify the label to geographically limit the use of dichlobenil on hybrid cottonwood-poplar plantations to the desert areas in Oregon and Washington defined as 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon.

f. Requirements for Forestry Dissipation

The forestry dissipation study is required to support the use of dichlobenil in hybrid cottonwood-poplar pulpwood production areas outside a defined area of the eastern Oregon-Washington desert which is 15 miles from the Columbia river in the counties of Walla Walla, Franklin and Benton in Washington and Umatilla and Morrow in Oregon. Alternatively, registrants may modify the label to geographically limit the use of dichlobenil on hybrid cottonwood-poplar plantations to the desert areas in Oregon and Washington defined above.

g. Requirements for Avian Reproduction Studies

Avian reproduction studies (Guideline 71-4) preferably with bobwhite quail and mallard duck are required on the technical grade of dichlobenil.

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 a Herbicide for the following use(s)_____ [fill blank only with those uses that are being supported by MP registrant.]"

References to "fruit crops" and "nut crops" as sites should be removed from the label if this has not already been done, since these general sites are unsupported.

A 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 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 support of such use(s)."

B. End-Use Products

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

When end-use product DCIs are developed (e.g., at issuance of the RED), all end-use product labels should be amended such that they are consistent with the basic producer labels.

a. Ground-Water Advisory

The label must state the following:

"This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow may result in ground-water contamination."

b. Application Rate Reduction

Use rates at sites with maximum application rates at 20 lb. ai/A, including drainage systems, rights-of-way, fencerow, hedgerow, cemeteries, in industrial areas, recreational areas, and uncultivated areas must be **reduced** so the maximum application rates listed on the label are ≤ 10 lbs ai/A.

c. 10G Soil Incorporation Requirements

The labels for the 10G formulation must impose for all uses other than pre-paving sites that the user thoroughly incorporate the granules into the soil. The 10G may also be subject to incorporation requirements indicated below.

d. Occupational Labeling

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.

(1) PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain dichlobenil 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.

Multiple-active-ingredient end-use products that contain dichlobenil must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

(a) PPE Requirements for Products Intended Primarily for Occupational Use

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 below. 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.

Minimum (baseline) PPE requirements -- Some of the registered uses of dichlobenil 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.

Wettable Powder Formulations

Asphalt Use: The minimum (baseline) PPE for all occupational uses of dichlobenil end-use products formulated as wettable powders for the asphalt use is:

"Applicators and other handlers (other than mixers and loaders) must wear:
--Long-sleeved shirt and long pants
--Shoes plus socks"

Mixers and loaders must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves,
- Chemical-resistant apron.

Sewer Use: The minimum (baseline) PPE for **applicator and other handlers (other than mixers and loaders)** occupational uses of dichlobenil end-use products formulated as wettable powders and labeled for use in sewer sites is:

"Applicators and other handlers (other than mixers and loaders) must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks, and
- Chemical-resistant gloves"

Mixers and loaders must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves,
- Chemical-resistant apron.

Granular Formulations

The minimum (baseline) PPE for all occupational uses of dichlobenil end-use products formulated as granulars is:

"Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves when mixing or loading."

Respirator Type

If the acute inhalation toxicity of the **end-use product** is in category I or II, a respirator is required for pesticide handlers. The following type of respirator is appropriate to mitigate dichlobenil inhalation concerns:

"A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)"

**(b) PPE Requirements for Products Intended
Primarily for Homeowner Use**

There are no minimum (baseline) PPE being established for homeowner uses of dichlobenil end-use products formulated as granulars.

**(2) Post-Application/Entry Restrictions for Products Intended
Primarily for Occupational Use**

WPS uses

Restricted-entry interval -- a 24-hour restricted entry interval (REI) is required for horticultural/nursery 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). The REI for all other uses within the scope of WPS is 12 hours.

Exception: If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances allows workers to enter the treated area if there will be no contact with anything that has been treated.

Early-entry personal protective equipment (PPE) --

The PPE required for early entry following applications is:

- Coveralls,
- Chemical-resistant gloves, and
- 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.

NonWPS uses

Entry restrictions --

There are no nonWPS entry restrictions for outdoor uses on shelterbelt plantings, rights-of-way, fence rows, hedge rows, pre-paving treatment, uncultivated areas, buildings and structures, industrial and recreational areas, and sewage and drainage systems.

For uses on ornamental woody shrubs and vines, ornamental/shade trees, and residential and commercial landscaping:

"Do not enter or allow workers to enter the treated area until granules are thoroughly watered in and the treated soil has dried."

(3) Post-Application/Entry Restrictions for Products Intended Primarily for Home Use

"Do not enter or allow persons or pets to enter the treated area until granules are thoroughly watered in and the treated soil has dried."

(4) Other Labeling Requirements for Products Intended Primarily for Occupational Use

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

Application Restrictions:

For Granular Formulations:

"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."

For Granular Formulations With Use Directions on Ground (Soil or Gravel) in Liners in Which Ornamental Stock Will Be Placed: (associate the following statement with the directions for this use)

"Thoroughly incorporate the granules into the soil (or other target surface) through watering-in. Once the application has been correctly incorporated through watering-in and the treated surface is dry, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface."

For Wettable Powder Formulations with Directions for Sewer Treatments:

"When used in inhabited buildings (residences, offices, hospitals, etc.), windows must be open or an exhaust fan must be operating during the application."

Engineering Controls:

For wettable powder formulations:

"When handlers use closed systems (including water soluble bags) or enclosed cabs 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."

For granular formulations that may be applied from enclosed cabs or aircraft:

"When handlers use 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 there are no such instructions for washable PPE, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

- "Users should wash 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."

(5) Other Labeling Requirements for Products Intended Primarily for Home Use

Application restrictions

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

Immediately following application, thoroughly water-in the granules.

User safety recommendations

- "Users should wash 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."

C. Tolerance Revocation and Import Tolerances

"The citrus, figs, mangoes, nuts (other than filberts), and stone fruits (other than cherries) uses of dichlobenil were voluntarily cancelled during EPA's preparation of the reregistration eligibility decision regarding this pesticide. It is the Agency's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or **following** the cancellation of a related food-use registration. As a result, any parties interested in supporting the tolerance/regulation for import purposes in the absence of a registered U.S. use should notify EPA as soon as possible.

In responding, the Agency will provide detailed information on the outstanding data requirements for these tolerances and/or regulations. **The Agency** will consider commitments made to generate data to support such tolerances/regulations and the timeliness of data submissions in its assessment of whether the tolerances/regulations should be retained. Persons interested in establishing a new tolerance for import purposes only, or retaining a current tolerance for import purposes following cancellation of the related use, must submit a petition along with the appropriate fees and supporting data."

D. 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 on a case-by-case basis, 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 dichlobenil 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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Dichlobenil covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Dichlobenil 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) 605-6000.

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 Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
61-1	Chemical Identity	ALL 42452401, 43140101, CSF 7/18/96
61-2A	Start. Mat. & Mnfg. Process	ALL 42452401, 43140101
61-2B	Formation of Impurities	ALL 42452401, 43140101
62-1	Preliminary Analysis	ALL 42452402, 43498601
62-2	Certification of limits	ALL 42452401, CSF 7/18/96
62-3	Analytical Method	ALL 42452402
63-2	Color	ALL 42452403
63-3	Physical State	ALL 42452403
63-4	Odor	ALL 42452403
63-5	Melting Point	ALL 42452403
63-6	Boiling Point	N/A
63-7	Density	ALL 42452403
63-8	Solubility	ALL 40600605
63-9	Vapor Pressure	ALL 40600607
63-10	Dissociation Constant	ALL No MRID
63-11	Octanol/Water Partition	ALL 40600608
63-12	pH	ALL 42452403
63-13	Stability	ALL 42452403, 42452404, 43140102, 43916001 DATA GAP (Waiver Pending)

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)
63-14	Oxidizing/Reducing Action	ALL 43753901
63-16	Explodability	ALL 43753902
63-17	Storage stability	ALL 43140103
63-20	Corrosion characteristics	ALL DATA GAP
<u>ECOLOGICAL EFFECTS</u>		
71-1A	Acute Avian Oral - Quail/Duck	A B D G H 00160000, 40600601, 43469801
71-2A	Avian Dietary - Quail	A B D G H 00022923, 40600603
71-2B	Avian Dietary - Duck	A B D G H 00022923, 40600602
71-4A	Avian Reproduction - Quail	A B G H DATA GAP
71-4B	Avian Reproduction - Duck	A B G H DATA GAP
72-1A	Fish Toxicity Bluegill	A B D G H 40098001
72-1C	Fish Toxicity Rainbow Trout	A B D G H 40098001, 43846901
72-2A	Invertebrate Toxicity	A B D G H 05001497, 40775001
72-2B	Invertebrate Toxicity - TEP	A B D G H 40094602
72-3A	Estuarine/Marine Toxicity - Fish	C D 40228401, 43905403
72-3B	Estuarine/Marine Toxicity - Mollusk	C D 40228401, 43905404
72-3C	Estuarine/Marine Toxicity - Shrimp	C D 40228401, 43905405
72-4A	Early Life Stage Fish	C D 00156312, 40825101, 42224202
72-4B	Life Cycle Invertebrate	C D 00156312, 40775002, 42224201
72-7A	Simulated Field - Aquatic Organisms	D N/A 0013752 (supplemental)

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)
122-1A	Seed Germination/Seedling Emergence	B D G WAIVED
122-1B	Vegetative Vigor	B D G WAIVED
122-2	Aquatic Plant Growth	B D G WAIVED
123-1A	Seed Germination/Seedling Emergence	B D G 41280801, ADDENDUM WAIVED
123-1B	Vegetative Vigor	B D G 41280801
123-2	Aquatic Plant Growth	B D G 00156312, 40228401, 40758201, 40758202, 40758203, 40758204, 40758205
141-1	Honey Bee Acute Contact	00018842
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Rat	ALL 00112500
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL 43250401
81-3	Acute Inhalation Toxicity - Rat	ALL 43335703
81-4	Primary Eye Irritation - Rabbit	ALL 40425403
81-5	Primary Dermal Irritation - Rabbit	ALL 40425402
81-6	Dermal Sensitization - Guinea Pig	ALL 40548501
82-1A	90-Day Feeding - Rodent	A E 00107106
82-1B	90-Day Feeding - Hamster	A E 40600701
82-2	21-Day Dermal - Rabbit/Rat	ALL 43879301
83-1A	Chronic Feeding Toxicity - Rodent	A E 00147438, 40823801

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)
83-1B	Chronic Feeding Toxicity - Non-Rodent	A E 00067649, <u>43969701</u>
83-2A	Oncogenicity - Rat	A E 00147438, 40823801, 40401101
83-2B	Oncogenicity - Hamster	A E 41988301, 42015101, 42221201, 42563601
83-3A	Developmental Toxicity - Rat	A E 00147437
83-3B	Developmental Toxicity - Rabbit	A E 41257302
83-4	2-Generation Reproduction - Rat	A E 41257303, 42239101
84-2A	Gene Mutation (Ames Test)	ALL 00153579, 00153576, 00153586
84-2B	Structural Chromosomal Aberration	ALL 0015377, 41319101
84-4	Other Genotoxic Effects	ALL 00153580, 00153581
85-1	General Metabolism	A E 41227401, 41227402, 41227403, 41227404, 41299401
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>		
132-1A	Foliar Residue Dissipation	A B D G DATA GAP
132-1B	Soil Residue Dissipation	A B D G DATA GAP
133-3	Dermal Passive Dosimetry Exposure	A B D G DATA GAP
133-4	Inhalation Passive Dosimetry Exposure	A B D G DATA GAP
231	Estimation of Dermal Exposure at Outdoor Sites	A B D DATA GAP
232	Estimation of Inhalation Exposure at Outdoor Sites	A B D DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)	
<u>ENVIRONMENTAL FATE</u>			
161-1	Hydrolysis	ALL	40548502
161-2	Photodegradation - Water	A B D G	41709801
161-3	Photodegradation - Soil	A	41119001, 43006801
162-1	Aerobic Soil Metabolism	A B E G H	41340601, 43006803
162-3	Anaerobic Aquatic Metabolism	D G	41306001
162-4	Aerobic Aquatic Metabolism	D	41149501
163-1	Leaching/Adsorption/Desorption	ALL	00049725, 00151561, 40600604, 41709802, 43006800, 43611101
163-2	Volatility - Lab	A	43754001
163-3	Volatility - Field		Waived
164-1	Terrestrial Field Dissipation	A B H	41149502, 41170801, 41280802, 41385601, 43006800
164-2	Aquatic Field Dissipation	D	41780601, 41877301, 42191401
164-3	Forest Field Dissipation	G	DATA GAP
165-4	Bioaccumulation in Fish	A B D	40465801, 40465802
165-5	Bioaccumulation - Aquatic NonTarget	D G	41877301, 41780601
166-1	Ground Water - Small Prospective	G	DATA GAP
167-1	Drinking Water Monitoring	A B D G H	DATA GAP
201-1	Droplet Size Spectrum		Waived
202-1	Drift Field Evaluation		Waived

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)	
<u>RESIDUE CHEMISTRY</u>			
171-4A	Nature of Residue - Plants	A	00113758, 00137791, 41531601, 41631501
171-4B	Nature of Residue - Livestock	A	00067651, 00111219, 00113741, 41012201, 41012202, 41301101, 43361201, 43361202, 43361203, 43361204
171-4C	Residue Analytical Method - Plants	A	00109109, 00113739, 00113757, 00113759, 42026308, 42384801, 42729301, 42739601
171-4D	Residue Analytical Method - Animal	A	00042489, 00042490, 00042491, 00067652
171-4E	Storage Stability	A	42026301, 42026302, 42026303, 42026304, 42026305, 42026306, 42026307, 42177101, 42177102, 42304201, 42432601, 42432602, 42452801, 42452802, 42452803, 42452804, 42476101, 42476102, 42476103, 42679001, 43184201
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	A	DATA GAP
171-4K	Crop Field Trials		
	<u>Pome Fruits Group -</u>		
	- Apples	A	00109109, 00113790, 42177102, 42452802
	- Pears	A	00109109
	<u>Stone Fruits Group</u>		
	- Cherries	A	00113773, DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Dichlobenil

REQUIREMENT	USE PATTERN	CITATION(S)
<u>Small Fruits and Berries Group</u>		
- Blackberries	A	00113768, 42026301, 42452803
- Blueberries	A	00109109, 42026302, 42304201
- Cranberries	A	00109109, 00113778, 00113782, 00113790, 00113799, 42026303, 42452801
- Grapes	A	00113768, 00113790, 42177101, 42476103
- Raspberries	A	00113768, 42026307
<u>Tree Nuts Group</u>		
- Filberts	A	00113739, 42026304, 42476101
171-4L Processed Food		
- Apples	A	42432601, 43184201
- Grapes	A	42432602

APPENDIX B

Data Supporting Guideline Requirements for 2,6 Dichlorobenzamide (BAM)

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
63-8	Solubility	A B D G H
63-9	Vapor Pressure	A B D G H
<u>ECOLOGICAL EFFECTS</u>		
72-1A	Fish Toxicity Bluegill	A B D G H
72-1C	Fish Toxicity Rainbow Trout	A B D G H
72-2A	Invertebrate Toxicity	A B D G H
72-4A	Early Life Stage Fish	00156312 (supplemental)
123-2	Aquatic Plant Growth	B D G
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Mouse	ALL
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL
82-1A	90-Day Feeding - Rodent	A E
83-1A	Chronic Feeding Toxicity - Rodent	A E
		00147438, 40401101, 40823801, 42940202, 43747100, 44052901, 44043601
		DATA GAP
83-1B	Chronic Feeding Toxicity - Non-Rodent	A E
		00066983, 42940203, 43747100
		DATA GAP

Data Supporting Guideline Requirements for 2,6 Dichlorobenzamide (BAM)

REQUIREMENT	USE PATTERN	CITATION(S)
83-2A Oncogenicity - Rat	A E	00147438, 40401101, 40823801, 42940202, 43747100, 44052901, 44043601 DATA GAP
83-3B Developmental Toxicity - Rabbit	A E	43003601, 43265201
83-4 3-Generation Reproduction - Rat	A E	(42940204-not acceptable, but there is no data gap)
84-2A Gene Mutation (Ames Test)	A E	43003603
84-4 Other Genotoxic Effects	A E	43003602, 43003604, 43747101
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>		
132-1B Soil Residue Dissipation	A B D G	DATA GAP
<u>ENVIRONMENTAL FATE</u>		
161-2 Photodegradation - Water	A B D G	DATA GAP
162-1 Aerobic Soil Metabolism	A B E G H	DATA GAP
162-4 Aerobic Aquatic Metabolism	D	DATA GAP
163-1 Leaching/Adsorption /Desorption	ALL	DATA GAP
167-1 Drinking Water Monitoring	A B D G H	DATA GAP
<u>RESIDUE CHEMISTRY</u>		
171-4A Nature of Residue - Plants	A	00113758, 00137791, 41531601, 41631501
171-4B Nature of Residue - Livestock	A	00067651, 00111219, 00113741, 41012201, 41012202, 41301101, 43361201, 43361202, 43361203, 43361204

Data Supporting Guideline Requirements for 2,6 Dichlorobenzamide (BAM)

REQUIREMENT	USE PATTERN	CITATION(S)
171-4C Residue Analytical Method - Plants	A	00109109, 00113739, 00113757, 00113759, 42026308, 42384801, 42729301, 42739601
171-4D Residue Analytical Method - Animal	A	00042489, 00042490, 00042491, 00067652
171-4E Storage Stability	A	42026301, 42026302, 42026303, 42026304, 42026305, 42026306, 42026307, 42177101, 42177102, 42304201, 42432601, 42432602, 42452801, 42452802, 42452803, 42452804, 42476101, 42476102, 42476103, 42679001, 43184201
171-4J Magnitude of Residues - Meat/Milk/Poultry/Egg	A	DATA GAP
171-4K Crop Field Trials		
<u>Pome Fruits Group -</u>		
- Apples	A	00109109, 00113790, 42177102, 42452802
- Pears	A	00109109
<u>Stone Fruits Group</u>		
- Cherries	A	00113773, DATA GAP
<u>Small Fruits and Berries Group</u>		
- Blackberries	A	00113768, 42026301, 42452803
- Blueberries	A	00109109, 42026302, 42304201
- Cranberries	A	00109109, 00113778, 00113782, 00113790, 00113799, 42026303, 42452801

Data Supporting Guideline Requirements for 2,6 Dichlorobenzamide (BAM)

REQUIREMENT	USE PATTERN	CITATION(S)
- Grapes	A	00113768, 00113790, 42177101, 42476103
- Raspberries	A	00113768, 42026307
<u>Tree Nuts Group</u>		
- Filberts	A	00113739, 42026304, 42476101
171-4L Processed Food		
- Apples	A	42432601, 43184201
- Grapes	A	42432602

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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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 6; 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 six 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 - 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 ingredient(s).

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 Registrant'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. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant'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 guidelines 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 did 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 6. 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 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 submission of 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 documents 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 a 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 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 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.1., 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:

- a. 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.
 - b. Fulfill the commitment to develop and submit the data as required by this Notice; or
 - c. 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

DICHLORBENIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Dichlobenil. 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) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Dichlobenil Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Dichlobenil are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Dichlobenil 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 Dichlobenil 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 Dana Lateulere at (703) 308-8044.

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

Dana Lateulere
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: Dichlobenil

Dichlobenil DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Dichlobenil. 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 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Dichlobenil Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Dichlobenil are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Dichlobenil are needed. These data are needed to fully complete the reregistration of all eligible Dichlobenil 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 Dana Lateulere at (703) 308-308-8044.

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

Dana Lateulere, Chemical Review Manager
RB3
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Dichlobenil

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 2137, 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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

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.

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

- 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 2137, 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 "REQUIREMENTS STATUS AND REGISTRANT'S 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 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 Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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 Ingredient or Pure 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 product. For these

EPA'S BATCHING OF DICHLOBENIL PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

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 dichlobenil as an active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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. It is the registrant's option to participate in the process with all other registrants, only some of the other registrants, or 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. 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.

Thirty-three products were found which contain dichlobenil as an active ingredient. These products have been placed into five batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Acute data are not needed for products in batches 1, 2, 3, 4 and 5. These data requirements are satisfied by acute data performed with the technical. For the products in batches 1, 2 and 3, the appropriate acute dermal and inhalation categories will be extrapolated from the category II technical classification. Furthermore, the five sewer root control products (which contain dichlobenil and metam sodium) in the "no batch" category do not need to submit acute data. The appropriate precautionary labeling and hazard classifications have recently been defined by the Agency for these products.

Products 802-571, 11364-5 and 68464-1 are the only products which require a DCI. A complete acute six pack is needed for each of these products to support reregistration. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% active ingredient	Formulation Type
1	400-168	4.0	Solid
	400-170	2.0	Solid
	802-536	2.0	Solid
	802-570	1.0	Solid
	2217-675	4.0	Solid
	2217-678	2.0	Solid
	2217-682	4.0	Solid
	7401-395	2.0	Solid
	10583-16	4.0	Solid
	34704-720	2.0	Solid
	34704-738	4.0	Solid
	68153-1	0.5	Solid
	CA89004600	4.0	Solid
	OR95000300	4.0	Solid
	WA95000600	4.0	Solid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
2	400-178	10.0	Solid
	2217-679	10.0	Solid
3	400-169	50.0	Solid
	2217-676	50.0	Solid
4	400-176	85.0	Solid
	400-463	85.0	Solid
	2217-677	85.0	Solid
5	400-175	98.0	Solid
	400-462	99.0	Solid
	2217-680	99.5	Solid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately or through the accepted bridging scheme presented above.

Table 2 (No Batch)

EPA Reg. No.	% active ingredient	Formulation Type
802-571	1.5	Solid
9993-2	Dichlobenil 1.74 Metam sodium 28.4	Combination
9993-3	Dichlobenil 1.96 Metam sodium 24.3	Combination
11364-5	Dichlobenil 0.5 Sodium hydroxide 56.0	Solid
64503-2	Dichlobenil 50.0 Metam sodium 32.7	Combination
68464-1	0.55	Solid

EPA Reg. No.	% active ingredient	Formulation Type
64898-4	Dichlobenil 50.0 Metam sodium 32.7	Combination
64945-3	Dichlobenil 85.0 Metam sodium 32.7	Combination

List of All Registrants Sent This Data Call-In (Insert) Notice
(PLEASE REMOVE THIS PAGE AND INSERT MAILING LIST)

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.
- l. 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 all 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.



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 _____
b. % by Weight _____

14. Certified Limits % by Weight
a. Upper Limit _____
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



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
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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
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Name and Title (Please Type or Print)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date		EPA Reg No./File Symbol			Page of
Applicant's/Registrant's Name & Address		Product			
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Signature			Name and Title		Date

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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	Date	Typed or Printed Name and Title
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APPENDIX E - LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents for Dichlobenil that may 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 obtained from our website at www.epa.gov/REDs, or contact Dana Lateulere at (703)-308-8044.

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 Dichlobenil.

The following documents are part of the Administrative Record for Dichlobenil and may be 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