United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA738-R-97-011 January 1998

Reregistration Eligibility Decision (RED)

TERBACIL

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 terbacil, which includes the active ingredient (3-tert-butyl-5-chloro-6-methyl uracil). The enclosed Reregistration Eligibility Decision (RED) 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 receipt 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 the 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 also 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 rule-making 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 Karen Jones (703) 308-8047. Address any questions on required generic data to the Special Review and Reregistration Division representative Emily Mitchell (703) 308-8583.

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 703-487-4650).

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

TERBACIL

LIST A

CASE 0039

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

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TERBACIL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Neil Anderson	Herbicide/Insecticide Branch
Jihad Alsadek	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

James Hetrick	Environmental Risk Branch I
David Wells	Environmental Risk Branch II
Michael Davy	Environmental Risk Branch II
Mah Shamim	Environmental Risk Branch IV

Health Effects Risk Assessment

Jack Arthur	Risk Characterization and Analysis Branch
Melba Morrow	Registration Action Branch 1
David Miller	Chemistry and Exposure Branch 2
Brian Steinwand	Chemistry and Exposure Branch 1

Registration Support Risk Assessment

Wesley Allen	Fungicide-Herbicide Branch
Debbie McCall	Registration Support Branch
Vickie Walters	Fungicide-Herbicide Branch

Risk Management

Emily Mitchell	Reregistration Branch I
Joseph Bailey	Reregistration Branch I

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
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 © 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

ABSTRACT

This Reregistration Eligibility Decision Document (RED) addresses the reregistration eligibility of the pesticide terbacil, which includes the active ingredient 3-tert-butyl-5-chloro-6-methyluracil. Products containing terbacil are registered for use as herbicides.

Terbacil was registered for use as a herbicide in the United States in 1966. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Terbacil is a selective herbicide, formulated as a wettable powder, and is applied by aircraft or ground equipment on terrestrial food/feed crops (e.g., apples, mint/peppermint/spearmint, sugarcane, and ornamentals), forestry (e.g., cottonwood (forest/shelterbelt), terrestrial food (e.g., asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry and strawberry), and terrestrial feed (e.g., alfalfa, sainfoin (hay and fodder), and forage). Products containing terbacil are not currently registered for residential use.

The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration.

Short and intermediate term toxicity endpoints sufficient to be of occupational concern were not identified for terbacil. The oral and dermal LD_{50} and dermal irritation studies all resulted in Category IV toxicity classifications. Inhalation and eye irritation studies gave results to meet Category III requirements, and no dermal sensitization was found. Because of these findings, risk assessments were not necessary for occupational exposure scenarios, and therefore, are not factored into aggregate risk calculations.

Developmental toxicity was selected as the endpoint of concern for acute dietary risk (NOEL of 12.5 mg/kg/day, based on the decrease in the number of live fetuses seen at the next highest dose level in a rat study). All dietary food and drinking water sources of terbacil were analyzed relative to this NOEL, for females of child-bearing age (i.e., 13+ years-old). Based on these analyses, acute dietary exposure is not a concern for terbacil. Animal tests showed no evidence of carcinogenicity for terbacil (i.e., classified as E).

To assess the potential risks to infants and children under the new Food Quality Protection Act (FQPA), the Agency evaluated two developmental studies and one reproduction study. Because the developmental NOELs were the same as those for maternal toxicity, and the NOEL for systemic toxicity was higher than the NOEL for reproductive toxicity in these studies, the data do not suggest an increased pre- or post-natal sensitivity of children and infants exposure to terbacil. The standard 100-fold uncertainty factor is considered by the Agency to be sufficiently protective of infants and children, and an additional safety factor is not warranted.

The reference dose (RfD) for terbacil is 0.013 mg/kg/day, based on increased liver weights and serum alkaline phosphatase in dogs at the next highest dose level, and an uncertainty factor of 100.

Chronic dietary risks from food sources (expressed as %RfD) were calculated by the DRES model which used tolerance values for food crops before and after adjustments had been made (e.g., recommendations are made to revoke tolerances for citrus fruits and pears, and raise tolerances on caneberries, blueberries, peaches, apples and sugarcane). None of the scenarios for chronic dietary risk from food sources resulted in values that concern the Agency.

Chronic dietary risks from drinking water were analyzed for surface water using the results from a Tier Two model (PRZM), which gives values for each crop separately. Because of conservative model parameters, it is expected to over-estimate terbacil concentrations in drinking water. None of the scenarios exceeded 100% of the RfD. None of the aggregate risk numbers exceeded the RfD.

Terbacil is a persistent and potentially mobile herbicide in terrestrial environments. These environmental fate properties suggest terbacil can potentially move into both ground and surface waters. Tier II surface modeling suggest terbacil may potentially accumulate in surface water at concentrations from 28 to 1470 µg/L. Further analysis of Tier II peak Estimated Environmental Concentration (EECs) indicate the first year EEC and annual incremental concentration (slope) were 105 and 36 µg/L for Louisiana sugarcane; 24 and 4.3 µg/L for New York apples; 34 and 0.00 µg/L for Georgia peaches; and 5.2 and 0.52 µg/L for Washington apples. The peak ground water concentration, based on the Ground Water Interactive Concentration (GWIC) screening model, is not expected to exceed 125 µg/L. Since reliable ground and surface water monitoring data are not available, estimated environmental concentrations of terbacil are based solely on ground and surface water models.

All environmental fate data are fulfilled at this time. However, additional information on the aerobic aquatic metabolism (Guideline 162-4) of terbacil is needed because terbacil is likely to move into surface waters. These data will provide a more realistic assessment of terbacil concentrations in surface waters.

All ecological toxicity data are fulfilled except for chronic avian and aquatic toxicity studies (Guideline 71-4 Avian Reproduction Study; Guideline 72-4 Fish Early Life Stage and Aquatic Invertebrate Life Cycle). These data are needed because terbacil is a persistent compound which may pose long-term exposure in terrestrial and aquatic environments. Wild mammal toxicity study (Guideline 71-3) is reserved pending the result of avian reproduction studies (Guideline 71-4).

Minimal adverse acute effects are expected for avian, mammalian, and aquatic species from labeled terbacil uses. Chronic effects for avian and aquatic species cannot be evaluated because of insufficient data. However, chronic RQs for mammals indicate adverse effects are possible from terbacil labeled uses. The rat reproductive study shows the NOEL to be higher than

the greatest concentration tested. This concentration is below the maximum and mean predicted residue values (Kenaga/Fletcher) on mammalian food items. Since the rat reproductive endpoint is greater than the highest concentration tested, EPA used that concentration level as a default toxic reproductive endpoint. This assumption is more conservative and protective because toxic endpoints are expected to be higher than the default NOEL level. Based on the Agency's assessment, no evidence of carcinogenicity was detected. The Agency's mammal chronic feeding toxicity studies indicate there may be increased liver and thyroid weights for rats. Since terbacil is a persistent and mobile herbicide, non-target terrestrial plants are expected to be adversely effected from runoff and spray drift. Minimal adverse effects, however, are expected for non-target aquatic plants. The fact that terbacil is used exclusively on minor crops, terbacil exposure is expected to be very localized and dependent on site specific conditions. The localized nature of terbacil use is expected to limit human and ecological exposure.

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

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. As a result, 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. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency will therefore 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 terbacil including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes terbacil, 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 terbacil . Section V discusses the reregistration requirements for terbacil . 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:** Terbacil
- **Chemical Name:** 3-tert-butyl-5-chloro-6-methyl uracil
- **Other Chemical Nomenclature:** 5-chloro-3-(1,1-dimethylethyl)-6-methyl-2,4(1H,3H)-pyrimidinedione
- **CAS Registry Number:** 5902-51-2
- **OPP Chemical Code:** 012701
- **Empirical Formula:** $C_9H_{13}ClN_2O_2$
- **Trade and Other Names:** Sinbar®, DuPont Herbicide 732, and Geonter
- **Basic Manufacturer:** E.I. DuPont de Nemours Company, Inc.

1. Use Profile

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

For **Terbacil**:

Type of Pesticide: Herbicide

Use Sites: Terrestrial Food and Feed Crop:
apples, mint/peppermint/spearmint, sugarcane, and ornamentals

Forestry:
cottonwood (forest/shelterbelt)

Terrestrial Food:
asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry, and strawberry

Terrestrial Feed:
alfalfa and sainfoin (hay and fodder), and forage

Target Pests: A broad spectrum of broadleaf weeds and grasses

Formulation Types Registered:

Wettable Powder 80% &
Wettable Powder 40%

Method and Rates of Application:

Equipment - Boom Sprayer & Aircraft

Method and Rate - Tractor-mounted spray boom application to soil surface and small emerged weeds and aerial application-See APPENDIX A for detailed breakdown

Timing - Application times vary with crops.

Use Practice Limitations: Do not apply through any type of irrigation system. Do not graze treated crop or allow hay, seeds or seed screenings from treated crop to be used for food or feed. Do not graze or feed forage or hay from treated areas to livestock.

2. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of terbacil. 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. Table 1 below summarizes the pesticides use by site.

Table 1: Various U.S. Crops Treated Annually with Terbacil

		Acres Treated (000)		% of Crop Treated		LB a.i. Applied (000)		Application Rates		States of Most Usage
Site	0.00	Likely Average	Likely Max	Likely Average	Likely Max	Likely Average	Likely Max	LB a.i./ acre/yr	# appl /year	
AG SITES										
Alfalfa	24,338	50	70	0.00	0.00	20	35	0.4	1	NE, OK, OR, WA
Apples	457	40	50	9	11	40	50	1.0	1	WA, NY, PA
Asparagus	86	1	3	1	4	1	2	1.0	1	MI
Berries*	115	25	45	22	39	5	20	0.2	1	WI, OR, MI, ME
Mint	140	100	110	71	79	95	115	1.0	1	OR, WA, ID
Peaches	176	60	100	34	57	10	25	0.2	1	GA, SC
Sugarcane	936	125	175	13	19	50	200	0.4	1	LA
Ag Subtotal		401	533			221	447			
NON-AG SITES										
Fallow	-	2	5			7	10	3.5	-	-
Forest Trees	2,500	1	2	0.00	0.00	1	2	1.0	-	-
Ornamental	200	1	2	1	1	1	2	1.0	-	-
Non-Ag Subtotal		4	9			9	14			
Grand total		405	562			230	461			

NOTES:
Calculations of the above numbers may not appear to agree because they are displayed as rounded.
0 = < 500 acres treated or lb. a.i. because of rounding to the nearest 1,000.
0% = < 0.5% because of rounding to the nearest whole percentage point.
NO OBS = No Observations. This site is covered by EPA sources, but little or no usage is observed, or may be included with all other pesticides. For this sites a likely maximum percent treated is included, above which the actual usage is unlikely.
- = insufficient data to determine an amount for this field.
Usage data primarily covers 1990 - 1995 for most sites and as early as 1987 for some sites.
Likely averages are based on weighted averages of data with most recent years and more reliable data weighted more heavily.
Likely maximums are an amount above which the actual usage is unlikely to exceed.
Application rates are calculated from likely averages or are based on typical rather than maximum rates.
* Other/Crop Groups
Berries includes all berries.
SOURCES: EPA data, USDA, and National Center for Food and Agricultural Policy

(1) Data Requirements

Data requested in the 1989 Registration Standard for terbacil include studies on product chemistry, toxicological effects, ecological effects, and environmental fate. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

3. Regulatory History

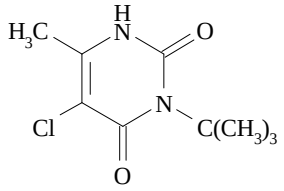
Terbacil was registered for use as a herbicide in the United States in 1966. A Registration Standard was issued for terbacil in May 1982. Additional data was required in the areas of product chemistry, toxicology, environmental fate and ecological effects. In August 1989 a Registration Standard (Second Round Review) was issued for terbacil. This document reviewed data submitted in response to the 1982 Registration Standard, updated the Agency's assessment of the terbacil data base, and included a tolerance reassessment. The Second Round Review required additional data in the area of toxicology, environmental fate, ecological effects, and residue chemistry. This Registration Eligibility Document reflects an assessment of all data submitted in response to the Second Round Review.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

Terbacil [3-*tert*-butyl-5-chloro-6-methyluracil] is a selective herbicide used for the control of many annual and some perennial weeds in crops.



Empirical Formula:	$C_9H_{13}ClN_2O_2$
Molecular Weight:	216.7
CAS Registry No.:	5902-51-2
OPP Chemical Code:	012701

a. Identification of the Active Ingredient

Terbacil is a white crystalline solid with a melting point of 175-177° C. Terbacil is soluble in water (710 ppm) at 25° C, and is moderately soluble in organic solvents including dimethylformamide (33.7 g/100 g), cyclohexanone (22 g/100 g), and xylene (6.5 g/100 g).

(1) Manufacturing-use Products

According to a search of the Agency's Reference Files conducted 9/9/96, there are no terbacil manufacturing-use products (MUPs) registered under the OPP Chemical Code 012701; however, the E.I. du Pont de Nemours and Company, Inc. 80% wettable powder (WP; EPA Reg. No. 352-317) is manufactured from

an unregistered TGAI (95%a.i.). Only the du Pont TGAI is subject to this reregistration eligibility decision.

(2) Regulatory Background

The Terbacil Guidance Document dated 5/82 required additional generic product chemistry data for terbacil; however, the Terbacil Reregistration Standard Second Round Review (SRR) dated 3/8/89, required that all new product chemistry data be submitted, and reviewed data submitted in response the Guidance Document. The Terbacil SRR required additional data concerning GLNs 61-2, 61-3, 62-1, 63-7, 63-9, 63-11, 63-12, and 63-13 (OPPTS 830.1620, 830.1670, 830.1700, 830.7300, 830.7950, and 830.7550-7570, 830.7000, and 830.6313) for the du Pont TGAI. No new data were submitted/reviewed under the Terbacil Reregistration Standard Update dated 10/8/91.

(3) Conclusions for Product Chemistry

All pertinent data requirements are satisfied for the du Pont TGAI except for a new data requirement concerning UV/visible absorption for the TGAI (OPPTS GLN 830.7050). The registrant should submit the data required for the terbacil TGAI, or either certify that the suppliers of beginning materials and the manufacturing process for the TGAI have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Hazard Assessment

The toxicology data base for terbacil is adequate and will support the reregistration eligibility of this chemical.

a. Acute Toxicity

Terbacil 80% wettable powder (WP) has been tested in acute oral toxicity studies with rats (Acc. Nos. 114693 and 24955) and has an acute oral LD_{50} of > 5,000 mg/kg/day (Toxicity Category IV). In an acute dermal toxicity study in rabbits, the LD_{50} was > 5,000 mg/kg/day (Toxicity Category IV), with no toxic signs noted (Acc. Nos. 114693 and 24955). Technical terbacil (97.8%) was tested in an acute inhalation study in rats (MRID 00125700), which indicated that the LC_{50} was > 4.4 mg/L (Toxicity Category III). Technical terbacil (96.1%) was tested in rabbits' eyes and produced only mild conjunctival effects, which cleared within 72 hours (Toxicity Category III). Although a primary dermal irritation study

is not available on technical terbacil, the Agency had indicated to the Registrant that if no dermal irritation was observed in a 21-day subchronic dermal study, then the requirements for the primary dermal irritation study would be satisfied (Tox. Doc. 003401). No dermal irritation was reported in that study (MRID 00125785). Terbacil is not a dermal sensitizing agent in guinea pigs (Acc. Nos. 157180). Table 2 below summarizes the values and toxicity categories for the various acute toxicity routes.

Table 2: Acute Toxicity Data for Terbacil

Test	%AI	Result	Category
Oral LD_{50}	80.0	> 5000 mg/kg/day	IV
Inhalation LC_{50}	97.8	> 4.4 mg/L	III
Dermal LD_{50}	80.0	> 5000 mg/kg/day	IV
Eye Irritation	96.1	Mild conjunctival irritant up to 72 hours	III
Dermal Irritation	80.0	Not a skin irritant	IV[a]
Dermal Sensitization	96.1	Not a dermal sensitizer	

[a] Based on a 21-day dermal toxicity study in rabbits.

b. Subchronic Toxicity

Subchronic oral toxicity was tested in a 90-day feeding study in rats (MRIDs 00039009 and 00068035). A NOEL of 100 ppm (equivalent to 5 mg/kg/day) and LOEL of 500 ppm, equivalent to 25 mg/kg/day (HDT) were established, based on increased absolute and relative liver weights, vacuolization and hypertrophy of hepatocytes. The data requirement for subchronic oral toxicity in a nonrodent was satisfied by a 2-year feeding study in beagle dogs (MRID 00060851), in which a NOEL of 50 ppm (equivalent to 1.25 mg/kg/day) and LOEL of 250 ppm (equivalent to 7.2 mg/kg/day) were established, based on increased thyroid to body weight ratios, slight increase in liver weights, and elevated alkaline phosphatase levels.

Subchronic dermal toxicity was tested in a 21-day study in rabbits (MRID 125785). Terbacil (80% a.i.) was applied to prepared skin of male and female rabbits at 5,000 mg/kg/day, 5 hours/day, 5 days/week. No systemic toxicity was observed; mild scaling and staining were reported at the test sites.

c. Chronic toxicity

Terbacil 80% a.i. was administered to beagle dogs (4/sex/group) in the diet for 2 years, at doses of 50, 250, or 2,500/10,000 ppm, equivalent

to 1.25, 6.25, 62.5/250 mg/kg/day (MRID 00060851). The NOEL was 50 ppm (1.25 mg/kg/day), and the LOEL was 250 ppm (equivalent to 6.25 mg/kg/day), based on increased thyroid to body weight ratios, slight increase in liver weights, and elevated alkaline phosphatase levels. Relative liver weights were also increased at 2,500 and 10,000 ppm in dogs sacrificed at 1 year and 2 years.

A 2-year rat study (MRID 42987601) was supplied to the Agency in response to the Registration Standard Data Call-In notice. In this study, terbacil 97.4% a.i. was administered to male and female Sprague-Dawley Crl:CD BR rats at dietary levels of 0, 25, 1500, or 7500 ppm (approximate doses for males of 0, 0.9, 58, and 308 mg/kg/day and for females of 0, 1.4, 83, and 484 mg/kg/day). Ten animals/sex/dose were sacrificed by study design at 12 months. Excessive mortality was observed in the control and low dose groups, and the study was terminated at 23 months. No clinical signs relating to dosing were reported. Body weight was significantly reduced in males receiving 7500 ppm and in females receiving 1500 and 7500 ppm throughout most of the study. At 51 weeks, body weight gain in males receiving 7500 ppm was 13% lower than controls and in females receiving 1500 ppm and 7500 ppm gains were 18% and 39% lower than in controls. No toxicologically significant changes in hematology parameters were observed.

Serum cholesterol was significantly increased in high dose females at all reporting periods. A marginal increase was observed in mid-dose females. A slight increase was observed in 7500 ppm males at 18 and 24 months but only the increase at 18 months was significant compared to controls.

At 1500 ppm, a significant increase in the mean liver to body weight ratio was observed in females at 12 months (16%) and at study termination (21%). At termination, the liver weight increase was accompanied by a marginally increased incidence of centrilobular hepatocyte hypertrophy (minimal) and a 20% decrease in mean body weight. At 7500 ppm, significant increases in liver to body weight ratios were seen in both sexes at 12 and 23 months and mean liver weight in males was 20% increased compared to controls at study termination.

Centrilobular hypertrophy as well as fatty changes were seen in both sexes at the high dose and an increase in biliary hyperplasia was observed in high dose females. Eosinophilic foci of cellular alteration in the liver were increased in incidence in dosed groups of male and females with a significant trend. However, this is of equivocal importance because it was not accompanied by hypertrophic or hyperplastic changes or hepatocellular

tumors. The systemic NOEL is 25 ppm (0.9 mg/kg/day for males and 1.4 mg/kg/day for females) and the LOEL is 1500 ppm (56 mg/kg/day for males and 83 mg/kg/day for females) based on the liver effects and decreased body weight gain in females. The study was conducted at adequate dosages as demonstrated by the decrement in body weight gain in both sexes. There was no evidence of increased tumor incidence in the treated animals when compared to the controls.

d. Carcinogenicity

Terbacil has been tested in a chronic 2-year feeding/oncogenicity study in mice (MRID 00126770) at doses of 0, 50, 1250, or 5000/7500 ppm (equivalent to 7, 179, 714/1071 mg/kg/day) The increase in dose occurred after week 54. A systemic NOEL of 50 ppm is based on the LOEL of 1250 ppm which resulted in mild hypertrophy of the centrilobular hepatocytes, and decreased pituitary weights in males. Pituitary weight was also decreased in high-dose females. There was an increased incidence of lung neoplasms (adenomas and adenocarcinomas) in all treated male mice, which was not dose-related; in addition, these tumors were within the range of similar tumors observed in historical control mice. Additional information (MRID 42031601), provided by the registrant demonstrated that, under the conditions of this study, administration of terbacil did not significantly increase the incidence of any proliferative hepatocellular carcinoma, single/multiple adenomas, or foci of cellular alteration, or combined hepatocellular adenomas and carcinomas, in either sex. Guideline requirements for 83-2 are satisfied by this information.

Terbacil was also tested in the rat (MRID 42987601, described under chronic feeding toxicity studies, above). Under the study conditions, terbacil did not induce any increase in tumor incidence in the treated animals.

e. Developmental Toxicity

Terbacil has been tested in rats and rabbits for its potential to produce developmental toxicity. Rats (MRID 00039001) were fed 0, 250, 1,250 or 5,000 ppm (equivalent to 0, 12.5, 62.5 or 250 mg/kg/day) of terbacil in the diet from days 6 through 15 of gestation. The study was graded core-Supplementary, because of concerns raised about an increased number of pre-implantation losses and increased hydronephrosis in fetuses from the treated dams. These concerns were subsequently addressed by the registrant to the satisfaction of the Agency. The developmental NOEL was 250 ppm (12.5 mg/kg/day); the developmental LOEL of 1250 ppm (62.5 mg/kg/day) was based upon significantly decreased number of live fetuses

per litter, apparently due to fetal loss occurring before or near the time of implantation. The maternal NOEL was 250 ppm (12.5 mg/kg/day), based on decreased body weight at 1,250 ppm (62.5 mg/kg/day).

Rabbits were given doses of terbacil of 0, 30, 200, or 600 mg/kg/day by gavage, on gestation days 7 through 19 (MRID 00150945). The maternal NOEL was 200 mg/kg/day, based on maternal deaths (5 died and 2 were sacrificed in extremis) at the LOEL of 600 mg/kg/day. The developmental NOEL was also 200 mg/kg/day based on decreased live fetal weights in the high dose group (i.e., 600 mg/kg/day).

f. Reproductive Toxicity

Terbacil was tested in male and female rats at control (i.e., 0 ppm) and dietary levels of 50 or 250 ppm (equivalent to 2.5 or 12.5 mg/kg/day), over three generations (MRID 00060852). The first litter of each generation was discarded, and the second litter bred to produce the next generation. The study was reviewed for the 1982 Registration Standard, and graded core-Supplementary, based on testing only 2 dose levels and the use of antibiotics on the test animals during the study. In addition, necropsy records were not available for the first litters, and the breeding records were incomplete. After addressing these concerns (Acc. No. 249455), the study was upgraded to core-Minimum (Tox. Doc. 003401), with a systemic NOEL of equal to or less than 50 ppm (2.5 mg/kg/day), based on the reduction of body weight gain in male offspring at the 250 ppm dietary level. Because the weight gain appeared at late periods in the study, and not in the early development of the offspring, this effect is not considered to be reproductive effect. No reproductive effects were seen at the highest dose tested, therefore, the NOEL for reproductive toxicity was equal to, or greater than 250 ppm (12.5 mg/kg/day).

g. Mutagenicity

Terbacil technical (96.1%) was tested and found negative for clastogenicity in a chromosomal aberration study in rat bone marrow cells, at doses up to 500 mg/kg (MRID 00157181). It was also negative in a CHO (HGPRT) gene mutation assay (Acc. No. 260460) when tested up to cytotoxic levels, with and without S-9 activation (cytotoxicity > 3.0 mM without activation; > 2.75 mM with activation). Terbacil technical was also negative for unscheduled DNA synthesis when tested up to cytotoxic levels (5 mM) in the rat.

h. Metabolism

Radiolabeled terbacil was tested in rats (MRID 40104702) in single doses of 6.5 or 500 mg/kg; 97 to 103% of radioactivity was recovered within 5 days: 70-86% in urine, and 28% in feces. The major metabolites were glucuronide, sulfate, and N-acetylcysteine conjugates. The primary metabolic pathway is hydroxylation of the 6-methyl group to form the alcohol, which is conjugated to form the glucuronide (35% of the dose) and the sulfate derivatives (11%). Terbacil is also metabolized to the 5-hydroxy intermediate, which is further conjugated to form a sulfate derivative (17%).

2. Toxicological Endpoint of Concern Used in Risk Assessment

a. Reference Dose

The reference dose (RfD) for systemic toxicity was determined for terbacil as 0.013 mg/kg/day, by the Agency's RfD Committee in May, 1986. This was verified by the Agency's Review Committee in June, 1986. The RfD was calculated from a two-year feeding study in dogs (MRID 00060851) in which the NOEL was 1.25 mg/kg/day (based on increased relative liver weights and increased serum alkaline phosphatase, seen at 7.25 mg/kg/day), and an uncertainty factor of 100. The RfD of 0.013 mg/kg/day was reaffirmed by the Agency's RfD Committee on September 1, 1994.

b. Carcinogenicity Classification

Terbacil was classified in Group E (no evidence of carcinogenicity in animal studies) with respect to its carcinogenicity potential.

c. Other Toxicological Endpoints

Based upon a review of the TES Committee, the database for terbacil, a toxicology endpoint and the dose level of concern have been identified. Findings of the TES Committee are discussed and summarized in the Table 3 below.

Table 3: Summary of Toxicological Endpoints for Terbacil

Exposure Duration	Exposure Route	Endpoint and Toxicological Effect
Acute	Ingestion	Developmental NOEL (12.5 mg/kg/day): based on a decrease in number of live fetuses seen at 62.5 mg/kg/day in a rat developmental study.
Short-Term (1-7 days) Occupational/Residential	Dermal	None identified.
Intermediate-Term (one week to several months) Occupational/Residential	Dermal	None identified.
All time periods	Inhalation	None identified.
Chronic	Ingestion	RfD (0.013 mg/kg/day) based on increased thyroid: body weight ratio, slight increase in liver weight and elevated alkaline phosphatase seen at 7.2 mg/kg/day in a 2-year dog study.

(1) Acute Dietary

To estimate acute dietary risk, the endpoint selected was developmental toxicity. Female Sprague Dawley rats were administered terbacil at dietary doses of 250, 1250, or 5000 ppm (12.5, 62.5 or 250 mg/kg) on gestation day 6 through 15 (MRID No. 00039001). The developmental NOEL was 250 ppm (12.5 mg/kg/day); the developmental LOEL of 1250 ppm (62.5 mg/kg/day) was based upon significantly decreased number of live fetuses per litter, apparently due to fetal loss occurring before or near the time of implantation. The maternal NOEL was 250 ppm (12.5 mg/kg/day), based on decreased body weight at 1250 ppm (62.5 mg/kg/day). A risk assessment for acute dietary exposure is required.

It was noted that, although the compound was administered for a period that exceeded one day, the study was selected for the determination of acute dietary risk because it is uncertain whether the observed developmental toxicity resulted from exposure on the first day of dosing or resulted from cumulative exposure during the 10 day period that corresponded to organogenesis.

(2) Dermal Absorption

Dermal absorption data were not available for terbacil. It was assumed by the TES Committee that there would be 100% absorption.

(3) Short and Intermediate Term Occupational

The results of a 3-week dermal study conducted with rabbits demonstrated that at doses as high as 5000 mg/kg/day, there were no toxic signs or histopathological lesions that could be associated with the administration of the test material. Furthermore, in a 90-day feeding study with rats (doses tested: 100, 500 and 5000 ppm) there appeared to be low toxicity associated with the administration of the compound based on the observation of adaptive hepatic alterations of increased liver weight and hepatic vacuolation and hypertrophy at 500 ppm (25 mg/kg/day).

Because of these results, the TES Document stated that risk assessments for both short and intermediate term occupational or residential exposure are not required.

(4) Chronic Occupational (Non-Cancer)

The TES Document (12/01/94) identified no chronic toxicity endpoints to assess chronic occupational exposure and risk. A 2-year chronic feeding study in dogs was used for establishment of the RfD (0.013 mg/kg/day) to evaluate dietary exposures and risk. The lowest exposure level at which effects were seen in this study was 6.25 mg/kg/day. Because the chronic dose level at which effects were seen is relatively high, coupled with the fact that the 2-year duration of the study is longer than normally required for chronic toxicity studies (usually require only one year of dosing).

3. Exposure Assessment

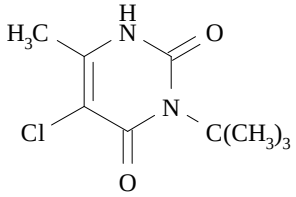
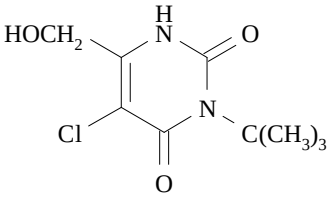
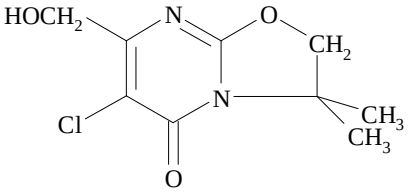
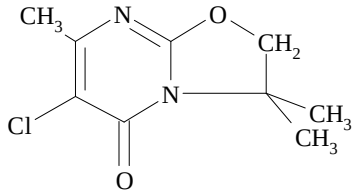
a. Dietary Exposure (Food Sources)

Tolerances for residues of terbacil in/on apples, citrus, peaches, pears, and sugarcane are currently expressed in terms of terbacil *per se* [40 CFR §180.209(a)]. Tolerances for residues of terbacil on other plant and animal commodities are expressed as the combined residues of terbacil and its metabolites, 3-*tert*-butyl-5-chloro-6-hydroxymethyluracil (Metabolite A), 6-chloro-2,3-dihydro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one (Metabolite B), 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one (Metabolite C), each calculated as terbacil [40 CFR §180.209(b)]. Tolerances range from 0.1 ppm for animal commodities, berries, and pecans to 5 ppm on forage and hay of alfalfa and sainfoin. No food/feed additive tolerances have been established for

residues of terbacil. Adequate methods are available for the enforcement of established tolerances, as currently defined.

The residues to be regulated in plants and animals are terbacil and its three currently regulated metabolites. The chemical names and structures of the terbacil residues of concern are depicted in Table 4.

Table 4: Terbacil and its Metabolites

Common Name/Chemical Name	Chemical Structure
Terbacil 3-*tert*-butyl-5-chloro-6-methyluracil	
Metabolite A IN-G2449 3-*tert*-butyl-5-chloro-6-hydroxymethyluracil	
Metabolite B IN-W2207 6-chloro-2,3-dihydro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one	
Metabolite C IN-T2170 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one	

(1) Directions for Use

A search of the Agency's Reference Files on 9/27/96 indicates that there is one terbacil end-use product (EPA Reg. No. 352-317, label dated 3/5/96) with food/feed uses registered to E. I. du Pont de Nemours & Company Inc. This product is formulated

as a 80% WP and is marketed under the trade name Sinbar®. The following special local need (SLN) labels for use on alfalfa are associated with this product: SLN Nos. OK920009, OR920003, PA900003, VA900004, and WA930007. These SLNs should be canceled and the use directions incorporated into the federal label. Three additional SLN labels are registered for use on grasses grown for seed (SLN Nos. ID800009, OR800021, and WA800010). These labels prohibit the grazing of treated fields and the feeding of seed or crop residues from treated areas to livestock. Given the use in only three states in the Pacific Northwest and the limited number of varieties on which use is permitted, the Agency believes that this restriction is appropriate in this instance.

Under the "General Information" section of the label (EPA Reg. No. 352-317), pecans are listed as a crop to which Sinbar® can be applied; however, no use directions for pecans are included on the label. The reference to pecans should be deleted from the label. In addition, a 150-day preharvest interval (PHI) should be specified for sugarcane and a 60-day PHI should be specified for apples. The label instructions for asparagus should be clarified to indicate a maximum *seasonal* rate of 3 lbs a.i./A.

(2) Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on alfalfa, blueberry, and sugarcane metabolism studies. The residues to be regulated in plants are terbacil and its metabolites A, B, and C.

(3) Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The residues of concern in animals are terbacil and its metabolites A, B, and C. However, the Agency has determined that based on CFR part 180.6(a)(3), there is no likelihood of finite residues. Therefore, tolerances in these commodities are not necessary (see "Magnitude of the Residue in Meat, Milk, Poultry, and Eggs").

(4) Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing terbacil tolerances. Method I in the

Pesticide Analytical Manual (PAM), Vol. II, is a GLC/microcoulometric detector (MCD) method that determines terbacil *per se* and has undergone a successful EPA method validation on oranges and peaches. As metabolites A, B, and C are not determined by Method I, this method is no longer adequate for tolerance enforcement.

Method II in PAM, Vol. II determines terbacil and its three regulated metabolites in plants and has undergone a successful EPA method validation on alfalfa. Residues are extracted into chloroform, further purified, and then silylated for GC analysis. Silylated residues are quantified by GC using a halogen-sensitive microcoulometric detector. The reported limits of detection for each analyte are 0.1 ppm in mint oil and hay and 0.04 ppm in other plant commodities. A confirmatory GC/MSD method is also listed in PAM Vol. II as Method A.

Data from analysis of terbacil residues in/on plants have been collected using PAM Methods I and II, and more recently using an adequate GC/nitrogen-phosphorus detector (NPD) method, which is a modification of Method II in PAM. For this GC/NPD method, residues of terbacil and its metabolites are extracted into chloroform:water and cleaned-up by liquid-liquid partitioning prior to derivatization with bis(trimethylsilyl)trifluoroacetamide and trimethylchlorosilane (BSTFA + 1% TMCS). Silylated residues are then further purified using sodium sulfate and Florisil columns and then quantified by GC/NPD. The reported limit of detection is 0.05 ppm for each analyte.

As Method I in PAM is no longer an acceptable enforcement method and Method II utilizes an obsolete microcoulometric detector, the Agency will require the registrant to submit the GC/NPD method for a Tolerance Method Validation prior to inclusion in PAM as an enforcement method. As the method is an improved method, we will not require that DuPont conduct any independent method validation.

(5) Multi-residue Method Testing

Data have been submitted pertaining to the analytical behavior of terbacil and its regulated metabolites through FDA Multiresidue Protocols and have been forwarded to FDA for inclusion in PAM Vol. I. The registrant has submitted the results of FDA Multiresidue Protocol C to the Agency (Protocols A, B,

and E are not applicable) which demonstrates that terbacil and its metabolites are completely recovered. Results from Protocol D were not submitted, and the registrant is required to use this method to test an appropriate commodity and submit the results for terbacil and its regulated metabolites for inclusion in PAM.

(6) Storage Stability Data

Requirements for storage stability data are satisfied for purposes of reregistration. Adequate storage stability data have been submitted for terbacil residues in RACs commodities of alfalfa, apples, blueberry, mint, milk, and sugarcane. These data indicate that terbacil and metabolites A, B, and C are stable in alfalfa at -20 C for up to 24 months, in frozen (< 0 C) apples, blueberries, and sugarcane for up to 6 months, in frozen (< 0 C) mint for up to 18 months, and in frozen milk for up to 1 month. Storage stability data on blueberries can be translated to caneberries, peaches, and strawberries. The Agency has also concluded that terbacil residues are stable in frozen asparagus and grass (forage, fodder, and hay) for up to 18 months based upon storage stability data translated from alfalfa and mint.

(7) Magnitude of the Residue in Crop Plants

For purposes of reregistration, requirements for magnitude of the residue in plants are fulfilled for the following crops: alfalfa, apples, asparagus, blueberries, caneberries, grass (grown for seed), mint, peaches, and sugarcane. Adequate field trial data depicting terbacil residues following applications made according to the maximum or proposed use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials were conducted.

(8) Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple and mint. Based on these studies, tolerances are not required on apple and mint processed commodities.

Data are required depicting the potential for concentration of terbacil and its metabolites in blackstrap molasses processed from sugarcane bearing detectable terbacil residues.

As the use on citrus fruits has been deleted from the label, the requirement for a citrus processing study is no longer applicable.

(9) Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The requirement for a poultry feeding study has been waived because the Agency has determined there is no likelihood of finite residues based upon the results of the poultry metabolism study which used a 65x feeding level.

Currently alfalfa forage and hay are the only livestock feed items having a registered use and established tolerances (the SLN uses on grass grown for seed prohibit the grazing or feeding of treated forage or hay to livestock--see "Directions for Use" section). The Agency concludes that terbacil residues in ruminant commodities show no likelihood of finite residues. The requirement for a ruminant feeding study is waived and the established animal tolerances should be revoked.

(10) Magnitude of the Residue in Water, Fish, and Irrigated Crops

Presently, terbacil is not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

(11) Magnitude of the Residue in Food-Handling Establishments

Terbacil is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

(12) Confined Accumulation in Rotational Crops

Data were required depicting the nature of terbacil residues in confined rotational crops. As a result of the aerobic soil metabolism study reviewed, the Agency considers this guideline fulfilled.

(13) Field Accumulation in Rotational Crops

Since the limited rotational field trials indicated that residues of concern can potentially be present in rotated crops planted at the

labeled 2-year plant-back interval at levels > 0.01 ppm, then extensive field rotational crop studies could be required. The Agency will instead require that these additional limited rotational studies be performed with crops to which rotations are likely (corn, and soybean). If residues of concern appear in these rotated crops, then establishment of rotational crop tolerances will be required.

b. Dietary Exposure (Drinking Water Sources)

(1) Groundwater

(a) Acute Exposure

Using the Ground Water Interactive Concentration (GWIC) screening model, the concentration of terbacil in shallow groundwater is not expected to exceed 125 µg/L for most uses. There are a number of uncertainties with this model, including that the predicted ground water concentrations are linearly extrapolated from the application rate, with no consideration of hydrology, soil properties, climatic conditions, agronomic practices, or volatilization. For this reason, the estimated GWIC value from this model can be used as an upper bound for the acute ground water exposure assessment calculations.

If the maximum estimated GWIC level (125 µg/L or 0.125 mg/L) is assumed, acute exposure from the ingestion of terbacil-contaminated ground water can be calculated for the most sensitive sub-population (60 kg female, age 13+ years) as follows:

For a 60 kilogram female, consuming 2 Liters per day

Exposure = (0.125 mg/L x 2 L/day) ÷ 60 kg = 0.004 mg/kg/day

(b) Chronic Exposure

The EPA Pesticides in Ground Water Database (EPA 734-12-92-001, September 1992) reports only 6 detects of terbacil (ranging from 0.3 to 8.9 µg/L) out of 288 wells tested in six states (i.e., California, Louisiana, Mississippi, Oregon, Washington, and West Virginia). One reason for low frequency of detections of terbacil in some of the

available ground water surveys is high minimum detection limits. In most of the state surveys, terbacil minimum detection limits have been 5 to 100 times higher (i.e., less sensitive) than detection limits that have been achieved in recent surveys for most widely used herbicides. Another reason why terbacil should not be detected frequently in general ground water surveys is because only a small percentage of the overall agricultural acreage in the United States is treated with terbacil in a given year.

While limited ground water data exist, they do give some indication of the potential presence of terbacil in drinking water sources, and are therefore used as representative of actual ground water concentrations in the chronic exposure calculations below.

If the maximum detected level (8.9 µg/L or 0.0089 mg/L) is assumed, chronic exposure from the ingestion of terbacil-contaminated ground water can be calculated for the general U.S. population and for children, as follows:

For the U.S population:

Exposure (mg/kg/day) = (0.0089 mg/L x 2 L/day) / 70 kg = 0.00025 mg/kg/day

For a 10-kilogram child, consuming 1 Liter per day

Exposure (mg/kg/day) = (0.0089 mg/L x 1 L/day)/ 10 kg = 0.00089 mg/kg/day

(2) Surface Water

Two environmental concentration models were used to estimate exposure to terbacil via ingestion of surface water: a tier one model named, GENEEC (GENeric Expected Environmental Concentration), and a tier two model named, PRZM 2.3. Risk calculations for surface water appear later in this section.

(a) Acute Exposure

GENEEC estimates expected concentrations from a few basic chemical parameters and pesticide label application information. GENEEC 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. GENEEC 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. GENEEC was designed for use in ecological risk-assessment and, therefore, it could substantially over-estimate the actual drinking water concentrations. Because of its conservative values, output from this model is used in the acute exposure calculations below.

The GENEEC model gives the peak Estimated Environmental Concentrations (EEC) of terbacil in surface water as 0.154 ppm (0.154 mg/L). Using this value, acute exposure from ingestion of terbacil-contaminated surface water can be calculated for the most sensitive subpopulation (females, 13+ years) as follows:

Exposure = (0.154 mg/L x 2 L/day) / (60 kg) = 0.005 mg/kg/day

(b) Chronic Exposure

PRZM 2.3, linked with a program named, EXAMS, models pesticide concentrations in surface water associated with usage on a given crop, in a given geographical location. Soil and hydrologic input parameters are used, and dissipation is projected on a yearly basis, over the period 1948 through 1983. Volatilization, soil binding and photodegradation predictions are used to calculate dissipation rates. Risk calculations for chronic exposure to terbacil-contaminated surface drinking water that appear later in this chapter, are based on the output from the PRZM/EXAMS model because it represents a more refined upper bound estimate of concentrations of terbacil in surface water than GENEEC.

PRZM/EXAMS, like GENEEC, also may overestimate concentrations of pesticides in drinking water. This model uses input parameters and assumptions that represent worst case scenarios. For example, PRZM/EXAMS models a static pond system, where

dissipation from outflow and aerobic aquatic metabolism are not factored in, nor is any other active degradation process other than photodegradation. Because of the static nature of the model, yearly concentration estimates increase with each successive year due to accumulation. The Agency determined the average annual incremental increases in predicted surface water terbacil concentrations due to this accumulation factor, for the major crop uses, e.g., Louisiana sugarcane (36 µg/L) and New York apples (4 µg/L).

For the purpose of calculating chronic exposure to terbacil-contaminated surface drinking water, the Agency has chosen to use a value from analysis of the 36-year period of terbacil use on sugarcane because this end-use resulted in the highest predicted concentrations. The last year of the model's 36-year analysis of sugarcane reflects the accumulation of terbacil at an average incremental increase of 36 µg/L/year. The Agency believes that a more reasonable and representative value to use is the value for the first year of the analysis. This value is conservative because of all the previously mentioned conservative input parameters, and because it comes from the highest end-use values. However, it does not incorporate the 36 µg/L annual accumulation factor which is unlikely to be seen in an open system. (It should be noted that STORET data also suggest that terbacil is not accumulating in surface water.)

The PRZM/EXAMS model gives the maximum EEC for the first year of the 36-year sugarcane analysis as 105 µg/L (105 ppb). Using this value, chronic exposure from ingesting terbacil-contaminated surface drinking water can be calculated as follows:

For the U.S population:

Exposure (mg/kg/day) = (0.105 mg/L x 2 L/day) / 70 kg = 0.003 mg/kg/day

For a 10-kilogram child, consuming 1 Liter per day

Exposure(mg/kg/day) = (0.105 mg/L x 1 L/day) / 10 kg = 0.0105 mg/kg/day

4. Dietary Risk Assessment

a. Toxicologic Endpoints

The Reference Dose (RfD) used in the analysis is 0.013 mg/kg bwt/day, based on a NOEL of 1.25 mg/kg bwt/day (and an uncertainty factor of 100) from a two-year feeding study in dogs that demonstrated increased relative liver weights, increased thyroid : body weight ratio and elevated alkaline phosphatase as endpoints.

Terbacil is classified as a Group E carcinogen.

The endpoint for acute dietary risk assessment is a developmental toxicity NOEL of 12.5 mg/kg bwt/day from a dietary study in rats, based upon a significantly decreased number of live fetuses per litter at the LOEL of 62.5 mg/kg bwt/day.

b. Residue Information

Tolerances for residues of terbacil are expressed in terms of terbacil *per se* in/on apples, pears and sugarcane and published in 40 CFR §180.209(a). For other plant and animal commodities, tolerances are currently expressed as the combined residues of terbacil and its metabolites A, B, and C in 40 CFR §180.209(b). No food/feed additive tolerances have been established for residues of terbacil.

c. Chronic Exposure/Risk (TMRC)

A DRES chronic exposure analysis was performed using tolerance level residues and a 100 percent crop treated assumption to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. No anticipated residue (AR) information was used in this analysis.

Existing tolerances result in a TMRC which represents 12.2% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (< 1 year old) occupies 62.3% of the RfD.

Incorporating the recommendations of the Agency (i.e., to revoke tolerances for citrus fruits and pears, and to raise tolerances on caneberries, blueberries, peaches, apples and sugarcane), results in a TMRC which represents 4.5% of the RfD for the U.S. general population. For the highest subgroup, Non-Nursing Infants (< 1 year old), 24.6% of the RfD is occupied.

The analysis for terbacil is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with terbacil. For both existing published tolerances and incorporating the changes recommended by the Agency, it appears that chronic dietary risk from the uses supported in reregistration, is not of concern.

d. Acute Exposure/Dietary Risk

Two acute analyses were performed showing results from all presently registered commodities and results following the recommendations of the Agency.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern. Because the endpoint of concern was a developmental effect, the only sub-population of concern is females of child bearing age (i.e., females, 13+ years old). The NOEL used in the calculation is from an animal study. In determining the high end exposure values below, the formula includes the relative dose value (RDV), which is a code chosen to cause the DRES model to create an appropriate spreadsheet of estimated values.

Presently registered commodities result in a MOE for Females (13+ years) of 3125

High End Exposure = RDV x X
= 0.001 x 4
= 0.004

MOE = NOEL ÷ Exposure
MOE = 12.5 mg/kg/day ÷ 0.004 mg/kg/day **= 3125**

Following the recommendations of the Agency results in a MOE of terbacil for Females (13+ years) of 4166

High End Exposure = RDV x X
= 0.001 x 3
= 0.003

MOE = NOEL ÷ Exposure

MOE = 12.5 mg/kg/day ÷ 0.003 mg/kg/day **= 4166**

The MOE values demonstrate that there is no cause for concern regarding the acute dietary exposure from terbacil for existing uses.

e. Drinking Water Risk (Ground Water)

(1) Acute Risk

The highest concentration of terbacil in shallow groundwater predicted by the Ground Water Interactive Concentration (GWIC) screening model (0.125 mg/kg/day), results in an acute exposure of 0.004 mg/kg/day. Using this value, acute risk from ingestion of terbacil-contaminated ground water, expressed as the Margin of Exposure (MOE), can be calculated for the most sensitive sub-population as follows:

For a female (13+ years), weighing 60 kg, and ingesting 2 liters per day:

MOE = (NOEL)/(Exposure)
MOE = (12.5 mg/kg/day) / (0.004 mg/kg/day) = 3100

(2) Chronic Risk

Chronic exposure levels had previously been derived by using the maximum detected terbacil level (0.0089 mg/L) in EPA's Ground Water Database. Using these values, chronic risk from the ingestion of terbacil-contaminated ground water can be calculated for the general U.S. population and for children, as follows:

For the U.S. population:

% RfD = (Exposure ÷ RfD) (100)
% RfD = (0.00025 ÷ 0.013) (100) = 2 %

For a 10-kg child:

%RfD = (Exposure ÷ RfD) x 100
%RfD = (0.00089 mg/kg/day ÷ 0.013 mg/kg/day) x 100 = 7 %

f. Drinking Water Risk (Surface Water - Acute)

The estimate of acute exposure derived from the GENEEC model's peak EEC of terbacil in surface water is 0.005 mg/kg/day. Using this

value, acute risk from ingestion of terbacil-contaminated surface water, expressed as the Margin of Exposure (MOE), can be calculated for the most sensitive sub-population as follows:

For a female (13+ years), weighing 60 kg, and ingesting 2 liters per day:

MOE = (NOEL)/(Exposure)
MOE = (12.5 mg/kg/day) / (0.005 mg/kg/day) = 2500

g. Drinking Water Risk (Surface Water - Chronic)

A chronic surface drinking water exposure value for terbacil was derived from the first year annual maximum EEC from the PRZM/EXAMS model for terbacil use on sugarcane. Using this estimated value, the upper bound chronic risk from ingesting terbacil-contaminated surface water (expressed as %RfD) is calculated as follows:

For the U.S. population:

% RfD = (Exposure ÷ RfD) (100)
% RfD = (0.003 ÷ 0.013) (100) = 23 %

For a 10-kg child:

%RfD = (Exposure ÷ RfD) x 100
%RfD = (0.0105 mg/kg/day ÷ 0.013 mg/kg/day) x 100 = 81 %

In summary, the Agency usually has no concerns when less than 100% of the RfD has been used. Even using upper bound estimates, none of drinking water scenarios analyzed above exceeds 100% of the RfD. Because of this, and the fact that actual ground water monitoring data, although limited, are not showing large amounts of terbacil present, the Agency does not believe that drinking water sources of terbacil are of concern.

5. Occupational Exposure and Risk Assessment

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. The Toxicity Endpoint Selection Committee found that neither dermal nor inhalation toxicity criteria were triggered

for terbacil. Therefore, no assessments are needed for occupational exposure/risk at this time.

a. Summary of Use Patterns and Formulations

Terbacil, 3-tert-butyl-5-chloro-6-methyluracil, is a herbicide formulated as a wettable powder (20 percent a.i.). Terbacil is used on terrestrial food/feed crops (apples, mint/peppermint/spearmint, and sugarcane), terrestrial food (asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry, and strawberry), terrestrial feed (alfalfa, forage, and hay) and on forest trees (cottonwood). Terbacil can be applied by aircraft and ground equipment (band treatment, broadcast, direct sprays). The maximum application rates range from 0.264 to 3.2 LB a.i./acre, with the lower rates generally used on coarse textured soils and higher rates on fine textured soils.

b. Occupational-use products and homeowner-use products

At this time products containing terbacil are intended primarily for occupational uses and are not registered for residential use, thus eliminating concern for homeowner exposure.

c. Additional Occupational Exposure Studies

Data on worker exposures to terbacil have not been submitted to the Agency. However, worker exposure studies are not required at this time since there are no toxicological endpoints of occupational concern identified for terbacil.

6. Food Quality Protection Act Considerations

a. Potential Risks to Infants and Children

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

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

(1) Developmental and Reproductive Effects

(a) Developmental Toxicity

In the rat developmental toxicity study, the developmental NOEL was 250 ppm (12.5 mg/kg/day); the developmental LOEL of 1250 ppm (62.5 mg/kg/day) was based upon significantly decreased number of live fetuses per litter, apparently due to fetal loss occurring before or near the time of implantation. The maternal NOEL was 250 ppm (12.5 mg/kg/day), based on decreased body weight at 1,250 ppm (62.5 mg/kg/day).

In the rabbit developmental toxicity study, the maternal NOEL was 200 mg/kg/day, based on maternal deaths (5 died and 2 were sacrificed in extremis) at the LOEL of 600 mg/kg/day. The developmental NOEL was also 200 mg/kg/day based on decreased live fetal weights in the high dose group (i.e., 600 mg/kg/day).

(b) Reproductive Toxicity

In a multigenerational reproductive toxicity study with rats, the systemic NOEL of < 50 ppm (2.5 mg/kg/day) was based on the reduction of body weight gain in males. The NOEL for reproductive toxicity was > 250 ppm (12.5 mg/kg/day).

(2) Uncertainty Factor

Because the developmental NOELs were the same as those for maternal toxicity, and the NOEL for systemic (parental) toxicity was higher than the NOEL for reproductive toxicity, these data do not suggest an increased pre- or post-natal sensitivity of children and infants to terbacil exposure. Therefore, the Agency concludes that the available toxicology data do not support an uncertainty factor of 1000 as specified in FQPA and that the present uncertainty factor of 100 is adequate to ensure the protection of infants and children from exposure to terbacil.

(3) Aggregate Exposure/Risk

Products containing terbacil are not registered for residential use at this time. With regard to occupational risk, no dermal or

inhalation endpoints of concern were identified and an assessment is not needed. Therefore, the following aggregate risk determinations are for dietary exposures only (from food and water).

(4) Total dietary (food source and drinking water)

Food source data are taken from the DRES Tables. Drinking water figures are taken from calculations presented in sections 4 f. and g. above.

Determination of Safety for U.S. Population (Chronic):

Aggregate Exposure = %RfD (food sources) + %RfD (surface drinking water)
= 4.6% + 23%
= 27.6%

For 10-kg children (1 to 6 years) (Chronic):

Aggregate Exposure = %RfD (food sources) + %RfD (surface drinking water)

= 12.8% + 81%
= 93.8%

For females (13+ years old) (Acute):

Aggregate Exposure = dietary exposure + drinking water exposure
= 0.003 mg/kg/day + 0.005 mg/kg/day
= 0.008 mg/kg/day

Aggregate MOE = NOEL ÷ Aggregate Exposure
= 12.5 mg/kg/day ÷ 0.008 mg/kg/day
= 1563

Conclusions:

Aggregate exposure/risk values are all below the level of Agency concern. This includes the acute exposure of females of child-bearing age.

b. Cumulative Effects

In assessing the potential risk from cumulative effects of terbacil and other chemical substances, the Agency has considered structural similarities that exist between terbacil and other substituted uracil compounds such as bromacil and lentacil.

A comparison of the available toxicological database for terbacil and bromacil revealed no clear common mode of toxicity these chemicals. The toxicology database for lentacil was not considered because there are currently no registered uses of lentacil. A summary of the most prominent clinical signs from terbacil and bromacil follows.

The following clinical signs were observed in the terbacil toxicology database: decrease in body weight, increase in liver weights, vacuolization and hypertrophy of hepatocytes, hypertrophy of centrilobular hepatocytes in males, decreased pituitary weights in males and females, increase in thyroid/body weight ratio, elevated alkaline phosphatase.

The following clinical signs were observed in the bromacil toxicology database: decreased body weight, focal atrophy of seminiferous tubules (testicular abnormalities), hydronephrosis, suggestive histological evidence for antithyroid activity (cystic follicles in the thyroid and enlargement of centrilobular cells of the liver) and a positive trend in thyroid tumors for male rats (basis of C classification for carcinogenicity).

Based on these data, the Agency has determined that there is no clear common mode of toxicity (thyroid or liver) between terbacil and bromacil. With both chemicals, there is marginal evidence of liver effects (principally enlargement of centrilobular cells). Enlargement of liver cells is not a specific enough effect to be considered a common mode of toxicity. The thyroid effects observed with bromacil were cystic follicles. Terbacil induced an increase in relative thyroid weights but no increase in absolute thyroid weights. An increase in relative weight without a corresponding increase in absolute weight has very little meaning, especially without any supporting histological or hormonal evidence. This conclusion was based on the marginal liver effects noted in the databases, and the absence of thyroid effects in the terbacil database (with the exception of increases in relative thyroid weights).

EPA has found no information indicating that any other chemical has a common mode of toxicity with terbacil. Therefore, aggregate risk assessment will indicate risks resulting only from terbacil.

C. Environmental Assessment

1. Ecological Toxicity Data

All ecological toxicity data are fulfilled except for chronic avian and aquatic toxicity studies (71-4 Avian Reproduction Study; 72-4 Fish Early Life Stage and Aquatic Invertebrate Life Cycle). These data are needed because terbacil is a persistent compound which may pose long-term exposure in terrestrial and aquatic environments. Wild mammal toxicity study (71-3) is reserved pending the results of avian reproduction studies (71-4).

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of terbacil to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated in Table 5 below.

Table 5: Avian Acute Oral Toxicity

Species	%a.i.	LD_{50} (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Northern bobwhite quail *(Colinus virginianus)*	96.1	> 2250	Practically non-toxic	acc. 157177 Beavers, 1986	Core

[1]Core (study satisfies guideline).

Terbacil is practically non-toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (Accession # 157177). Two subacute dietary studies using the TGAI are required to establish the toxicity of Terbacil to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated in Table 6 below.

Table 6: Avian Subacute Dietary Toxicity

Species	% a.i.	5-Day LC_{50} (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Peking mallard	80 WP	> 56,200	practically non-toxic	00012347 Wazeter, 1966	supplemental (formulated product)
Pheasant	80 WP	26,426[2]	practically non-toxic	00012346 Wazeter, 1966	supplemental (formulated product)
Mallard duck *(Anas platyrhynchos)*	96	> 5000[3]	practically non-toxic	acc. 241146 Moore, 1979	core

[1]Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline.
[2]It is unclear if the reported concentration is based on the formulated product or on active ingredient. The number corrected for percent active (80%) would be 21,141 ppm.
[3]No mortality was observed at the 5000 ppm concentration.

Terbacil is practically non-toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 00012347, 00012346, Acc. 241146).

(2) Birds, Chronic

Avian reproduction studies using the TGAI are required for terbacil because the birds may be subject to repeated or continuous exposure to terbacil due to the persistence, especially preceding or during the breeding season. The preferred test species are mallard duck and bobwhite quail. There are, currently, no data from avian reproduction studies. These studies are outstanding. The 71-4 Avian Reproduction data requirement is not fulfilled.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported in Table 7 below.

Table 7: Mammalian Toxicity

Species/ Study Duration	% a.i.	Test Type	Toxicity Value	Affected Endpoints	MRID No.
Rat *(Rattus norvegicus)*	80	Acute oral	$LD_{50} > 5,000$ mg/kg	none	Acc. #114693 and 24955
Rat	80	3-generation rat study	NOEL > 250 ppm	The NOEL for reproductive toxicity was > 250 ppm (12.5 mg/kg)	Acc. No. 249455

The results indicate that terbacil is practically non-toxic to small mammals on an acute oral basis.

(4) Insects

A honey bee acute contact study using the TGAI is required for terbacil because its use (apple, alfalfa, peach, caneberry, strawberry, mint, and sugarcane) will result in honey bee exposure. Results of this test are tabulated in Table 8 below.

Table 8: Nontarget Insect Acute Contact Toxicity

Species	% a.i.	LD_{50} (μg/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)*	80 WP	193	practically non-toxic	00018842 Atkins, 1969	core

The results indicate that terbacil is practically non-toxic to bees on an acute contact basis. The guideline (141-1) is fulfilled (MRID 00018842).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of terbacil to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated in Table 9 below.

Table 9: Freshwater Fish Acute Toxicity

Species (all of testing below are Static)	% a.i.	96-hour LC_{50} (ppm) (nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	96.6	46.2	slightly toxic	00390017 Smith, 1980	core
Bluegill sunfish *(Lepomis macrochirus)*	96.6	102.9	practically non-toxic	00390019 Summers, 1978	core
Bluegill sunfish *(Lepomis macrochirus)*	80	112	practically non-toxic	00025224 McCann, 1972	core, (formulated product)
Rainbow trout *(Oncorhynchus mykiss)*	80	79	slightly toxic	00025223 McCann, 1972	core, (formulated product)
Rainbow trout *(Oncorhynchus mykiss)*	80	54	slightly toxic	44150201 McCann, 1972	core, (formulated product)
Carp (48 hr.)	80	96	slightly toxic	acc. 249455 Yoshida, 1972	supplemental
Japanese Goldfish (48 hr.) Killifish (48 hr.) Loach (48 hr.)	80	> 40	slightly toxic	acc. 249455 Yoshida, 1972	supplemental

Since the LC_{50} falls in the range of 40 - 100 ppm, terbacil ranges from slightly to practically non-toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID 00390017, 00390019, 00025223, 00025224, 44150201, acc.#249455).

(2) Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for terbacil because the end-use product is very persistent in the aquatic environment. There are currently no data for assessing chronic effects to freshwater fish. A freshwater fish early life-stage test using the TGAI is outstanding. The preferred test species is rainbow trout. The guideline is not fulfilled.

(3) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of terbacil to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated in Table 10 below.

Table 10: Freshwater Invertebrate Acute Toxicity

Species (all of testing below are Static)	% a.i.	48-hour EC_{50} (ppm) (nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	95	65	slightly toxic	00390018 McCann, 1981	core
Waterflea *(Daphnia magna)*	not stated	68	slightly toxic	acc.#249455 Hall, 1981	supplemental
Waterflea *(Daphnia magna)*	not stated	63	slightly toxic	acc.#125705 Phillips, 1981	supplemental

Since the EC_{50} falls in the range of 10-100 ppm, terbacil is slightly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 00390018, accession #249455, accession #125705).

(4) Freshwater Invertebrates, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for terbacil since the end-use product is intended for use such that its presence in water is likely to be continuous or recurrent because of the persistence of terbacil. The preferred test species is *Daphnia magna*. Currently, there are no data available from this study and it is currently outstanding. The guideline is not fulfilled.

(5) Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for terbacil because the end-use product

is intended for application sites near coastal counties such as apple, forestry, and alfalfa. The preferred test species is sheepshead minnow. Results of these tests are tabulated in Table 10 below.

Table 10: Estuarine/Marine Fish Acute Toxicity

Species	% a.i.	96-hour LC_{50} (ppm a.i.)	Toxicity Category	MRID No. Author/Year	Study Classification
Sheepshead minnow *(Cyprinodon variegatus)*	97.4	108.5 (measured)[1]	practically non-toxic	41896100 Ward, 1990	core

[1]Test was conducted under static conditions.

Terbacil is practically non-toxic to estuarine/marine fish on an acute basis. The guideline (72-3(a)) is fulfilled (MRID 41896100).

(6) Estuarine and Marine Fish, Chronic

An estuarine/marine fish early life-stage toxicity test using the TGAI is reserved pending results of the freshwater fish early life-stage toxicity test.

(7) Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for terbacil because the end-use product is intended for application near coastal counties such as apple, forestry, and alfalfa. The preferred test species are mysid shrimp and eastern oyster. Results of these tests are tabulated in Table 10 below.

Table 10: Estuarine/Marine Invertebrate Acute Toxicity

Species (all tested under static conditions)	% a.i.	96-hour LC_{50}/EC_{50} (ppm a.i.) (nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Eastern oyster (embryo-larvae) *(Crassostrea virginica)*	84.7	> 4.9 (48 hr.)	moderately toxic	00012333 Bentley, 1973	core[1]
Fiddler crab	84.7	> 1000	practically non-toxic	00012332 Bentley, 1973	supplemental
Grass shrimp	84.7	56.4	slightly toxic	00012332 Bentley, 1973	core

[1] This study was made core because the ECC was not expected to exceed 4.15 ppm a.i..

Terbacil ranges from moderately toxic to practically non-toxic to estuarine/marine invertebrates on an acute basis. The

guideline (72-3(b) and 72-3(c)) is fulfilled (MRID 00012332, 00012333).

(8) Estuarine and Marine Invertebrate, Chronic

An estuarine/marine invertebrate life cycle toxicity test using the TGAI is reserved pending results from freshwater aquatic invertebrate life cycle toxicity test.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required because terbacil has terrestrial non-residential outdoor use patterns and it may move off the application site through spray drift or runoff. For seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (*Zea mays*).

Terrestrial Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs a.i./A or less) and any pesticide showing a negative response equal to or greater than 25% in Tier I tests. Tier II tests measure the response of plants, relative to a control, and five or more test concentrations. Results of Tier II toxicity testing on the technical/TEP material are tabulated in Table 11 below.

Table 11: Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II)

Species	% a.i.	EC_{25} (lb a.i./A)	EC_{25} Endpoint Affected	EC_{05}/NOEC (lb a.i./A)	EC_{05}/NOEC Endpoint Affected	MRID No. Author/Year	Study Classification
Monocot- Corn	96.9	0.0622	dry weight	0.0250	dry weight	43895801 Heldreth, 1996	core
Monocot- onion	96.9	0.0286	dry weight	0.0125	dry weight	same as above	core
Monocot- sorghum	96.9	0.0913	dry weight	0.0500	dry weight	same as above	core
Monocot- wheat	96.9	0.0299	dry weight	0.0125	dry weight	same as above	core
Dicot- cucumber	96.9	0.0736	dry weight	0.0500	dry weight	same as above	core
Dicot- pea	96.9	0.1173	dry weight	0.0286	dry weight	same as above	core
Dicot- rape	96.9	0.0149	dry weight	0.0063	dry weight	same as above	core
Dicot- soybean	96.9	0.0963	dry weight	0.0500	dry weight	same as above	core
Dicot- sugar beet	96.9	0.0192	dry weight	0.0125	dry weight	same as above	core
Dicot- tomato	96.9	0.0180	dry weight	0.0125	dry weight	same as above	core
Monocot - wheat	97.4	0.0250	shoot height	0.0310	shoot height	McKelvey, 1992 42336701	core
Monocot- corn	97.4	0.6600	shoot height	0.0310	shoot height	same as above	core[1]
Monocot- sorghum	97.4	0.1100	shoot height	0.0620	shoot height	same as above	core
Dicot- sugar beet	97.4	0.0270	shoot height	0.0150	shoot height	same as above	core
Dicot - pea	97.4	17.0	shoot height	0.5000	shoot height	same as above	core[1]
Dicot- soybean	97.4	15.0	shoot height	4.0	shoot height	same as above	core
Dicot- tomato	97.4	0.016	shoot height	0.0070	shoot height	same as above	core
Dicot- rape	97.4	0.013	shoot height	0.0070	shoot height	same as above	core
Dicot- cucumber	97.4	0.045	shoot height	0.0070	shoot height	same as above	core[1]

[1]Species was upgraded to core since EPA now accepts thiram and captan seed treatments in the testing protocol.

For Tier II seedling emergence, rape is the most sensitive dicot (EC_{25} = 0.013 lb a.i./A). Wheat is the most sensitive monocot (EC_{25} = 0.0299 lb a.i./A). The guideline (123-1(a)) is fulfilled (MRID 43895801, 42336701).

Table 12: Nontarget Terrestrial Plant Vegetative Vigor Toxicity (Tier II)

Species	% a.i.	EC_{25} (lb a.i./A)	EC_{25} Endpoint Affected	EC_{05}/NOEC (lb a.i./A)	EC_{05}/NOEC Endpoint Affected	MRID No. Author/Year	Study Classification
Monocot- Corn	96.9	0.0297	dry weight	0.0250	dry weight	43895801 Heldreth, 1996	core
Monocot- onion	96.9	0.0741	dry weight	0.0500	dry weight	same as above	core
Monocot- sorghum	96.9	0.0426	dry weight	0.0500	dry weight	same as above	core
Monocot-Wheat	96.9	0.0087	dry weight	0.0063	dry weight	same as above	core
Dicot- cucumber	96.9	0.0058	dry weight	0.0031	dry weight	same as above	core
Dicot- pea	96.9	0.0357	dry weight	0.0250	dry weight	same as above	core
Dicot- rape	96.9	0.0048	dry weight	0.0031	dry weight	same as above	core
Dicot- soybean	96.9	0.0108	dry weight	0.0018	dry weight	same as above	core
Dicot- sugar beet	96.9	0.0176	dry weight	0.0063	dry weight	same as above	core
Dicot- tomato	96.9	0.0126	dry weight	0.0063	dry weight	same as above	core
Monocot - wheat	97.4	0.062[1]	shoot height	0.12	shoot height	McKelvey, 1992 42336701	core
Monocot- corn	97.4	> 2.0	all parameters	> 2.0	all parameters	same as above	core
Monocot- onion	97.4	0.12	shoot weight	0.12	shoot weight	same as above	core
Monocot- sorghum	97.4	> 2.0	all parameters	> 2.0	all parameters	same as above	core
Dicot- sugar beet	97.4	0.0008[3]	root weight	< 0.0070[3]	root weight	same as above	supplemental
Dicot- cucumber	97.4	0.0022	root weight	0.0070	root weight	same as above	core
Dicot- pea	97.4	1.0[4]	shoot weight	0.0170[4]	shoot weight	same as above	core
Dicot- soybean	97.4	0.0180	shoot weight	0.0150	shoot weight	same as above	core
Dicot- tomato	97.4	0.0110	root weight	0.0070	root weight	same as above	core
Dicot- rape	97.4	0.0035	total weight	0.0070	total weight	same as above	core

[1]The value is not statistically valid.
[2]Species were upgraded to core since EPA now accepts thiram and captan seed treatments in the testing protocol.
[3]The results may not be accurate because they were obtained by extrapolating far outside the range of data.
[4]Positive rate response.

For Tier II vegetative vigor, cucumber is the most sensitive dicot (EC_{25} = 0.0022 lb a.i./A). Wheat is the most sensitive monocot (EC_{25} = 0.0087 lb a.i./A). The guideline (123-1(b)) is fulfilled (MRID 43895801,42336701).

(2) Aquatic

Aquatic plant testing (tier II) is required for terbacil because it move off-site by runoff and by aerial spray drift. The following species should be tested at Tier II: *Kirchneria subcapitata (Selenastrum capricornutum)*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. Results of Tier II toxicity testing on the technical/TEP material are tabulated in Tale 13 below.

Table 13: Nontarget Aquatic Plant Toxicity (Tier II)

Species	% a.i.	EC_{50} (ppm a.i.)	EC_{05}/NOEC (ppm a.i.)	MRID No. Author/Year	Study Classification
Vascular Plants					
Duckweed *Lemna gibba*	96.44	0.140	0.065	43929801 Thompson, 1996	core
Nonvascular Plants					
Green algae *Kirchneria subcapitata*	97.4	0.018	0.004	42306101 Hoberg, 1990	core
Marine diatom *Skeletonema costatum*	96.44	0.140	0.081	43929802 Thompson, 1996	core
Freshwater diatom *Navicula pelliculosa*	96.9	0.011	0.007	43909802 Hughes, 1996	core
Blue-green algae *Anabaena flos-aquae*	96.44	0.120	0.062	43929802 Thompson, 1996	core

The Tier II results indicate that *Navicula pelliculosa* is the most sensitive nonvascular aquatic plant. The guideline (123-2) is fulfilled (MRID 43929802, 43909802, 42306101, 43929801).

2. Environmental Fate

All environmental fate data are fulfilled at this time. However, additional information on aerobic aquatic metabolism (162-4) of terbacil is needed because terbacil is likely to move into surface waters. These data will provide a more realistic assessment of terbacil concentration in surface waters.

a. Environmental Fate Assessment

Based on acceptable, supplemental, and ancillary environmental fate data, terbacil dissipation appears to dependent on microbial-mediated degradation, photodegradation in water, and movement into ground and surface waters. The relative importance of degradation and mobility in controlling terbacil dissipation under actual use conditions cannot be fully evaluated from the existing environmental fate data. However, the data indicate that terbacil is very persistent and potentially very mobile in terrestrial environments. Compounds with similar environmental fate behavior (*e.g.*, bromacil) have been detected in ground and surface waters.

Terbacil is stable to abiotic hydrolysis and slowly degrades through photolysis in natural and reference laboratory water samples ($t_{1/2}$ = 29 to 54 days) and soil ($t_{1/2}$ = 122 days). The photodegradation rate appears to be dramatically enhanced by the presence of some photosensitizers (riboflavin

and methylene blue). Major photodegradation transformation products (> 10% of applied) are 5-chloro-6-methyluracil, 3-tert-butyl-6-methyluracil, and 6-chloro-2,3-dihydro-3,3, 7-trimethyl-5H oxazolo (3,2-a)-pyrimidine-5-one, tert-butyl-5-acetyl-5-hydroxyhydantoin (Compound II), 3-tert-butyl-5-hydroxyhydantoin (Compound III), and 5-chloro-6-methyl-(3',5')-5'-chloro-6'-methyl-5',6'-dihydro-6',2-anhydro-3'-tert-butyluracilyluracil (Compound VI). Terbacil is persistent under aerobic and anaerobic soil conditions ($t_{1/2}$ = 235 to 653 days). Minor nonvolatile transformation products are t-butylurea and 3-t-butyl-5-chloro-6-hydroxymethyuracil. The major volatile transformation product is CO_2. The reported laboratory degradation data indicate terbacil is persistent in terrestrial environments.

Terbacil has a low sorption affinity to soil (K_{ad} = 0.39 to 1.3 ml/g; K_{oc} = 44 to 61 ml/g). Therefore, terbacil is expected to be very mobile in soil. Soil column studies also indicate that terbacil and its transformation products can move through soil columns. Laboratory mobility studies indicate terbacil and its transformation products are potentially mobile in terrestrial environments.

Marginally acceptable field dissipation studies indicate terbacil, at 5 lbs a.i./A, is persistent and mobile under actual use conditions. Field dissipation half-lives in Delaware, Illinois, and California ranged from 204 to 252 days. The maximum depth of terbacil detection was 45 to 50 cm . Ancillary field studies using plants as biological indicators also suggest that phytotoxic "terbacil residues" are persistent and mobile. Field dissipation studies confirm that terbacil is persistent and potentially mobile under actual use conditions.

Terbacil was bioaccumulated (< 8 µg/g) in bluegill sunfish tissues under static concentrations of 0.01 and 1.00 µg/ml. Bioaccumulated terbacil declined below the detection limit (< 0.01 µg/g) during a 3 day depuration period. Terbacil is not expected to bioaccumulate in fish tissues.

b. Environmental Fate and Transport

(1) Degradation

(a) Abiotic Hydrolysis

Radiolabeled terbacil was stable (> 6 weeks) in pH 5, 7, and 9 buffer solutions in the dark at 25°C (Acc. No. 0001946). Ancillary data also indicate terbacil was stable

in pH 4 to 10 buffer solutions at 25°C (Archer et al., 1981). The hydrolysis (161-1) data requirement is fulfilled. No additional hydrolysis data are needed at this time.

(b) Photodegradation in Water

Radiolabeled terbacil, under natural sunlight, had a first-order photodegradation half-life of 29 days in standard reference water, 37 days in Brandywine River Water, 54 days in the Brandywine River Water with suspended sediment, and 3.25 days in reference water with a riboflavin sensitizer (Rhodes, 1975). Under UV light from fluorescent and black lights, radiolabeled terbacil had a first-order photodegradation half-life of 44 days in standard reference water, 82.91 days in Brandywine River Water, and 4.8 days in reference water with a riboflavin sensitizer. Major photodegradation products (> 10% of applied were 5-chloro-6-methyluracil, 3-tert-butyl-6-methyluracil, and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H oxazolo (3,2-a)-pyrimidine-5-one. Radiolabeled terbacil, at 700 µg/ml, under natural sunlight had a first-order photodegradation half-life of < 2 hours in non-buffered aqueous solutions (pH 3.4 to 9.2) containing methylene blue (3 µg/ml) or riboflavin (10 µg/ml) photosensitizer (Archer, 1981). Terbacil, at 250 ppm, was photolytically stable in non-buffered aqueous solutions (pH 4-10) irradiated with a mercury (Hg) vapor lamp at 25°C. Rose bengal and methylene blue were effective sensitizers in near- neutral to alkaline non-buffered aqueous solution (pH > 6.6). Riboflavin, at 10 µg/ml, was an effective photosensitizer in non buffered aqueous solutions (pH 4 to 10). Humic acid, however, was not an effective sensitizer in aqueous solutions. Major photodegradation products (> 10% of applied) were 3-tert-butyl-5-acetyl-5-hydroxyhydantoin (Compound II), 3-tert-butyl-5-hydroxyhydantoin (Compound III), and 5-chloro-6-methyl-(3',5')-5'-chloro-6'-methyl-5',6'-dihydro-6',2-anhydro-3'-tert-butyluracil (Compound VI). Also, an unidentified photoproduct (Compound V) was precipitated during photodegradation of terbacil. Compound III, 3-tert-butyl-5-hydroxyhydantoin, does not appear to be a photodegradate because it was detected in dark controls. The Photodegradation in Water (161-2) data requirement is fulfilled. No additional photolysis in water data are needed at this time.

(c) Photodegradation on Soil

Radiolabeled terbacil at 1.2 lbs/A had an extrapolated first-order degradation half-life of 61 days on a Drummer silty clay loam when continuously irradiated for 15 days with a xenon arc lamp at 25°C (Accession No. 00160235). A corrected photodegradation half-life, based on a 12 hour photoperiod, would theoretically be 122 days. Radiolabeled terbacil was stable in the dark controls. The degradation product, 5-chloro-6-methyluracil, was detectable in both irradiated and dark control treatments. However, unidentified radioactivity was detected in the methanol soil extracts and non-extractable soil organic matter.

In an ancillary study, radiolabeled terbacil had a first-order degradation half-life of 46 days on a Keyport silt loam when continuously irradiated with fluorescent sunlamps and black light (1500 $\mu W/cm^2$) for 8 weeks (Rhodes, 1975). Dark controls were not used in this study. The major degradate (> 10% of applied) was 5-chloro-6-methyluracil.

The Photodegradation on Soil (161-3) data requirement is fulfilled. No additional photodegradation on soil data are needed at this time.

(d) Photodegradation in Air

The Photodegradation in Air (161-4) data requirement is waived because terbacil has a low vapor pressure (4.7×10^{-7} mm Hg at 29.5°C) and low Henry's Constant (1.9×10^{-9} atm. m^3/mole). The Photodegradation in Air (161-4) data requirement is waived.

(e) Aerobic Soil Metabolism

Radiolabeled terbacil, at 9.3 µg /g, had an extrapolated, first-order half-life of 653 days in a Sassafras sandy loam soil when incubated for 12 months at 25° C in the dark (MRID 42369901). The major transformation product (> 10% of applied) was $^{14}C0_2$. Minor transformation products (< 10% of applied) were t-butylurea and 3-tert-butyl-6-methyluracil. In an ancillary study, radiolabeled terbacil had a half-life of 2 to 3 months

in nonsterile soils (Fallsington sandy loam and Flanagan silt loam) when incubated in a greenhouse (Rhodes, 1981). Unacceptable aerobic soil metabolism data indicate radiolabeled terbacil, at 4 µg a.i./g, had an extrapolated, first-order half-life of 520 days in non-sterile silty clay loam soil when incubated for one year in the dark at 25°C (MRID 40253601). In sterile soil, terbacil had an extrapolated half-life of 1007 days. Non-volatile transformation products were not identified; $^{14}CO_2$ accounted for 9.7% of applied terbacil.

Terbacil (Sinbar 80 WP), at 100 µg/g, had an estimated first-order half-life of 720 days in Triangle and Boddington sandy loam soils (05013201; Marsh and Davis, 1978). Radiolabeled terbacil, at 4.5 lbs a.i./A, had an estimated first-order half-life of 32.5 days when incubated in Keyport silt loam soil irradiated with 12 hour per day photoperiod of UV light (mercury vapor light) for 6.5 weeks (Rhodes, et al. 1969). The major degradate was $^{14}CO_2$ (32% of applied radioactivity). Radiolabeled terbacil, at 2.8 µg/g, degraded to form $^{14}CO_2$ (28 to 38% of applied) in a Greenfield sandy loam soil unamended or amended with plant residues with different carbon : nitrogen ratios when incubated at 60% of field capacity at 22°C (05024336, Wolf, D.A. Ph.D. dissertation; 05013204; 05016176, Wolf and Martin, 1974).

The Aerobic Soil Metabolism (162-1) data requirement is fulfilled. No additional aerobic soil metabolism data are needed at this time.

(f) Anaerobic Soil Metabolism

Radiolabeled terbacil, at 9.3 µg/g, had an extrapolated, first-order half-life of 235 days when incubated for 90 days in anaerobic Sassafras sandy loam soil at 25°C in the dark (MRID 42370001). Minor transformation products (< 10% of applied) were t-butylurea and 3-tert-butyl-5-chloro-6-hydroxymethyluracil.

In an ancillary study, radiolabeled terbacil, at 2.1 µg/g, had a half-life of > 60 days when incubated for 60 days in anaerobic mineral soils (Fallsington and Flanagan) under greenhouse conditions (Rhodes, 1981). In an

unacceptable study, radiolabeled terbacil, at 4 µg/g, had an extrapolated, first-order half-life of 178 days when incubated in anaerobic silty clay loam soil in the dark at 25°C (MRID 40104701). Under sterile conditions, radiolabeled terbacil was stable ($t_{1/2}$ > 60 days). Radiolabeled terbacil, at 2.8 µg/g, did not degrade to form $^{14}CO_2$ (0.2 % of applied) in Greenfield sandy loam soil unamended or amended with plant residues with different carbon:nitrogen ratios when incubated under flooded conditions at 22°C (05024336, Wolf, D.A. Ph.D. dissertation; 05013204, Wolf, D.C., 1974.; 05016176, Wolf and Martin, 1974). Terbacil (unspecified formulation), at 8 µg/g, degraded with a half-lives of 5 and 8 months in a Chehalis loam soil at 31°C and 13°C, respectively (Zimdahl et al., 1970). Terbacil degradation was dependent on first-order degradation kinetics.

The Anaerobic Soil Metabolism (162-1) data requirement is fulfilled. No additional data are needed at this time.

(g) Aerobic Aquatic Metabolism

Although the aerobic aquatic metabolism data are not needed to support terrestrial uses of terbacil, environmental fate properties of terbacil are similar to compounds commonly detected in surface waters. Therefore, terbacil is expected to move into surface waters from terrestrial use sites. Aerobic aquatic metabolism data are needed to define the rates and routes of terbacil dissipation in aquatic environments. These data will be used to provide more refined estimated environmental concentrations of terbacil in surface water.

(2) Mobility

(a) Batch equilibrium/soil column leaching

Radiolabeled terbacil, at 0.27 to 6.28 µg/ml, had a Freundlich adsorption coefficient of 0.39 ml/g (K_{oc} = 61 ml/g; 1/n = 0.78) in Woodstown sandy loam, 0.71 ml/g (K_{oc} = 58 ml/g; 1/n = 0.82) in Cecil sandy loam; 1.3 ml/g (K_{oc} = 52 ml/g; 1/n = 0.90), 1.2 ml/g (K_{oc} = 44 ml/g; 1/n = 0.97) in a Keyport silt loam (Accession No.

00155104). The Freundlich desorption coefficient for terbacil were 0.67 ml/g (K_{oc} = 61 ml/g; 1/n = 0.45) in Woodstown sandy loam, 1.5 ml/g (K_{oc} = 71 ml/g; 1/n = 0.35) in Cecil sandy loam; 2.6 ml/g (K_{oc} = 104 ml/g; 1/n = 0.26), and 2.5 ml/g (K_{oc} = 92 ml/g; 1/n = 0.26) in a Keyport silt loam. Radiolabeled terbacil had Freundlich adsorption coefficient of 2.46 ml/g (K_{oc} = 63.6 ml/g) in a Webster silty clay loam, 0.38 ml/g K_{oc} = 42.2 ml/g) in a Cecil sandy loam, 0.38 ml/g (K_{oc} = 76 ml/g) in a Glendale sandy clay loam, and 0.12 ml/g (K_{oc} = 21.4) in Eustis fine sand (05014424, Davidison et al., 1978;05008371, Rao and Davidison, 1979). Radiolabeled terbacil, at 1 µg/ml, had Freundlich adsorption coefficients ranging from 0.72 ml/g (K_{oc} = 57.6 ml/g; 1/n = 0.73) to 1.65 ml/g (K_{oc} = 84.6 ml/g; 1/n = 0.97) for twelve mineral soils (05014175, Liu et al., 1971). Terbacil had a soil TLC Rf of 0.54 for a Woodstown sandy loam, 0.36 for a Cecil sandy loam, 0.28 for a Flanagan silt loam, and 0.27 for Keyport silt loam.

Terbacil and its minor transformation products were leached through 30 cm columns of Flanagan silt loam and Sassafras sandy loam soil when eluted with 20 inches of 0.01 M $CaCl_2$ (MRID 42335401). Terbacil was predominately detected in leachate samples. Minor transformation products (9 to 11% of applied terbacil) in the leachate samples were t-butylurea, and 3-t-butyl-6-methyluracil and 6-chloro-2,3-dihydro-7 (hydroxymethyl)-3,3-dimethyl-5H-oxazolo(3,2-a)pyrimidin-5-one. In an ancillary study, Radiolabeled terbacil, at 2 lbs/A, was leached (4 to 64% of applied radioactivity) through 18 inch packed soil columns of Fallsington sandy loam and Flanagan silt loam when eluted with 20 inches of water (Rhodes, 1981). Also, "unidentified" terbacil residues were leached (4 to 52% of applied radioactivity) through packed soil columns of Fallsington sandy loam and Flanagan silt loam. Radiolabeled terbacil (73 to 90% of applied radioactivity) was leached through 30 cm columns of surface and subsurface Wabasso fine sand when eluted with 15.5-to-20 inches of 0.01 M $CaSO_4$. Based on plant bioassays, phytotoxic terbacil residues were eluted with 10 to 20 cm of water to a depth of 27.5 to 30 cm in packed 30 cm soil columns of Fox sandy orchard soil (05013202, Marriage, et al. 1977).

The Batch Equilibrium/Soil Column Leaching (163-1) data requirement is fulfilled. No additional mobility data are needed at this time.

(b) Laboratory Volatility

The Laboratory Volatility (163-2) data requirement is waived because terbacil has a low vapor pressure (4.7 x 10^{-7} mm Hg at 29.5°C) and low Henry's Constant (1.9 X 10-9 atm m3/mol).

(3) Accumulation

(a) Fish

Radiolabeled terbacil, at 0.01 and 1.00 µg/ml, was accumulated, respectively, at concentrations of 0.11 and 7.9 µg/g in viscera, 0.02 and 1.8 µg/g in head, 0.07 and 4.4 µg/g in the livers, and 0.02 and 1.7 µg/g in edible tissues of bluegill sunfish over 4 week exposure period (Accession No. 00011947). Terbacil residues in all fish tissues declined below the detection limit (< 0.01 µg/g) during a 3 day depuration period. Terbacil was the only radioactive residue identified in fish tissues. The Bioaccumulation in Fish (165-4) data requirement is fulfilled. No additional data are needed at this time.

(4) Field Dissipation

Terbacil (Sinbar 80% wettable powder), spray or broadcast applied at 5 lbs a.i./A, had a first order half-life of 212 days on silt loam soil in Delaware, 204 days on a silty clay soil in Illinois, and 252 days on a sandy loam soil in California (MRID 43585500). Terbacil "residues" were detected (< 0.09 µg/g) at a maximum soil depth of 45 to 50 cm. In California and Delaware field studies, the terbacil transformation product, 3-t-butyl-5-chloro-6-hydroxymethyluracil, had a maximum concentration of 0.14 µg/g at 15 days and then declined to < 0.8 µg/g at 60 days posttreatment. The transformation product, 6-chloro-2,3-dihydro-7-(hydroxymethyl)-3,3-dimethyl-5H-oxazolo[3,2-a]pyrimidin-5-one, had a maximum concentration of 0.07 µg/g at 60 days posttreatment in the California study.

In a supplemental microplot field dissipation study, radiolabeled terbacil at 2 lbs a.i./A had a half-life of 1 to 2 months when incubated in the field for 4 months with a cumulative rainfall of 18.33 inches (Rhodes, 1981). Terbacil was detected in the 12 to 15 inch soil segment. In an unacceptable long-term field dissipation study, terbacil (Sinbar 80% wettable powder), applied at 1.0, 2.0, and 4.0 lbs/A/year for 16 consecutive years, did not appear to accumulate on a study site in Delaware. Terbacil was detected (< 1 µg/g) in the surface 12 inches of soil in the 2.0 and 4.0 lbs a.i./A treatments. The transformation product, [6-Clair-2,3-dihydro-3,3-dimethyl-7-hydroxymetyl-5H-oxazolo(3,2-)pyrimidine-5-one], was detected at maximum concentration of 0.06 µg/g. Radiolabeled terbacil, at 4 lbs a.i./A, had an estimated first-order half-life of 131 days when incubated for 52 weeks in microplot field studies (4 inch diameter x 12 inch depth in situ lysimeter) in a Butlertown silt loam (Gardiner, et al. 1969) Radiolabeled residues were detected throughout the lysimeter at 5 weeks posttreatment. The study site location and climatic conditions were not reported.

Several field dissipation studies for terbacil have been reported using chemical non-specific bioassay techniques for detection of "terbacil residues". Although chemical non-specific bioassays are not accepted as a reliable analytical technique, the Agency believes that field dissipation studies using chemical non-specific bioassays provide ancillary qualitative data on the dissipation of "terbacil residues". Such data, however, cannot be used to fulfill the terrestrial field dissipation (164-1) data requirement.

Terbacil applied at 1.6 lbs a.i./A in a Washington orchard soil was detected 1 year posttreatment using oats, beans, and cucumbers as phytotoxicity indicators (05020698; Benson, 1973). Phytotoxic terbacil residues were detected at a maximum depth of 18 to 24 inches. No rainfall data were reported. Terbacil, 2.24 kg/ha/year for 4 consecutive years, caused phytotoxic effects on oats and beans at two years posttreatment on an acidic Camas clay loam soil (05013351; Doughty, 1978). In contrast, phytotoxic terbacil residues (< 0.03 µg/g) were not detected on a high organic matter, acidic, Mossy Rock silt loam amended with terbacil at 4.48 kg/ha for 4 consecutive years. Phytotoxic residues from terbacil (unspecified source), at 2 to 16 lbs/A, were detected 13 months posttreatment in surface soil of Mabi clay soil planted with sugar cane in Puerto Rico (00017711; Liu, L.C. et al. 1977). Phytotoxic residues from terbacil (unspecified source), as a banded application

at 1.2 and 2.4 lbs/A, were detected at 7 months posttreatment on clay loam soil in California (00028135, Isom, et al., 1969; 05019594, Isom, et al., 1970). Terbacil (unspecified formulation), applied on the soil surface or incorporated at rates 2.24 and 4.48 kg/ha for three consecutive years, degraded with an estimated half-life of 157 days on peach orchard sandy soil (sites unspecified) (05013212, Skroch et al., 1971). Terbacil was detected (< 0.07 µg/g) at a maximum soil depth of 15 to 30 cm soil following the second and third year applications.

Terbacil applied at 4.5 kg/ha/year over three applications was detected (< 100 µg/L; 0.5 to 1.8% of terbacil) in subsurface waters at 107 cm in "lysimeters" on a field plot with a Oldsmar sand in Florida citrus orchard (05017062, Mansell et al., 1979; 05014421, Mansell et al., 1977)

The Terrestrial Field Dissipation (164-1) data requirement is fulfilled. No additional data are needed at this time.

(5) Spray Drift

No terbacil spray drift-specific studies were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required since the different products may be applied by aircraft and orchard airblast and due to the concern for potential risk to nontarget aquatic organisms. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. Until these data are evaluated, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The rates are 1% of the applied spray volume from ground applications and 5% from aerial and orchard airblast applications at 100 feet downwind. After its review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks from the application of terbacil to nontarget organisms.

c. Water Resources

Terbacil is currently regulated under the Safe Drinking Water Act (SDWA). EPA's Office of Water has not established a Maximum

Contaminant Level (MCL) however it has set Health Advisories (HA's) for terbacil residues in drinking water. The reference dose (RfD) for a 70-kg adult was established at 0.013 mg/kg/day. The one day, ten day and "longer-term" HA for a 10-kg child is 300 µg/l. The "longer-term" HA for a 70-kg adult is 900 µg/l, and the Lifetime HA has been set at 90 µg/l (US EPA, 1996).

(1) Ground Water

Terbacil has the characteristics of compounds known to leach to ground water. (See Environmental Fate Assessment.) Based on the environmental fate data, terbacil exceeds the mobility and persistence triggers for the proposed Restricted Use Classification for ground water concerns. Currently, there are an insufficient number of terbacil detections in ground water to warrant a Restricted Use classification. However, future expansion of the terbacil use areas is expected to increase the potential for terbacil to move into ground water.

(a) Leaching Potential

There are no ground-water monitoring studies which allow an evaluation of the leaching potential of terbacil into ground water. The environmental fate data indicate that terbacil may leach into ground water because of terbacil's persistence and potential mobility. Barrett (1995) concluded from a generic screen of leaching potential that terbacil has a greater leaching potential than other herbicides commonly detected in ground water at numerous locations.

Table 14: Leaching potential of terbacil compared with some major use herbicides

Compound	GUS Scores	Major uses	GW Concerns
terbacil	6.38	mint, apples, alfalfa	Compound
GUS Scores	Major uses	GW Concerns	terbacil
6.38	mint, apples,	Compound	GUS Scores
Major uses	GW Concerns	terbacil	6.38
mint, apples, alfalfa	Compound	GUS Scores	Major uses
GW Concerns	terbacil	6.38	mint, apples,
Compound	GUS Scores	Major uses	GW Concerns
terbacil	6.38	mint, apples, alfalfa	Compound
GUS Scores	Major uses	GW Concerns	terbacil
6.38	mint, apples,	Compound	GUS Scores

A Groundwater Ubiquity Score (GUS) score above 2.8 indicates relatively high leaching potential; a score above 1.8 indicates moderate leaching potential. Median or typical Koc and half-lives were selected to calculate GUS scores. Herbicides in the upper half of this list have been detected in numerous ground-water samples with the exception of newer, ultra-low rate compounds for which little monitoring of any kind has been completed to date. "Yes" indicates a ground-water study has been required to support registration, environmental fate and field studies have shown high leaching potential, or there is evidence of relatively widespread contamination of ground water from past use; "marginal" indicates that some concerns for leaching to ground water have been raised in registration or reregistration but no study to support registration has been conducted; "no" indicates that concerns for leaching to ground water have not been identified.

Table 15: Leaching potential of terbacil compared with herbicides with similar use patterns.

Compound	GUS Scores	Uses
terbacil	6.38	alfalfa, apples, mint, sugarcane
terbacil (best case)	5.32	alfalfa, apples, mint, sugarcane
hexazinone	5.29	alfalfa, sugarcane
metribuzin	4.48	alfalfa, sugarcane
simazine	3.77	alfalfa, apples
ametryn	3.41	sugarcane
asulam	2.84	sugarcane
diuron	2.73	alfalfa, sugarcane, apples
2,4-D	2.70	alfalfa, apples, sugarcane
pendimethalin	0.66	mint, sugarcane
bromoxynil	0.25	alfalfa, mint
trifluralin	0.19	alfalfa, mint, sugarcane

(b) Ground Water Monitoring Data

Based on information from the "Pesticides in Ground Water Database", terbacil has not been detected frequently in ground water (Hoheisel et al., 1992). The monitoring data indicate that terbacil was detected in six wells from a total 288 wells across six states. Terbacil was detected in a well in Oregon at a concentration of 8.9 µg/L and five wells in West Virginia at a concentration range of 0.3 to 1.2 µg/L.

The lack of detections of terbacil in ground water may be associated with the limited geographical extent of the terbacil use area as well as the relatively low total environmental loading compared to other herbicides. Additionally, ground water monitoring data has been reported for areas with no terbacil use. For example, the single largest groundwater monitoring program, as reported in the "Pesticides in Ground Water Database", was conducted in Mississippi. Forty-one percent of the monitoring data were taken from wells in Mississippi. However, terbacil usage data indicate that terbacil is not used in Mississippi (DuPont and Resources for the Future) data. Also, the estimated annual use of terbacil, in terms of pounds of active ingredient, is one tenth to one hundredth of the annual use of herbicides commonly detected in ground water such as atrazine, alachlor, metolachlor, cyanazine, dicamba, metribuzin, and simazine. Another possible reason for the low frequency of detections of terbacil in some ground-water monitoring surveys are high limits of detection for terbacil. In most of the state surveys, the limits of detection for terbacil has been 5 to 100 times higher (*i.e.*, less sensitive) than the limits of detection for widely used herbicides. Barrett (1995) reported that limits of detection for terbacil from the Mississippi and Washington monitoring programs ranged from 3.5 to 4.6 µg/L.

(c) Comparative Leaching Assessment

The PATRIOT model was used to perform a comparative leaching assessment of terbacil relative to a conservative tracer, and other common herbicides. PATRIOT is a program to run Pesticide Root Zone Model - 2 (PRZM). PRZM is a one-dimensional, dynamic, compartmental model that can be used to simulate pesticide movement in unsaturated soil systems within and immediately below the plant root zone.

PATRIOT modeling for terbacil was conducted on representative soils for apple production in New York and Oregon, peaches in Georgia and sugarcane in Louisiana. The leaching of terbacil was then compared to the potential leaching of atrazine and bromide. Atrazine was selected because it is a well characterized corn herbicide and is

known to leach to ground water. Bromide was selected because it is an anion in aqueous environments, resists binding, will move with the water front and is often used as a tracer for ground water research and studies. Additional assumptions and input from the PATRIOT modeling are appended to the end of this document.

Hydrologic Group C soils were used for modeling of apple production in New York and Oregon. These soils are less prone to leaching and have a much higher potential for surface water runoff. PATRIOT modeling predicted that approximately 40% of the terbacil mass applied could leach to shallow ground water (4.5 feet) on the apple use sites. Comparative modeling on the same soils predicted that < 1% of atrazine could leach, while 70-87% of bromide could leach.

Georgia peach production areas were modeled using Hydrologic Group D soils which have the least potential for leaching. PATRIOT modeling predicted that approximately 51% of the applied terbacil could leach to shallow ground water. In comparison, 18% of atrazine could leach, and 59% of bromide could leach.

Ten Louisiana sugarcane soils were selected for modeling with PATRIOT. The PATRIOT database indicates that the Commerce (Aeric Fluvaquent) and Patoutville (Aeric Orchraqualf) soils account the largest acreage of sugarcane in Louisiana. These soils are classified as Hydrologic Group C and were predicted to have a moderate potential to leach. PATRIOT predicted that 47-51% of the applied terbacil would leach to shallow ground water. Several of the lower acreage Group D soils had the highest leaching potential with 64-75% of the terbacil mass predicted to leach. These soils only represent a small portion of the Louisiana sugarcane production area.

Not unexpectedly, leaching is related to the amount of precipitation received. Thus the estimates of the annual leaching of terbacil on Group B, C, and D soils is strongly controlled by the rainfall, which can be highly variable. Calculations are presented as ten year mean values to account for variability in precipitation. Since terbacil is persistent in soil, terbacil will probably accumulate in the

soil and thus the total mass reaching ground water in a particular year may exceed the total mass applied in a given year. The mass of terbacil estimated to leach to ground water for each year ranged from approximately 0 to 125% of the annual application.

PATRIOT modeling was not conducted on Group A soils because Group A soils do not appear to be representative of the terbacil use areas. In addition, no modeling was conducted for mint or alfalfa production because of incomplete usage and soils data.

Figure 1 - Predicted Leaching Using PATRIOT Model (Sugarcane)

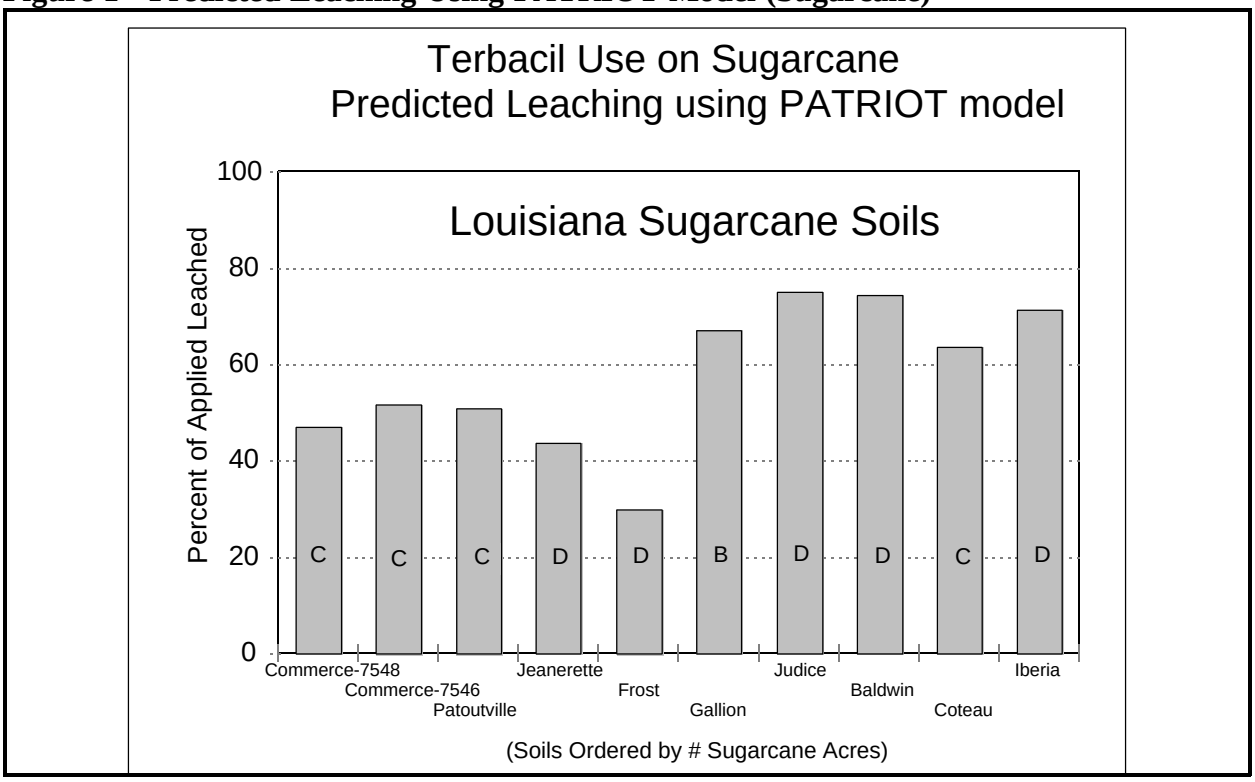
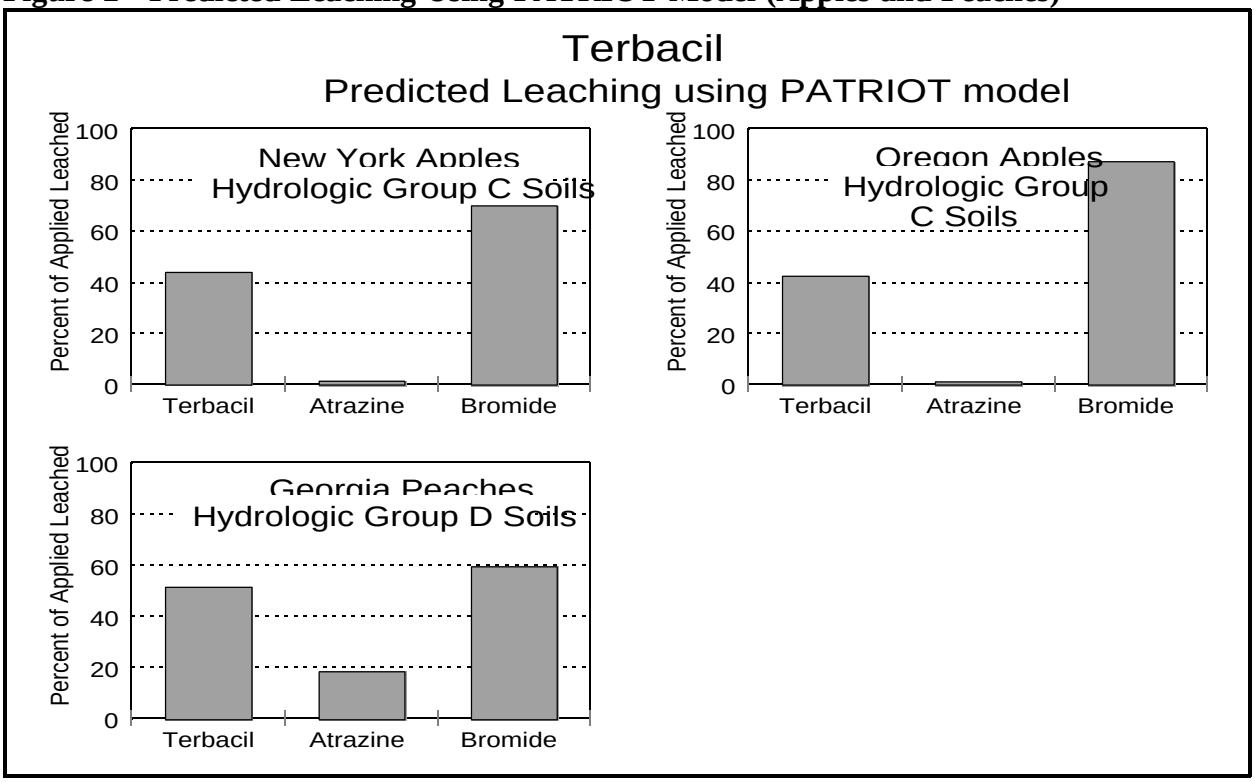


Figure 2 - Predicted Leaching Using PATRIOT Model (Apples and Peaches)



The generic screen (using GUS scores) and PATRIOT modeling results indicate that terbacil has a very high potential to leach into ground water. Since terbacil is used only on minor crops, the impact of terbacil use on ground water is expected to be limited to very localized site specific soil/hydrological conditions. Most of the use areas are Hydrologic Group B soils. Group B soils have moderately high saturated hydraulic conductivity (K_{sat} = 1.417 to 7.0 inches/hour) with deep to very deep groundwater (SCS, 1993). Based on the use pattern and site conditions, the vulnerable ground water areas for terbacil contamination are associated with the mint and sugarcane production areas (Oregon, Washington, northern Illinois and Indiana, Louisiana, and southern Florida). PATRIOT modeling suggest that terbacil could reach shallow ground water at high concentrations in these areas.

(d) "Screening Concentrations In Ground Water" (SCI-GRO)

The Screening Concentrations In Ground Water (SCI-GRO) screening model is based on scaled ground

water concentrations from ground water monitoring studies, environmental fate properties (aerobic soil half-lives and organic carbon partitioning coefficients-Kocs) and application rates.

Results from the SCI-GRO screening model show that the maximum chronic concentration of terbacil in shallow groundwater is not expected to exceed 125 µg/L for the majority of the use sites. Uncertainties in the SCI-GRO are: 1) The screening model does not consider site specific factors regarding hydrology, soil properties, climatic conditions, and agronomic practices; 2) The screening model does not account for volatilization; and 3) Predicted ground water concentrations are linearly extrapolated from the application rates. Drinking water standards for human health are 1.) the childrens HA is 300 µg/l (ppb), 2.)the adult "longer term" HA is 900 ppb, and 3.) the adult lifetime HA is 90 ppb.

Although groundwater screening models indicate terbacil could potentially contaminate shallow ground water near specific use sites, there is a small chance terbacil concentrations in groundwater would exceed EPA's drinking water standards from the current terbacil use patterns. This assessment is based on the fact that terbacil is used in limited use areas on minor crops coupled with relatively low environmental loading. Expanded use of terbacil, especially on major crops, may trigger the need for a small-scale prospective ground water study and surface water monitoring.

(2) Surface Water

Since terbacil is applied as an aerial and ground spray, there is potential for direct spray drift deposition into surface waters adjoining target use sites. The drift potential for aerial and ground spray is assumed to be equivalent to 5% of applied and 1% of applied, respectively. Terbacil is very persistent ($t_{1/2}$ = 653 days) and potentially mobile (K_{oc} = 54 ml/g) in terrestrial environments. The major routes of terbacil dissipation appear to be dependent on microbial-mediated degradation and movement into ground and surface waters. Volatilization is not expected to be a major route of dissipation for terbacil because it has a low vapor pressure (4.80 x 10^{-7} Torr) and low Henry's Constant (1.90 X 10^{-10} atm*m^3/mole) for terbacil. The reported environmental fate data suggest terbacil can be dissolved in runoff waters.

Once in surface water, the dissipation of dissolved terbacil appears to be dependent on photodegradation. The photodegradation half-life for terbacil is 29 days. Photodegradation of terbacil is enhanced in the presence of some photosensitzers. Photodegradation is expected to be a predominant dissipation pathway in clear, shallow waters with long hydrologic residence times. Terbacil is not expected to be found in bottom sediments because it exhibits low soil/sediment sorption affinity (average. K_{oc} = 54 ml/g). No data are available to assess the persistence of terbacil in aquatic environments.

The following data (Table 15) were used for input into the GENEEC and PRZM-EXAMS modeling for terbacil:

Table 15: Data Used for GENEEC and PRZM- EXAMS Modeling

Parameter	Value	Source
soil K_{oc}	54 ml/gl	00155104
Aerobic soil half-life	653 days[2]	42369901
Aerobic aquatic half-life	No available data	
Photolysis Half-life (pH 7)	29 days	Rhodes, 1975
Hydrolysis (pH 7)	Stable	0001946
Water Solubility	710 mg/l	EFGWB One-Liner

[1]Mean Koc
[2]Extrapolated half-life
[3]Photodegradation half-life does not reflect enhanced degradation from photosensitzers.

Table 16: Estimated Environmental Concentrations (EECs) For Aquatic Exposure

Site	Application Method	Application Rate (lbs a.i./A)	Initial (PEAK) EEC(ppb)	21-day average EEC (ppb)	56-day average EEC (ppb)
GENEEC					
Sugarcane, peach, apple, blueberry and Poplar (Kentucky)	ground unincorporated	3.2	154	153	151
Asparagus	ground unincorporated	2.4	115	115	113
Sugarcane	ground unincorporated	2.0	96	95	94
Sugarcane	aerial	2.0	97	96	95
Alfalfa - North East States	ground unincorporated	1.8	86	86	85
Mint, caneberries and Poplar - Washington, Oregon	ground unincorporated	1.6	77	76	75
Mint	aerial	1.6	77	77	76
Alfalfa	ground unincorporated	1.2	58	57	57
Alfalfa	aerial	1.2	58	57	57
Strawberry, Grass seed - Oregon	ground unincorporated	1.0	48	47	47
Grass seed - Washington	ground unincorporated	0.6	28	28	28
Strawberry	ground unincorporated	0.4	19	19	19

Tier 1 GENEEC modeling indicates that terbacil may reach surface waters at concentrations ranging from 19 to 154 µg/L (Table 19). The higher EEC's for terbacil correspond with ground application of terbacil at rates of 3.2 lbs a.i./A/season on sugarcane, apples, peaches, blueberry, and poplar-Kentucky. A more refined Tier II PRZM-EXAMS modeling for sugarcane, peaches, and apples was used for the dietary risk assessment. More refined modeling was not conducted for blueberries and hybrid poplar because they have a limited production area. Tier II surface water modeling was conducted using the following scenarios:

Table 17: Tier II PRZM-EXAMS Modeling Input Parameters

Crop	Location	Weather (MLRA)	Soil	Soil Taxonomy
Peaches	Peach Co., GA	P133A	Boswell sandy loam (D)	Vertic Paleudalf
Sugarcane	Jackson Co., LA	O-134	Commerce silt loam ©	Aeric Fluvaquvent
Apples	Washington Co., OR Columbia Co., NY	A2 144B	Cornelius silt loam © Sharkey clay loam (D)	Mollic Fragixeralf Vertic Haplaquept

( )-Indicates Hydrologic Soil Grouping

The runoff scenarios were conducted using the standard 1:10 ratio farm pond watershed. Conservative runoff simulations were conducted from 1948 to 1983. Actual weather data were used for the 36 year simulation (Burns, et al. 1992). Average annual EECs in the water column were calculated for the peak EEC (immediately after loading), 96 hour EEC, 21 day EEC, 60 day EEC, and 90 day EEC. The runoff simulations were conducted for Hydrologic Group C and D soils. Group C and D soils are considered to be more suspectable to runoff because of lower saturated hydraulic conductivities (K_{sat} < 1.417 inches/hr) and/or high water tables (SCS, 1993). The soil classification for Commerce and Sharkey soils (*e.g.*, aquic moisture regime) indicates the presence of seasonally high water tables. The Environmental Fate Division notes the Sharkey soil classification for the New York apple scenario was derived from an outdated soil survey manual. More recent soil classification indicates the Sharkey soil is found in Mississippi and Louisiana. The soil classification of the Sharkey and Boswell soils (*e.g.*, Vertic subgroup) contain expansive clays (*e.g.*, montorillonite). These soils may have extensive cracks which serve as macropores for by-pass flow conditions. In contrast, soil classification of the Cornelius soil indicates the presence of a fragipan. A fragipan is expected to limit water flow through the soil profile. These specific soil hydrological conditions were not considered in the environmental fate modeling.

PRZM-EXAMS EECs suggest terbacil may accumulate in static surface waters from long-term use. (See below Figure.) Exceedance EECs for terbacil were not calculated because there was residue accumulation in the surface water body with successive annual applications. Instead, the 36 year cumulative peak EECs are reported as the representative upper bound Tier II EECs (Table 2). The PRZM-EXAMS cumulative peak EECs were 63 µg/L (70% of est. HA) for peaches, 1470 µg/L (1500 % of est HA) for sugarcane, 28 µg/L (31% of est. HA) for western apples, and 178 µg/L (198% of est. HA) for eastern apples. Further analysis of the Tier II peak EECs indicate the first year EEC and annual incremental concentration (slope) were 105 and 36 µg/L for LA sugarcane, 24 and 4.3 µg/L for NY apples, 34 and 0.81 µg/L for GA peaches; and 5.2 and 0.52 µg/L for WA apples. The annual incremental concentration was derived from the slope of a linear regression models fit to Tier II peak EECs accumulation over a 36 year computer simulation period. There is uncertainty in the slope estimates for GA peaches and WA apples because of a poor fit of the linear regression models. Results of the simulation suggest that surface water runoff may be an important route of dissipation for terbacil. The model predicted accumulation of terbacil in surface waters may be an artifact of the computer simulation for several reasons: 1.) surface water hydrology of the pond does not account for outflow and/or dilution processes; and 2.) aerobic aquatic metabolism for terbacil was not considered as a route of dissipation.

Table 18: Tier II Maximum PRZM-EXAMS Aquatic Estimated Environmental Concentrations for Terbacil

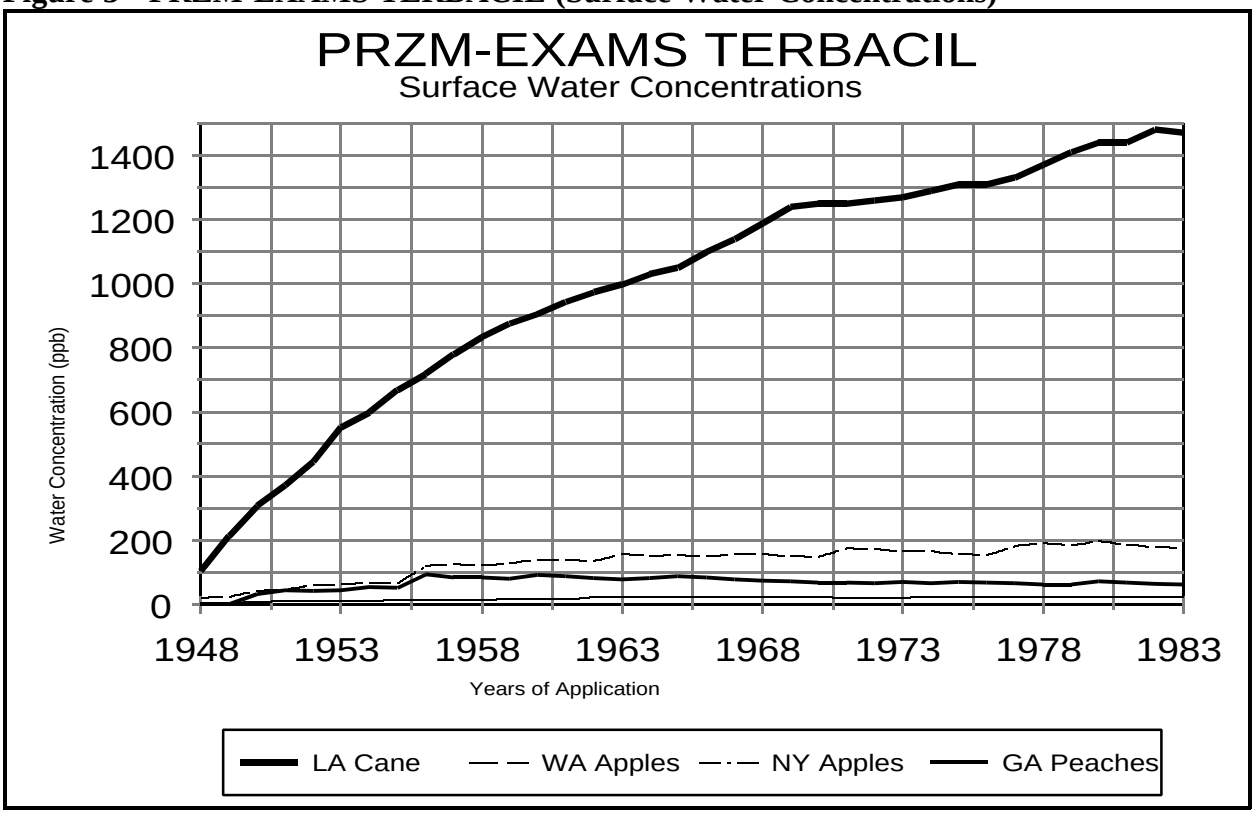
Crop	Location	Rate kg a.i./ha	Peak EEC (ppb)	Day 4 EEC (ppb)	Day 21 EEC (ppb)	Day 56 EEC (ppb)
Peaches	GA	2.554	63	63	63	62
Sugarcane	LA	3.400[a]	1470	1460	1460	1455
Apples	OR NY	2.980 3.400	28 178	28 177	28 176	27 176

[a]Terbacil was applied as split application at 1.70 kg a.i./ha/application or 3.400 kg a.i./ha.

Data from the STORET database indicates that 4790 water samples across 42 states were analyzed for terbacil. No detections of terbacil were reported in the database. The detection limits for terbacil were < 0. 1 µg/L. STORET monitoring data suggest that terbacil is not accumulating in surface waters. Monitoring data in the Louisiana sugar cane production area were from the following

parishes: Cameron, Point Coupee, Madison, West Feliciana, Rapides, and Richland. The 1992 Census of Agriculture indicates that sugarcane production in Louisiana can be found only in Point Coupee Parish (12,583 acres or 4% of production area) and Rapides Parish (2,336 or 0.65% of the production area). GIS analysis of the terbacil use area in Louisiana indicates that Point Coupee is the only parish to overlap the terbacil use area (See attached Figures). The integration of the sugarcane production area and monitoring data suggests STORET monitoring data for terbacil may not be representative of the sugarcane production area. Surface water drinking water facilities on major rivers and bayous are present in the sugarcane production area and serve a total population of 148,200 people (ReachScan, 1991). Activated charcoal filtration is not expected to remove terbacil from surface water because terbacil sorption affinity (expressed as a K_d) does not appear to be dependent on the organic carbon content of soils.

Figure 3 - PRZM-EXAMS TERBACIL (Surface Water Concentrations)



3. Exposure and Risk Characterization

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

RQS are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds) (2) LD_{50} (birds and mammals (3) EC_{50} (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement end point is production of offspring or survival.

Risk presumptions, along with the corresponding RQS and LOCs are tabulated in Table 19 below.

Table 19: Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC_{50} or LD_{50}/sqft or LD_{50}/day[3]	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1

[1]abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{mg/ft^2}{LD_{50} * wt. of bird}$ [3] $\frac{mg of toxicant consumed/day}{LD_{50} * wt. of bird}$

Table 20: Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1]EEC = (ppm or ppb) in water

Table 21: Risk Presumptions for Non-Target Plants

Risk Presumption	RQ	LOC
Terrestrial Plants		
Acute High Risk	EEC[1]/EC25	1
Endangered Species	EEC/EC05 or NOEC	1
Aquatic Plants		
Acute High Risk	EEC[2]/EC_{50}	1
Endangered Species	EEC/EC05 or NOEC	1

[1]EEC = lbs a.i./A

[2]EEC = (ppb/ppm) in water

a. Ecological Exposure and Risk Characterization

(1) Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food

items following product application are compared to LC_{50} values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb a.i./A are tabulated in Table 22 below.

Table 22: Estimated Environmental Concentrations on Avian and Mammalian Food Items

Food Items	EEC (ppm) Predicted Maximum Residue[1]	EEC (ppm) Predicted Mean Residue[1]
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants, and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

[1]Predicted maximum and mean residues are for a 1 lb a.i./a application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

(a) Birds

The acute risk quotients for broadcast applications of nongranular terbacil products are tabulated below.

Table 23: Avian Acute Risk Quotients for Single Application of Nongranular Products (Broadcast) Based on pheasant[1] LC_{50} = 21,141 ppm a.i..

Site/App. Method	App. Rate (lbs a.i./A)	Food Items	Maximum EEC (ppm)	LC_{50} (ppm)	Acute RQ (EEC/LC_{50})
Sugarcane, peach, apple, blueberry. Popular - Kentucky. (ground application)	3.2[2]	Short grass	768	21141	0.04
		Tall grass	352	21141	0.02
		Broadleaf plants/Insects	432	21141	0.02
		Seeds	48	21141	0.00

[1]The LC_{50} for pheasant was used as a toxicity endpoint for birds because pheasant was the only agency approved species with a measurable LC_{50}. All other approved species have greater LC50's when compared to pheasants.
[2]Since the highest rate of application did not exceed any LOC for the level of acute risk, RQ's for lower application rates were not calculated.

There is no acute risk to birds at the highest application rate (3.2 lbs a.i./acre) for terbacil. A chronic risk assessment for birds can not be made because of lack of reproduction data.

(b) Mammals

Estimating the potential for adverse effects to wild mammals is based upon the Environmental Fate's draft 1995 SOP of mammalian risk assessments and methods used by

Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The concentration of Terbacil in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (usually rat LD_{50}) by the % (decimal of) body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC_{50} value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). The acute risk quotients for 3.2 lb a.i./A broadcast application of terbacil are tabulated in Table 24 below.

Table 24 : Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Single Application of Nongranular Products (Broadcast) of Terbacil[2]

Application Rate in lbs a.i./A	Body Weight (g)	% Body Weight Consumed	Rat LD_{50} (mg/kg)	EEC (ppm) Short Grass	EEC (ppm) Forage & Small Insects	EEC (ppm) Large Insects	Acute RQ[2] Short Grass	Acute RQ Forage & Small Insects	Acute RQ Large Insects
3.2[3]	15	95	5000	768	432	48	0.15	0.08	< .0.01
3.2	35	66	5000	768	432	48	0.10	0.06	< .0.01
3.2	1000	15	5000	768	432	48	0.02	0.01	< .0.01

[1]Based on a rat LD_{50} > 5000 mg/kg.

[1]$RQ = \frac{\text{EEC (ppm)}}{LD_{50}\text{ (mg/kg)/ \% Body Weight Consumed}}$

[2]Use sites are Sugarcane, Peach, Apple, Blueberry.

The maximum rate of application (3.2 lb a.i./A) was used for the calculation. Assuming a broadcast application at 3.2 lb a.i./A, the mammalian endangered species levels of concern are exceeded for only mammals that feed on short grass. The chronic risk quotients for broadcast applications of terbacil are tabulated in Table 25 below.

Table 25: Mammalian Chronic Risk Quotients for Terbacil Based on a Rat NOEL > 250 ppm in a 3-generation rat study

Site/Application Method	Application Rate in lbs a.i./A	Food Items	Maximum EEC[1] (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
Sugarcane, peach, apple, blueberry. Popular - Kentucky. (ground application)	3.2	Short grass	768	250	3.07
		Tall grass	352	250	1.41
		Broadleaf plants/Insects	432	250	1.73
		Seeds	48	250	0.19
Asparagus (ground application)	2.4	Short grass	576	250	2.30
		Tall Grass	264	250	1.06
		Broadleaf plants/Insects	324	250	1.30
		Seeds	36	250	0.14
Sugarcane (aerial application)	2.0	Short grass	480	250	1.92
		Tall Grass	220	250	0.88
		Broadleaf plants/Insects	270	250	1.08
		Seeds	30	250	0.12
Alfalfa - north eastern states (ground application)	1.8	Short grass	432	250	1.73
		Tall Grass	198	250	0.79
		Broadleaf plants/Insects	243	250	0.97
Mint, Caneberries, Poplar - Washington and Oregon (aerial and ground application)	1.6	Short grass	384	250	1.54
		Tall Grass	176	250	0.70
		Broadleaf plants/Insects	216	250	0.86
Alfalfa (aerial and ground application)	1.2	Short grass	288	250	1.15
		Tall Grass	132	250	0.53
		Broadleaf plants/Insects	162	250	0.65
Strawberry, Grass Seed - Oregon (ground application)	1.0	Short grass	240	250	0.96

[1]Based on Fletcher without degradation.

The results indicate the mammalian chronic LOC could be exceeded at an application rate of 1.2 lb a.i./A or greater.

(c) Insects

Currently, the Agency does not assess risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions. Labeling precautions are not needed.

(2) Exposure and Risk to Nontarget Aquatic Freshwater Animals

The Agency calculates EECs using the GENeric Expected Environmental Concentration Program (GENEEC). The EECs are

used for assessing acute and chronic risks to aquatic organisms. Acute risk assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day average EECs for invertebrates and 56-day EECs for fish.

(a) Freshwater Fish

For a possible "worst case" scenario for acute risk, a direct application of terbacil to 6 inches of water should result in the highest possible exposure to aquatic organisms from the labeled use of terbacil. The only scenario for direct exposure to water would be from aerial application to alfalfa, mint and sugarcane. A simple dilution of the maximum rate of application for terbacil (3.2 lb a.i./A) to a surface acre of water at 6 inches deep is expected to yield a maximum concentration of 2,316 ppb . Since aerial application is assumed to have a 60% application efficiency, aquatic organisms will be exposed to 1,380 ppb. The lowest LC_{50} for fish is 46.2 ppm for rainbow trout. The risk quotient (RQ) is derived by dividing the exposure (1.4 ppm) by the toxicity value (46.2 ppm). The RQ for freshwater fish is 0.03 which is below the level of concern (LOC) for fish. A chronic risk assessment cannot be completed because of insufficient toxicity data.

(b) Freshwater Invertebrates

For a possible "worst case" scenario for acute risk, a direct application of terbacil to 6 inches of water should result in the highest possible exposure to aquatic organisms from the labeled use of terbacil. The only scenario for direct exposure to water would be from aerial application to alfalfa, mint and sugarcane. A simple dilution of the maximum rate of application for terbacil (3.2 lb a.i./A) to a surface acre of water at 6 inches deep is expected to yield a maximum concentration of 2,316 ppb. Since aerial application is assumed to have a 60% application efficiency, aquatic organisms will be exposed to 1,380 ppb. The lowest LC_{50} for aquatic invertebrates is 65 ppm for *Daphnia magna*. The risk quotient (RQ) is derived by dividing the exposure (1.4 ppm) by the toxicity value (65 ppm). The calculated RQ for freshwater fish is 0.02 which is below the levels of concern (LOC) for aquatic invertebrates. A

complete chronic risk assessment cannot be completed because of insufficient toxicity data.

(c) Estuarine and Marine Animals

In order to estimate risk to estuarine and marine animals, the toxicity values for estuarine/marine animals are compared to the toxicity of freshwater aquatic animals. Estuarine/marine fish is less sensitive to terbacil than the freshwater fish. The estuarine/marine aquatic invertebrates have similar toxicity values to the freshwater invertebrates. Based on the risk quotients for freshwater fish and invertebrates, it is assumed the LOCs will not be exceeded for estuarine/marine animals from the labeled use of terbacil. A chronic risk assessment cannot be completed because of insufficient toxicity data.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Terrestrial plants may be exposed to pesticides from runoff, spray drift or volatilization. Plants in semi-aquatic areas are those that inhabit low-lying wet areas that may be dry at certain times of the year. The Environmental Fate Division's runoff scenario is: (1) based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one inch (2) characterized as "sheet runoff" (one treated acre to an adjacent acre) for terrestrial plants (3) characterized as "channelized runoff" (10 treatedacres to a distant low-lying acre) for semi-aquatic plants and (4) based on % runoff values of 0.01, 0.02, and 0.05 for water solubility of < 10 ppm, 10-100 ppm, and > 100 ppm, respectively. Spray drift exposure from ground application is assumed to be 1% of the application rate. Spray drift from aerial, airblast, forced-air, and chemigation applications is assumed to be 5% of the application rate. EECs are calculated for the following application methods: (1) unincorporated ground applications, (2) incorporated ground application, and (3) aerial, airblast, forced-air, and chemigation applications. Formulae for calculating EECs for terrestrial plants inhabiting areas adjacent to treatment sites and EECs for plants in semi-aquatic areas are in an addendum. Estimated environmental concentrations for

terrestrial and semi-aquatic plants are tabulated in Table 26 below.

Table 26: Estimated Environmental Concentrations (lbs a.i./A) For Terrestrial and Semi-Aquatic Plants for a Single Application

Site/ Application Method/ Rate of Application in lbs a.i./A	Minimum Incorpor. Depth (in)	Runoff Value	Sheet Run-off (lbs a.i./A)	Channelized Runoff (lbs a.i./A)	Drift (lbs a.i./A)	Total Loading to Adjacent Area (Sheet Run-off + Drift)	Total Loading to Semi-aquatic Area (Channel Run-off + Drift)
Sugarcane, peach, apple, blueberry Popular- Kentucky (Unincorporated Ground) 3.2	0	0.05	0.16	1.60	0.03	0.19	1.63
Asparagus (Unincorporated Ground) 2.4	0	0.05	0.12	1.20	0.02	0.14	1.22
Sugarcane (Unincorporated Ground) 2.0	0	0.05	0.10	1.00	0.02	0.12	1.02
Sugarcane (Aerial) 2.0	0	0.05	0.06	0.36	0.10	0.16	0.46
Alfalfa- Northeast States (ground) 1.8	0	0.05	0.09	0.90	0.02	0.11	0.92
Mint, caneberries Poplar- Washington, Oregon (Unincorp. Ground) 1.6	0	0.05	0.08	0.80	0.02	0.10	0.82
Mint (aerial) 1.6	0	0.05	0.05	0.30	0.08	0.13	0.38
Alfalfa (Aerial) 1.2	0	0.05	0.04	0.24	0.06	0.10	0.30
Alfalfa (Unincorporated Ground) 1.2	0	0.05	0.06	0.60	0.01	0.07	0.61
Strawberry (Unincorporated Ground) 1.0	0	0.05	0.05	0.50	0.01	0.06	0.51
Grass Seed- Washington (Ground) 0.6	0	0.05	0.03	0.30	0.01	0.04	0.31
Strawberry (Ground) 0.4	0	0.05	0.02	0.20	0.00	0.02	0.20

The EC_{25} value of the most sensitive species in the seedling emergence study is compared to runoff plus drift exposure to determine the risk quotient (EEC/toxicity value). The EC_{25} value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the acute risk quotient. EECs and acute high risk quotients for terrestrial and semi-aquatic plants based on a single application are tabulated in Table 27 below.

Table 27: Acute High Risk Quotients from a Single Application for Terrestrial and Semi-Aquatic Plants Based On a (rape) Seedling Emergence EC25 of 0.013 lb a.i./A and a (cucumber) Vegetative Vigor EC25 of 0.0022 lb a.i./A

Site, Method and Rate of Application (lbs a.i./A)	Seedling Emergence EC25 (lbs a.i./A)	Vegetative Vigor EC25 (lbs a.i./A)	Drift (lbs a.i./A)	Total Loading to Adjacent Area (Sheet Runoff + Drift)	Total Loading to Semi-aquatic Area (Channel Runoff + Drift)	Runoff RQ Terrestrial Plants	Runoff RQ Semi-Aquatic Plants	Drift RQ Terrestrial and Semi-Aquatic Plants
Sugarcane, peach, apple, blueberry (Ground) 3.2	0.013	0.0022	0.03	0.19	1.63	14.62	125.38	13.64
Asparagus (Ground) 2.4	0.013	0.0022	0.02	0.14	1.22	10.77	93.85	9.09
Sugarcane (Ground) 2.0	0.013	0.0022	0.02	0.12	1.02	9.23	78.46	9.09
Sugarcane (Aerial) 2.0	0.013	0.0022	0.10	0.16	0.46	12.31	35.38	45.45
Alfalfa- Northeast (Ground) 1.8	0.013	0.0022	0.02	0.11	0.92	8.46	70.77	9.09
Mint, caneberries (Ground) 1.6	0.013	0.0022	0.02	0.10	0.82	7.69	63.08	9.09
Mint (Aerial) 1.6	0.013	0.0022	0.08	0.13	0.38	10.00	29.23	36.36
Alfalfa (Aerial) 1.2	0.013	0.0022	0.06	0.10	0.30	7.69	23.08	27.27
Alfalfa (ground) 1.2	0.013	0.0022	0.01	0.07	0.61	5.38	46.92	4.55
Strawberry (ground) 1.0	0.013	0.0022	0.01	0.06	0.51	4.62	39.23	4.55
Grass Seed- Washington (Ground) 0.6	0.013	0.0022	0.01	0.04	0.31	3.08	23.85	4.55
Strawberry (Ground) 0.4	0.013	0.0022	0.00	0.02	0.20	1.54	15.38	0.00

The results indicate that for a single application, acute risk and endangered species levels of concern are exceeded for terrestrial and semi-aquatic plants (including endangered species) for all registered application rates of terbacil. Currently, the Agency does not perform assessments for chronic risk to terrestrial and semi-aquatic plants. The NOEC or EC05 (if NOEC is unavailable) value of the most sensitive species in the seedling emergence study is compared to runoff plus drift exposure to determine the endangered species risk quotient. The NOEC or EC05 value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the endangered species risk quotient. Since the LOCs for non-target plants are exceeded at all rates of application, it is assumed that the labeled use of terbacil may affect endangered species of plants.

(b) Aquatic

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from such uses as aquatic weed or mosquito larvae control. An aquatic plant risk assessment for acute risk is

usually performed for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Non-vascular acute aquatic plant risk assessments are performed using either algae or a diatom, whichever is the most sensitive species. An aquatic plant risk assessment for endangered species is usually performed for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. To date there are no known non-vascular plant species on the endangered species list. Runoff and drift exposure is computed from GENEEC. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC_{50} value. Acute risk quotients for vascular and non-vascular plants are tabulated in Table 28 below.

Table 28: Acute Risk Quotients for Aquatic Plants based upon a duckweed (*Lemna gibba*) EC_{50} of 0.140 ppm a.i. and a nonvascular plant (*Navicula pelliculosa*) EC_{50} of 0.011 ppm a.i.. For endangered species, the *L. gibba* NOEC of 0.065 ppm a.i..

Site/ Application Method/ Rate of application in lbs a.i./A	Species	EC_{50} (ppm)	EEC (ppm)	NOEC (ppm)	Endangered Species RQ EEC/NOEC	Non-target plant RQ (EEC/EC_{50})
Sugarcane, peach, apple, blueberry and Poplar- Kentucky (Ground)	duckweed	0.140	0.154	0.065	2.37	1.10
3.2	algae or diatom	0.011	0.154	-----	-----	14.00
Asparagus (Ground)	duckweed	0.140	0.115	0.065	1.77	0.82
2.4	algae or diatom	0.011	0.115	-----	-----	10.45
Sugarcane (Ground)	duckweed	0.140	0.096	0.065	1.48	0.69
2.0	algae or diatom	0.011	0.096	-----	-----	8.73
Sugarcane (Aerial)	duckweed	0.140	0.095	0.065	1.46	0.68
2.0	algae or diatom	0.011	0.095	-----	-----	8.64
Alfalfa- Northeast (Ground)	duckweed	0.140	0.086	0.065	1.32	0.61
1.8	algae or diatom	0.011	0.086	-----	-----	7.82
Mint, caneberries (Ground) Poplar- Washington, Oregon	duckweed	0.140	0.075	0.065	1.15	0.54
1.6	algae or diatom	0.011	0.075	-----	-----	6.82
Mint (aerial)	duckweed	0.140	0.076	0.065	1.17	0.54
1.6	algae or diatom	0.011	0.076	-----	-----	6.91
Alfalfa (Aerial)	duckweed	0.140	0.056	0.065	0.86	0.40
1.2	algae or diatom	0.011	0.056	------	-----	5.09
Alfalfa (Ground)	duckweed	0.140	0.057	0.065	0.88	0.41
1.2	algae or diatom	0.011	0.057	-----	-----	5.18
Strawberry, Grass Seed - Oregon (Ground)	duckweed	0.140	0.048	0.065	0.74	0.34
1.0	algae or diatom	0.011	0.048	-----	-----	4.36
Grass Seed - Washington (Ground)	duckweed	0.140	0.028	0.065	0.43	0.20
0.6	algae or diatom	0.011	0.028	-----	-----	2.55
Strawberry (Ground)	duckweed	0.140	0.019	0.065	0.29	0.14
0.4	algae or diatom	0.011	0.019	-----	-----	1.73

The LOC for non-target aquatic vascular plants are exceeded at all application levels. The LOC for algae or diatoms are not exceeded at any level of rate of application. The LOC for endangered species of aquatic plants are exceeded at 1.6 lb a.i./A application rate or higher. (Non-vascular endangered species are not known to exist at this time).

(4) Endangered Species

Endangered species LOCs are exceeded for mammals (chronic basis) and non-target terrestrial/ aquatic plants. The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of terbacil will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

b. Water Resources Risk Implication for Human Health

The Agency concludes that terbacil can potentially move into ground and surface waters. However, the fact that terbacil is used exclusively on minor crops with very localized site conditions is expect to limit the potential ecological and human exposure.

(1) Ground Water

In general, the soils in the terbacil use area are classified as Hydrologic Group B soils. However, terbacil use areas with potentially vulnerable groundwater are expected to be associated with mint production in the Pacific Northwest and Midwest (IL and IN) as well as the sugarcane production in Louisiana and southern Florida. The sugarcane production area of Louisiana also has a high concentration of Hydrologic Group C/D soils which are prone to runoff. Additionally, the sugarcane production areas are expected to have GW/SW interactions because of the presence of high water tables.

PATRIOT modeling suggest that terbacil could contaminate very shallow ground water (2.5 to 5 feet) at high concentrations. The SCI-GRO screening model predicts that the maximum chronic concentration of terbacil in shallow groundwater (10-30 feet) is not expected to exceed 125 µg/L for the majority of the use sites.

(2) Surface Water

The water resource assessment for terbacil indicates that terbacil can move into ground and surface waters. The maximum GENEEC EEC for terbacil was 154 µg/L for sugarcane, apples, and peaches at application rates of 3.2 lbs a.i./A.

Tier II surface water assessments were focused on the major productions areas for sugarcane, peaches, and apples. These growing areas are located: 1) Pacific Northwest Region (OR and WA) for apples/peaches ; 2) Mid-Atlantic Region (NY) for apples; 3) southern Piedmont Region (GA) for peaches; and 4) Mississippi River Delta Region (LA) for sugarcane. Tier II surface water assessments indicate that terbacil can potentially accumulate in the "farm pond" runoff scenario. Cumulative 36 year Tier II PRZM-EXAMS concentrations ranged from 28 µg/L for apples in Washington to 1470 µg/L for sugarcane in Louisiana. Further analysis of Tier II EECs indicate the first year EEC and annual incremental concentration (slope) were 105 and 36 µg/L for LA sugarcane; 24 and 4.3 µg/L for NY apples; 0.00 and 0.81 µg/L for GA peaches; and, 5.2 and 0.52 µg/L for WA apples. Predicted terbacil accumulation in the "farm pond" runoff scenario may be high because some potential routes of dissipation (*e.g.*, metabolism, dilution, *etc*.) have not been taken into account in the surface water modeling. Drinking water derived from surface waters is expected have concentrations less than the farm-pond scenario.

4. Environmental Risk Characterization

The risk analysis indicates terbacil is a persistent and potentially mobile herbicide in terrestrial environments. These environmental fate properties also suggest that terbacil can potentially move into both ground and surface waters. The available ground and surface water monitoring data are not representative of the terbacil use area. Hence, estimated environmental concentrations of terbacil are based solely on ground and surface water models.

Tier II surface modeling suggest terbacil may potentially accumulate in surface water at concentrations ranging from 28 to 1470 µg/L. Further analysis of Tier II peak EECs indicate the first year EEC and annual incremental concentration (slope) were 105 and 36 µg/L for LA sugarcane; 24 and 4.3 µg/L for NY apples; 0.0 and 0.81 µg/L for GA peaches; and 5.2 and 0.52 µg/L for WA apples . The annual incremental concentration was derived from the slope of a linear regression models fit to Tier II peak EECs accumulation over a 36 year computer simulation period. The peak ground water concentration, based on the SCI-GRO screening model, is not expected to exceed 125 µg/L.

Minimal adverse acute effects are expected for avian, mammalian, and aquatic species from labeled uses of terbacil. Chronic effects for avian and aquatic species cannot be evaluated at this time because of insufficient data. However, chronic RQs for mammals indicate that adverse effects are possible from labeled uses of terbacil. There is some uncertainty in assessing adverse chronic mammalian effects because the NOEL is greater than the maximum concentration tested in rat reproduction study design. Therefore, the highest concentration is a default toxicity endpoint which is a conservative estimate of risk. Since terbacil is a persistent and mobile herbicide, non-target terrestrial plants are expected to be adversely affected from runoff and spray drift. Minimal adverse effects, however, are expected for non-target aquatic plants. Because terbacil is used exclusively on minor crops, terbacil exposure is expected to be very localized and dependent on site specific conditions. The localized nature of terbacil use areas is expected to limit human and ecological exposure.

Additional data are needed for a complete risk assessment. Chronic toxicity studies (71-4 Avian Reproduction Study ; 72-4 Fish Early Life Stage and Aquatic Invertebrate Life Cycle) are needed to assess chronic risk to avian and aquatic organisms. Wild mammal toxicity study (71-3) is reserved pending a review of avian reproduction studies. Aerobic aquatic metabolism data (162-4) are needed to assess the rates and routes of terbacil dissipation in aquatic environments.

5. Integrated Risk Characterization

Analysis of the use characterization information indicate terbacil is used in localized regions across the United States. These regions have varying potentials for runoff because of the agronomic/ horticultural practices, climatic conditions, and site characteristics. Since terbacil is used exclusively on perennial crops (except sugarcane), a continuous ground cover or minimal soil tillage is expected which should reduce the potential for runoff. Climatic data indicate the range in average precipitation can range from 10 to 70 inches in Washington and Oregon to 45-65 inches in LA. Additionally, soil data indicate the terbacil use areas are predominately Hydrologic Group B soils. Hydrologic Group D soils, however, are a dominate soil type in the sugarcane production area of LA. In comparison

to other terbacil use sites, the runoff potential for terbacil is expected to be greater in the sugarcane production area. Aerial applications of terbacil is limited to mint, alfalfa, and sugarcane. These uses are expected to pose the greatest drift potential of terbacil. Based solely on terbacil use data, approximately one-half of the total terbacil use area is associated with mint production in the Pacific Northwest, Indiana, and Illinois. Since the Pacific Northwest region is a major production area which has relatively low rainfall (east of Cascade Mountains), spray drift of terbacil may be an important route of dissipation in this region (Grant, Yakima, and Adams Counties in Washington ; Crook and Jefferson Counties in Oregon).

Acceptable environmental fate laboratory and field data indicate that terbacil is persistent ($t_{1/2}$ = 653 days) and mobile (K_{oc} = 54 ml/g) in terrestrial environments. The predominant routes of terbacil dissipation are dependent on microbial-mediated degradation, photodegradation in water, and movement into ground and surface waters. Since terbacil is expected to move and potentially accumulate into surface waters, aerobic aquatic metabolism data are needed for a more complete environmental fate assessment.

Ground and surface water modeling indicates that terbacil can potentially move into surface waters and shallow ground water. The available ground and surface water monitoring data cannot be used to estimate terbacil concentrations because it is not representative of the terbacil use areas. Therefore, estimated concentrations are based solely on ground and surface water models. Since terbacil is used exclusively on minor crops with very localized site conditions, the Agency concludes the ground and surface water exposure estimates for terbacil are site specific and, therefore, are not representative of national exposure estimates.

Preliminary surface water modeling indicates that terbacil can move into surface water at high concentrations. The maximum GENEEC EEC for terbacil was 154 µg/L for sugarcane, apples, and peaches at application rates of 3.2 lbs a.i./A. More refined PRZM-EXAMS modeling indicate terbacil may potentially accumulate in the surface water (e.g., "farm-pond") from year to year. Some possible reasons for terbacil accumulation in surface water are as follows: 1.) The "farm-pond" runoff scenario is a static pond with no adjustment for water outflow or dilution; and 2.) Aerobic aquatic metabolism was not considered as a route of dissipation for terbacil in surface water. Since terbacil accumulation in surface water was observed in surface water modeling, a probabilistic assessment of terbacil concentration was not conducted. Instead, the 36 year cumulative PRZM-EXAMS EECs for terbacil were used as the representative EECs for sugarcane, apples, and peaches. The cumulative EECs were 1470 µg/L forsugarcane in LA, 178 µg/L for apples in NY, 28 µg/L for apples in OR, and 63 µg/L for peaches in GA. These EECs are considered to be very conservative because they represent 36 years of a continuous cropping regime.

Since the cumulative EECs represent a 36 year accumulation period, a correction of the cumulative EECs would be needed to determine the annual accumulation. This type of refinement would allow a direct comparison between PRZM-EXAMS and GENEEC EECs. Tier II peak EECs indicate the first year EEC and annual incremental concentration (slope) were 105 and 36 µg/L for LA sugarcane; 24 and 4.3 µg/L for NY apples; 0.0 and 0.81 µg/L for GA peaches; and , 5.2 and 0.52 µg/L for WA apples . The annual incremental concentration was derived from the slope of a linear regression models fit to Tier II peak EECs accumulation over a 36 year computer simulation period. STORET monitoring data also indicate terbacil was not detected in surface water. There is, however, uncertainty in the representativeness (or overlap) of the STORET surface water monitoring data for terbacil use areas. For example, only 5 % of the sugarcane production area in LA is represented by the STORET monitoring data. Therefore, most of the surface water monitoring samples in LA were not collected within the sugarcane production area.

Terbacil exhibits environmental fate properties similar to herbicides commonly detected in ground water. A generic GW vulnerability screen (GUS) and more refined PATRIOT modeling indicate that terbacil has a very high potential to leach into ground water. The GUS comparison score, based solely on persistence and mobility, exceeds the GUS score of most herbicides commonly detected in groundwater (*e.g.*, dicambia, fluometuron, atrazine). Based on ground water vulnerability screening tools, terbacil is expected to be more mobile than most herbicides commonly detected in ground water (*e.g.*, atrazine, dicamba, alachlor). PATRIOT modeling suggest that terbacil could reach shallow ground water (4.5 feet) at high concentrations. SCI-GRO screening model predicts the maximum chronic concentration of terbacil in shallow groundwater (10 to 30 feet) is not expected to exceed 125 µg/L for the majority of the use sites.

Avian species are expected to have minimal acute adverse effects from the labeled uses of terbacil. Since no chronic data are available for avian species, a complete chronic avian toxicity assessment cannot be completed at this time. Avian reproduction studies are necessary because terbacil is a very persistent herbicide which is applied during the avian reproduction season (early spring). Additionally, the RQ for chronic adverse effects to mammals at maximum potential exposure Kenaga values suggest chronic LOC (RQ = 1.0) exceedances may occur. It is generally assumed birds are more sensitive than mammals. Therefore, chronic toxicity data (71-4 Avian Reproduction Study) for bobwhite quail and mallard duck are needed for a more complete chronic toxicity assessment of terbacil.

Minimal acute adverse effects are expected to mammalian species. Since there are no acute LOC exceedances. However there are chronic exceedances for

mammals (including endangered species) feeding on short grasses, tall grasses, broadleaf plants, and insects, at application rates greater than 1.2 lbs a.i./acre.

The chronic LOC's for mammals are uncertain at this time. The rat reproductive study shows the NOEL to be higher than the greatest concentration tested. This concentration is below the maximum and mean predicted residue values (Kenaga/Fletcher) on mammalian food items. Since the rat reproductive endpoint is greater than the highest concentration tested, we must use that concentration level as a default toxic reproductive endpoint. Based on the Agency's assessment, no evidence of carcinogenicity was detected. The mammal's chronic feeding toxicity studies indicate there may be increased liver and thyroid weights at doses between 50 and 250 ppm for dogs, and 1500 ppm for rats. Since birds generally are more sensitive than mammals to pesticides, the wild mammal toxicity study (71-3) will be held in reserve pending the review of avian reproduction studies.

Freshwater aquatic species are expected to have minimal acute adverse effects from labeled terbacil uses. A chronic risk assessment for aquatic species can not be made because of insufficient data. Early fish life cycle and aquatic invertebrate life cycle (72-4) studies are necessary because terbacil is a mobile and persistent herbicide that may accumulate in surface water bodies.

Since estuarine/marine species and freshwater have similar toxicity, minimal adverse effects are expected. Since terbacil is a persistent and mobile herbicide with the potential for accumulation in terrestrial environments, it is anticipated that non-target plants will be exposed to terbacil via runoff. In addition, non-target plants are expected to be exposed to terbacil from spray drift applications on sugarcane, mints, and alfalfa. At all rates of applications, terbacil can adversely effect non-target plants from a combination of runoff and drift. Based on the runoff exposure model, the LOC exceedances for channelized runoff ranges from 15 to 125X. The LOC exceedance for sheet runoff range from 1.5 to 14.6X. The LOC exceedance for spray drift can range from 27.3 to 45.5X and 4.6 to 13.6X for aerial and ground spray application, respectively.

Mitigation options for labeled terbacil uses are associated with rate reductions (reduce rate from maximum rate to typical rate) coupled with label advisories for spray drift, groundwater, and surface water. Table 29 below lists typical terbacil application rates.

Table 29: Typical Terbacil Use Rates

Crop	Use Rate		Applications	
	Maximum	Typical	Maximum	Typical
Alfalfa-Application by Air as well as ground				
U.S.	1 1/2 LB/A/YR	1 to 1 1/2	2	1
NE U.S.	2 1/4 LB/A/YR	1 1/2	2	1-2
SLN'S: (PA, VA)	1/2 LB/A/YR	1/2 LB	2	2
(WA, OR) Seedling Alfalfa	1 1/2 LB/A/YR	1 1/2 LB	1	1
(NM) Aerial Use	1 1/2 LB/A/YR	1 1/2 LB	1	1
(OK)	2 1/4 LB/A/YR	1 1/2-2 LB	2	1-2
Supplemental Aerial Use	1 1/2 LB/A	1 1/2	1	1
Apples, Peaches-Broadcast and Banded	4 LB/A/YR	2-4[a]	1	1
Asparagus-Broadcast	3 LB/A/YR	1.5-2.5[b]	2	1-2
Blueberries-Broadcast and Banded; Ground Only	4 LB/A/YR	2-3 LB	1	1
Caneberries-Broadcast, Ground Only	2 LB/A/YR	2 LB	1	1
Mint-Ground and Air[c]	2 LB/A/YR	2 LB	1	1
Sugarcane-Broadcast and Banded, Ground and Air[c]				
(LA)	4 LB/A/YR	1 1/2-24/10	3	2
(TX)	4 LB/A/YR	1-2 LB	2	2
(HI)	2 1/2 LB/A	1-2 1/2 LB	1	1
(PR)	2 1/2 LB/A	1-2 1/2 LB	1	1
Strawberries-Banded, Ground Only; Recommended by Supplemental Label Only	1/2 lb/A	1/2 LB	1	1
Hybrid Poplars-Banded Ground Only				
SLN'S: (OR, WA)	2 LB/A	2 LB	1	1
Grass Seed-Broadcast; Ground Only; Forage Restriction				
SLN (ID)	1 LB/A	1 LB	1	1
SLN (OR)	1 1/4 LB/A/YR	1 1/4 LB	1	1
SLN (WA-East of Cascades)	1 LB/A/YR	1 LB	1	1

[a]Based on organic matter
[b]A single use application
[c]Aerial use is limited

Since terbacil is persistent and mobile herbicide, terrestrial non-target plants can be adversely impacted from spray drift and runoff at all application rates. Additionally, terbacil exhibits properties of pesticides commonly detected in surface and ground waters. Analysis of the usage data indicate that typical application rates of terbacil are generally lower than the maximum labeled application rates. For example, the typical application rate for sugarcane is approximately one-third of the maximum application rate. Maximum label application rates should be more representative of typical application rates. Standard label advisories for spray drift, ground and surface waters are recommended to alert users of potential environmental impacts from terbacil. Other mitigation factors taken into account are : 1.) the limited

geographical extent of the current terbacil use area and 2.) Labeled terbacil application rates are determined according to the soil organic matter content. These factors are expected to limit potential ground and surface water contamination. However, the use of terbacil on major crops would require a re-evaluation of the water resource assessment. Specifically, expanded use of terbacil may trigger the need for a small-scale prospective ground water study and surface water monitoring.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of terbacil and to determine that terbacil can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing terbacil as the active ingredient are eligible for reregistration. 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 all uses of terbacil are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing terbacil, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient terbacil, the Agency has sufficient information on the health effects of terbacil and on its

potential for causing adverse effects in fish, wildlife, and the environment. The Agency has determined that terbacil products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act of 1996, the Agency has determined that a reasonable certainty of no harm will result to infants and children or to the general population from aggregate exposure to terbacil. Therefore, the Agency concludes that products containing terbacil for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of terbacil are eligible for reregistration subject to conditions imposed in this RED.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for terbacil meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered available information on aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from terbacil and other chemicals with a similar mechanism of toxicity.

Since there are no residential or lawn uses of terbacil, no dermal or inhalation exposure is expected in and around the home.

In assessing acute dietary risk from food, the endpoint selected was developmental toxicity. Because the endpoint of concern is a developmental effect, the only sub-population of concern is females of child-bearing age (i.e., females, 13+ years old).

In assessing chronic dietary risk from food, EPA estimates that terbacil residues in food account for 12.2 % of the RfD, based on existing tolerances and assuming 100% of the crop treated. Incorporating the results of the Agency's reregistration review (i.e., to revoke tolerances for

citrus fruits and pears, and to raise tolerances on caneberries, blueberries, peaches, apples, and sugarcane), 4.5% of the RfD is utilized (using tolerance levels and assuming 100% crop treated).

In assessing aggregate risk, dietary exposures from food and drinking water were considered. Aggregate acute dietary risk for females of child-bearing age was calculated and the MOE = 1563. Acute dietary risk from food alone was calculated for females of child-bearing age and the MOE = 4166, (based on tolerance levels reassessed in this RED and 100% crop treated).

In assessing aggregate chronic dietary risk, exposures from food and drinking water were considered. The aggregate exposures account for 27.6% of the RfD.

In evaluating the potential for cumulative effects, EPA compared terbacil with other structurally similar substituted uracil compounds, such as bromacil and lentacil, and then with other compounds producing similar effects. A comparison of the available toxicological database for terbacil and bromacil revealed no clear common mode of toxicity for the chemicals. The toxicology database for lentacil was not considered because there are currently no registered uses of lentacil. Based on the available data, the Agency has determined that there is no clear common mode of toxicity between terbacil and bromacil.

b. Determination of Safety for Infants and Children

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

In determining whether or not infants and children are particularly susceptible to toxic effects from terbacil residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on current data requirements, terbacil has a complete database for developmental and reproductive toxicity. Because the developmental NOELs were the same as those for maternal toxicity, and

the NOEL for systemic (parental) toxicity was higher than the NOEL for reproductive toxicity, these data do not suggest an increased pre- or post-natal sensitivity of children and infants to terbacil exposure. Therefore,EPA concludes that the available toxicology data do not support an uncertainty factor of 1000 as specified in FQPA and that the present uncertainty factor of 100 is adequate to ensure the protection of infants and children from exposure to terbacil.

EPA estimates that terbacil residues in the diet of infants and children account for 12.8% of the RfD and residues in drinking water account for 81% of the RfD. Thus, the aggregate exposure from all sources of terbacil account for 93.8% of the RfD. Therefore, the Agency concludes that aggregate risks for infants and children resulting from terbacil uses are not of concern.

In deciding to continue to make reregistration determinations during 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 to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and 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 consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Tolerance Reassessment

A summary of the terbacil tolerance reassessment and recommended modifications in commodity definitions is presented in Table 30.

a. Tolerances Listed Under 40 CFR §180.209(a)

Sufficient data are available to ascertain the adequacy of the established tolerances on apples, peaches, and sugarcane. The tolerance on peaches should be increased to 0.2 ppm to reflect the combined limit of detection for terbacil and its three regulated metabolites (each at 0.05 ppm). Tolerances on apples and sugarcane should be increased to 0.3 ppm and 0.4 ppm, respectively, based upon the available residue data. Data

from the apple processing study indicate that tolerances are not required for any regulated processed apple commodity (i.e., apple juice and wet pomace). The tolerance on pears and citrus fruits will be revoked since terbacil is no longer used on these commodities.

b. Tolerances Listed Under 40 CFR §180.209(b)

Sufficient data are available to ascertain the adequacy of the established tolerances on caneberries, blueberries, alfalfa (forage and hay), asparagus, mint, and animal commodities. The tolerance on caneberries and blueberries should be increased to 0.2 ppm to reflect the combined limit of detection for terbacil and its three regulated metabolites (each at 0.05 ppm). Data from the mint processing studies also indicate that a tolerance is not required for mint oil (the only regulated processed commodity of mint). Additional residue data are required for strawberries.

The available data indicate that tolerances on alfalfa forage and hay should be lowered from 5 ppm to 1 and 2 ppm, respectively, and that the tolerance on asparagus should be increased from 0.2 ppm to 0.4 ppm.

The Agency has determined that residues of terbacil in animal commodities will be based on CFR part 180.6(a)(3). There is no likelihood of finite residues of terbacil in animal commodities once tolerances on alfalfa forage and hay are reduced to 1 and 2 ppm, respectively. Once the lower alfalfa tolerances are established, terbacil tolerances on all animal commodities should be revoked.

Tolerances on pecans, and sainfoin should be revoked as uses on these commodities have been canceled.

Table 30: Tolerance Reassessment Summary for Terbacil

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *Correct Commodity Definition*
Tolerances listed under 40 CFR §180.209 (a)[a]:			
Apples	0.1	0.3	The available data indicate that the tolerance should be increased.
Citrus fruits	0.1	Revoke	No registered uses.
Peaches	0.1	0.2	Tolerance should be increased as the combined LOD for residues of concern is 0.2 ppm.
Pears	0.1	Revoke	No registered uses.
Sugarcane	0.1	0.4	The available data indicate that the tolerance should be increased.
Tolerances listed under 40 CFR §180.209 (b)[a]:			
Alfalfa, forage	5.0	1	The available data support lowering the tolerances on alfalfa forage and hay.
Alfalfa, hay	5.0	2	
Asparagus	0.2	0.4	The available data indicate that the tolerance should be increased.
Blueberries	0.1	0.2	If the required data indicate that residues are similar on blueberries and caneberries. The registrant can propose a single tolerance for the *berries crop group*, and separate tolerances on blueberries and caneberries could be revoked.
Caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries)	0.1	0.2	
Cattle, fat	0.1	Revoke	The Agency has determined that terbacil residues in animal commodities will represent a 180.6(a)(3) situation once tolerances on alfalfa forage and hay are reduced to 1 and 2 ppm, respectively. Once the lower alfalfa tolerances are established, terbacil tolerances on all animal commodities should be revoked.
Cattle, mbyp	0.1		
Cattle, meat	0.1		
Goat, fat	0.1		
Goat, mbyp	0.1		
Goat, meat	0.1		
Hogs, fat	0.1		
Hogs, mbyp	0.1		
Hogs, meat	0.1		
Horses, fat	0.1		
Horses, mbyp	0.1		
Horses, meat	0.1		
Milk, fat (=0.1 ppm in whole milk)	0.5		
Mint, hay, peppermint	2.0	2	
Mint, hay, spearmint	2.0	2	
Pecans	0.1	Revoke	No registered uses.
Sainfoin, forage	5.0	Revoke	No registered uses.
Sainfoin, hay	5.0		
Sheep, fat	0.1	Revoke	See above comments under cattle.
Sheep, mbyp	0.1		
Sheep, meat	0.1		
Strawberries		TBD [b]	IR-4 is supporting this use and is currently developing residue data.

[a]Since the Agency is recommending that the tolerance expressions be unified to include Terbacil and Metabolites A, B, and C, these two CFR sections should be combined at the time of tolerance reassessment.
[b]TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

c. Codex Harmonization

No Codex Maximum Residue Limits (MRLs) have been established for terbacil for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

3. Tolerance Revocations and Import Tolerances

Several food/feed uses of terbacil have been voluntarily canceled. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is EPA'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. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/regulation on the grounds that the Agency cannot conclude that the tolerance/regulation is protective of the public's health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation 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 and/or food/feed regulation. 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 and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing terbacil 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 and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public's health.

4. Ecological Effects

Minimal adverse acute effects are expected for avian, mammalian, and aquatic species from labeled uses of terbacil. Chronic effects for avian and aquatic species cannot be evaluated at this time because of insufficient data. However,

chronic RQs for mammals indicate that adverse effects are possible from labeled uses of terbacil. There is some uncertainty in assessing adverse chronic mammalian effects because the NOEL is greater than the maximum concentration tested in rat reproduction study design. Therefore, the highest concentration is a default toxicity endpoint which is a conservative estimate of risk. Since terbacil is a persistent and mobile herbicide, non-target terrestrial plants are expected to be adversely affected from runoff and spray drift. Minimal adverse effects, however, are expected for non-target aquatic plants. Because terbacil is used exclusively on minor crops, terbacil exposure is expected to be very localized and dependent on site specific conditions. The localized nature of terbacil use areas is expected to limit human and ecological exposure.

5. Endangered Species Statement

The Agency has developed a program (the "Endangered Species Protection Program") to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register Notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register Notice. The Agency 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.

6. Surface Water

The Agency recommends a surface water label advisory on terbacil because it has characteristics (persistent and very mobile) of pesticides (e.g. atrazine, etc.) in surface waters. Surface water modeling for a Louisiana sugarcane scenario indicate terbacil may accumulate at concentrations greater than 1 mg/L. Since terbacil is used on vulnerable soils for surface water contamination such as the Louisiana production area, a surface water label advisory is required. The label advisory must state: *"Terbacil has properties that may result in surface water contamination via dissolved runoff and runoff erosion. Practices should be followed to minimize the potential for dissolved runoff and/or runoff erosion."*

7. Ground Water

Terbacil is more mobile and persistent than a number of herbicides which have been found to contaminate ground water. EPA recommended a ground water label advisory be placed on the terbacil label in 1989 and in 1995. The Agency

continues to recommend a ground water label advisory. The following label language is appropriate: *"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."*

Ground and surface water monitoring studies for terbacil are not considered necessary at this time and are placed in reserve. If terbacil use should expand in the future or the use pattern changes significantly, a small-scale prospective study or a limited monitoring program may become necessary. Additionally, a surface water monitoring program may be needed with expanded use on major crops.

8. Occupational Labeling Rationale/Risk Mitigation

a. The Worker Protection Standard (WPS)

The 1992 Worker Protection Standard for Agricultural 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, fiber plants, trees, turfgrass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

All currently registered uses of terbacil are within the scope of the Worker Protection Standard for Agricultural Pesticides.

b. Personal Protective Equipment/Engineering Controls for Handlers

(1) Occupational-Use Products

For each end-use product, PPE/engineering control 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 the result of the acute effects 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 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 or engineering-control 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.

   * The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

The Agency has determined that there are no special toxicological concerns about terbacil to warrant the establishment of active-ingredient-based handler PPE/engineering-control requirements. Handler PPE requirements for terbacil products are to be based on the acute toxicity of individual end-use products.

(2) Homeowner Use Products

There are no homeowner uses registered for terbacil.

c. Post-Application/Entry Restrictions

(1) Restricted Entry Interval

Under the Worker Protection Standard (WPS), interim restricted entry intervals(REIs) for all uses within the scope of the WPS are based on 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: (1) product-specific REIs established on the basis of adequate data, and (2) interim REIs that are longer than those that would be established under the WPS.

The interim WPS REI in effect until now for occupational use products that contain terbacil and are within the scope of the WPS is 12 hours. During the reregistration process EPA found no reason to lengthen the previously established REI.

(2) 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 the requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA determines that no regulatory action must be taken as the result of the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity, skin irritation potential, and eye irritation potential 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.

Terbacil is classified as category IV for acute oral, acute dermal and dermal irritation, and category III for acute inhalation toxicity and for eye irritation. EPA has determined that no regulatory action must be taken due to acute effects or other adverse effects of terbacil. Therefore the PPE required for early entry is the minimum early-entry PPE permitted under the WPS: coveralls, chemical-resistant gloves, shoes and socks.

(3) WPS Double Notification Statement

The WPS double notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. Since neither of these classifications apply to terbacil, double notification is not required for terbacil end-use products.

(4) Entry Restrictions for Occupational-Use Products (Non-WPS Uses)

There are no non-WPS uses registered for terbacil.

d. Other Labeling Requirements

For the specific labeling statements, refer to Section V of this document.

9. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

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 terbacil for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required to be conducted on the generic active ingredient.

- Aerobic Aquatic Metabolism [162-4]
- Avian Reproduction Quail [71-4(a)]
- Avian Reproduction Duck [71-4(b)]
- Early Life-Stage Fish [72-4(a)]
- Life-Cycle Aquatic Invertebrate [72-4(b)]

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) [terrestrial food/feed crops (e.g., apples, mint/peppermint, and sugarcane), forestry (e.g., cottonwood (forest/shelterbelt), terrestrial food (e.g., asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry and strawberry), and terrestrial feed (e.g., alfalfa, sainfoin (hay and fodder), and forage)] being supported by MP registrant."

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

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

Other labeling requirements include:

(a) Maximum label application rates should be reduced to be representative of typical application rates. Table 31 below lists typical terbacil application rates.

Table 31: Typical Terbacil Use Rates

Crop	Use Rate		Applications	
	Maximum	**Typical**	**Maximum**	**Typical**
Alfalfa-Application by Air as well as ground				
U.S.	1 1/2 LB/A/YR	1 to 1 1/2	2	1
NE U.S.	2 1/4 LB/A/YR	1 1/2	2	1-2
SLN'S: (PA, VA)	1/2 LB/A/YR	1/2 LB	2	2
(WA, OR) Seedling Alfalfa	1 1/2 LB/A/YR	1 1/2 LB	1	1
(NM) Aerial Use	1 1/2 LB/A/YR	1 1/2 LB	1	1
(OK)	2 1/4 LB/A/YR	1 1/2-2 LB	2	1-2
Supplemental Aerial Use	1 1/2 LB/A	1 1/2	1	1
Apples, Peaches-Broadcast and Banded	4 LB/A/YR	2-4[a]	1	1
Asparagus-Broadcast	3 LB/A/YR	1.5-2.5[b]	2	1-2
Blueberries-Broadcast and Banded; Ground Only	4 LB/A/YR	2-3 LB	1	1
Caneberries-Broadcast, Ground Only	2 LB/A/YR	2 LB	1	1
Mint-Ground and Air[c]	2 LB/A/YR	2 LB	1	1
Sugarcane-Broadcast and Banded, Ground and Air[c]				
(LA)	4 LB/A/YR	1 1/2-24/10	3	2
(TX)	4 LB/A/YR	1-2 LB	2	2
(HI)	2 1/2 LB/A	1-2 1/2 LB	1	1
(PR)	2 1/2 LB/A	1-2 1/2 LB	1	1
Strawberries-Banded, Ground Only; Recommended by Supplemental Label Only	1/2 lb/A	1/2 LB	1	1
Hybrid Poplars-Banded Ground Only				
SLN'S: (OR, WA)	2 LB/A	2 LB	1	1
Grass Seed-Broadcast; Ground Only; Forage Restriction				
SLN (ID)	1 LB/A	1 LB	1	1
SLN (OR)	1 1/4 LB/A/YR	1 1/4 LB	1	1
SLN (WA-East of Cascades)	1 LB/A/YR	1 LB	1	1

[a]Based on organic matter
[b]A single use application
[c]Aerial use is limited

(b) "Terbacil has properties that may result in surface water contamination via dissolved runoff and runoff erosion. Practices

should be followed to minimize the potential for dissolved runoff and/or runoff erosion."

(c) "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. 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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria 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. PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain terbacil, the product labeling must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain terbacil, the handler personal protective equipment requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

a. Minimum PPE/Engineering Control Requirements

EPA is not establishing active ingredient-specific PPE or engineering control requirements for terbacil end-use products.

b. Actual end-use product PPE requirements

Any necessary PPE for each terbacil occupational end-use product will be established on the basis of the end-use product's acute toxicity category.

c. 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.

3. Entry Restrictions

For sole-active-ingredient end-use products that contain terbacil the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain terbacil the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

a. Restricted-entry interval

A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all terbacil end-use products.

b. Early-entry personal protective equipment (PPE)

The PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls over short-sleeve shirt and short pants
- Chemical-resistant gloves
- Shoes and socks

c. 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.

4. Spray Drift Labeling

The following aerial drift reduction advisory information must be contained in the product labeling:

AERIAL SPRAY DRIFT MANAGEMENT

Avoiding Spray Drift at the Application Site is the Responsibility of the Applicator.

The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory.

5. Other Labeling Requirements

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

Application Restrictions:

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

User Safety Requirements:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables,

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. As soon as possible, wash thoroughly and change into clean clothing."

Engineering Controls:

"When handlers use closed systems, or 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."

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

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

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

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

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

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

BOOM LENGTH

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

APPLICATION HEIGHT

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

SWATH ADJUSTMENT

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

WIND

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

TEMPERATURE AND HUMIDITY

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

TEMPERATURE INVERSIONS

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

SENSITIVE AREAS

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

6. Existing Stocks

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

The Agency has determined that registrants may distribute and sell terbacil products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than 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 stock requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
ALFALFA			Use Group: TERRESTRIAL FEED CROP										
Broadcast, Dormant, Boom sprayer	WP	NA	1.2 lb A .6 lb A	F C	2	NS	1.8 lb	NS	60	12 h	001 Geo.013: Do not use in California south of Interstate 80.	013	C46, CAU, CCB
Broadcast, Dormant, Ground	WP	NA	.4 lb A .264 lb A	F C	NS	NS	NS	NS	NS	12 h	OR		CAU, CCB
	WP	NA	.4 lb A .264 lb A	F C	NS	NS	NS	NS	NS	12 h	WA		CAU, CCB
Broadcast, Dormant, Sprayer	WP	NA	.6 lb A .4 lb A	F C	2	NS	1.8 lb	NS	60	NS	OK		
Broadcast, Early postemergence, Boom sprayer	WP	NA	1.2 lb A .6 lb A	F C	2	NS	1.8 lb	NS	60	12 h	001 Geo.013: Do not use in California south of Interstate 80.	013	C46, CAU, CCB
Broadcast, Early postemergence, Ground	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	PA		
	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	VA		
Broadcast, Post-final harvest, Boom sprayer	WP	NA	1.2 lb A .4 lb A	F C	1	NS	NS	NS	NS	12 h	013, 001 Geo.013: Do not use in California south of Interstate 80.		C46, CAU, CCB
Broadcast, Post-final harvest, Ground	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	PA		
	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	VA		
Broadcast, Postemergence, Ground	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	PA		
	WP	NA	.4 lb A	*	NS	NS	NS	NS	NS	NS	VA		
Broadcast, Postharvest, Sprayer	WP	NA	.6 lb A .4 lb A	F C	2	NS	1.8 lb	NS	60	NS	OK		
Broadcast, Preemergence, Aircraft	WP	NA	1.2 lb A .4 lb A	F C	1	NS	NS	NS	NS	12 h	013, 001 Geo.013: Do not use in California south of Interstate 80.		C46, CAU, CCB

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USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
ALFALFA (con't)			Use Group: TERRESTRIAL FEED CROP (con't)									
Broadcast, Preemergence, Boom sprayer	WP	NA	1.2 lb A .4 lb A	F C	1 Geo.013: See above	NS	NS	NS	NS	12 h	013, 001	C46, CAU, CCB
Broadcast, Stubble, Boom sprayer	WP	NA	1.2 lb A .6 lb A	F C	2 Geo.013: See above	NS	1.8 lb	NS	60	12 h	001 013	C46, CAU, CCB
APPLE			Use Group: TERRESTRIAL FOOD+FEED CROP									
Band treatment, Postharvest, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS		NS	NS	12 h		C46, CAU, CCB, GI6
Band treatment, Spring, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS		NS	NS	12 h		C46, CAU, CCB, GI6
Directed spray, Postharvest, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS		NS	NS	12 h		C46, CAU, CCB, GI6
Directed spray, Spring, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS		NS	NS	12 h		C46, CAU, CCB, GI6
ASPARAGUS			Use Group: TERRESTRIAL FOOD CROP									
Broadcast, Postharvest, Boom sprayer	WP	NA	2.4 lb A 1.2 lb A	F C	NS 2/1 yr	2.4 lb		NS	NS	12 h		C46, CAU, CCB, H01(5)
Broadcast, Postplant, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS		NS	NS	12 h		C46, CAU, CCB, H01(5)
Broadcast, Preemergence, Boom sprayer	WP	NA	2.4 lb A 1.2 lb A	F C	NS 2/1 yr	2.4 lb		NS	NS	12 h		C46, CAU, CCB, H01(5)

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USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
BLACKBERRY			Use Group: TERRESTRIAL FOOD CROP								
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)
BLUEBERRY			Use Group: TERRESTRIAL FOOD CROP								
Soil band treatment, Postharvest, Boom sprayer	WP	NA	3.2 lb A 3.2 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB
Soil band treatment, Spring, Boom sprayer	WP	NA	3.2 lb A 3.2 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB
Soil broadcast treatment, Postharvest, Boom sprayer	WP	NA	3.2 lb A 3.2 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB
Soil broadcast treatment, Spring, Boom sprayer	WP	NA	3.2 lb A 3.2 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB
BOYSENBERRY			Use Group: TERRESTRIAL FOOD CROP								
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS 12 h			C46, CAU, CCB, H01(70)

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USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
BOYSENBERRY (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
DEWBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
GRASS FORAGE/FODDER/HAY			Use Group: TERRESTRIAL FEED CROP										
Broadcast, Postharvest, Boom sprayer	WP	NA	.8 lb A .6 lb A .6 lb A	F M C	NS	NS	NS	NS	NS	NS	ID		C14, GF9
	WP	NA	1 lb A .6 lb A .6 lb A	F M C	NS	NS	NS	NS	NS	NS	OR		C14, GF9
	WP	NA	.8 lb A .6 lb A .6 lb A	F M C	NS	NS	NS	NS	NS	NS	WA		C14, GF9
LOGANBERRY			Use Group: TERRESTRIAL FOOD CROP										

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USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
LOGANBERRY (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)								
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
MINT/PEPPERMINT/SPEARMINT			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Postemergence, Boom sprayer	WP	NA	1.2 lb A .8 lb A	F C	NS NS	1.6 lb	NS	NS	12 h		C46, CAU, CCB, H01(60)
Broadcast, Preemergence, Aircraft	WP	NA	1.6 lb A .8 lb A	F C	1 NS	1.6 lb	NS	NS	12 h		C46, CAU, CCB, H01(60)
Broadcast, Preemergence, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	1 NS	1.6 lb	NS	NS	12 h		C46, CAU, CCB, H01(60)
PEACH			Use Group: TERRESTRIAL FOOD CROP								
Band treatment, Postharvest, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, GI6
Band treatment, Spring, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, GI6
Directed spray, Postharvest, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, GI6

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]

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USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
PEACH (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)									
Directed spray, Spring, Boom sprayer	WP	NA	3.2 lb A 2.8 lb A 2.4 lb A	F M C	NS 1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, GI6
RASPBERRY (BLACK, RED)			Use Group: TERRESTRIAL FOOD CROP									
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS 1/1 yr	NS	NS	NS	12 h			C46, CAU, CCB, H01(70)
SUGARCANE			Use Group: TERRESTRIAL FOOD+FEED CROP									
Band treatment, Preemergence, Boom sprayer	WP	NA	1.6 lb A	*	NS NS	NS	NS	NS	12 h	LA, TX		C46, CAU, CCB
Band treatment, Spring, Boom sprayer	WP	NA	3.2 lb A	*	NS NS	NS	NS	NS	12 h	LA		C46, CAU, CCB
Broadcast, Preemergence, Aircraft	WP	NA	2 lb A .8 lb A	F C	NS NS	NS	NS	NS	12 h	HI, PR		C46, CAU, CCB
Broadcast, Preemergence, Boom sprayer	WP	NA	2 lb A .8 lb A	F C	NS NS	NS	NS	NS	12 h	HI, PR		C46, CAU, CCB
Broadcast, Spring, Boom sprayer	WP	NA	3.2 lb A	*	NS NS	NS	NS	NS	12 h	LA		C46, CAU, CCB
Directed spray, Layby, Boom sprayer	WP	NA	.4 lb A	*	NS NS	NS	NS	NS	12 h	LA		C46, CAU, CCB

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Case 0039 [Terbacil] Chemical 012701 [Terbacil]

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USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
YOUNGBERRY			Use Group: TERRESTRIAL FOOD CROP									
Soil band treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil band treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil broadcast treatment, Early spring, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
Soil broadcast treatment, Fall, Boom sprayer	WP	NA	1.6 lb A .8 lb A	F C	NS	1/1 yr	NS	NS	NS	12 h		C46, CAU, CCB, H01(70)
NON-FOOD/NON-FEED												
ASH (FOREST/SHELTERBELT)			Use Group: FORESTRY									
Band treatment, Dormant, Band sprayer	WP	NA	3.2 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS	KY	
Broadcast, Dormant, Boom sprayer	WP	NA	3.2 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS	KY	
COTTONWOOD (FOREST/SHELTERBELT)			Use Group: FORESTRY									
Band treatment, Dormant, Band sprayer	WP	NA	3.2 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS	KY	
Broadcast, Dormant, Boom sprayer	WP	NA	3.2 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS	KY	

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]

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USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
COTTONWOOD (FOREST/SHELTERBELT) (con't)			Use Group: FORESTRY (con't)									
Broadcast, Dormant, Sprayer	WP	NA	1.6 lb A 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	NS	WA	C46
Broadcast, Postplant, Sprayer	WP	NA	1.6 lb A 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	NS	WA	C46
Broadcast, Preplant, Sprayer	WP	NA	1.6 lb A 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	NS	WA	C46
Directed spray, Delayed dormant, Sprayer	WP	NA	1.6 lb A 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	NS	WA	C46
POPLAR (FOREST/SHELTERBELT)			Use Group: FORESTRY									
Broadcast, Dormant, Boom sprayer	WP	NA	UC 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	12 h	OR	C46, CAU, CCB
Soil treatment, Postplant, Boom sprayer	WP	NA	UC 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	12 h	OR	C46, CAU, CCB
Soil treatment, Preplant, Boom sprayer	WP	NA	UC 1.6 lb A 1.2 lb A	F M C	NS	NS	NS	NS	NS	12 h	OR	C46, CAU, CCB
SYCAMORE (FOREST)			Use Group: FORESTRY									
Band treatment, Dormant, Band sprayer	WP	NA	3.2 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS	KY	

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
SYCAMORE (FOREST) (con't)			Use Group: FORESTRY (con't)									
Broadcast, Dormant, Boom sprayer	WP	NA	3.2 lb A	F	NS	NS	NS	NS	NS	NS	KY	
			2.4 lb A	M								
			1.6 lb A	C								

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

LEGEND
444444

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

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

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
WP : WETTABLE POWDER

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

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C14 : Grown for seed only.

APPENDIX A REPORT

Case 0039 [Terbacil] Chemical 012701 [Terbacil]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

USE LIMITATIONS CODES (Cont.)
C46 : Do not apply through any type of irrigation system.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

CCB : Rotational/plant back crop restriction.
GF9 : Do not graze treated crop or allow hay, seeds or seed screenings from treated crop to be used for food or feed.
GI6 : Do not graze or feed forage or hay from treated areas to livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
001 : Northeast
013 : Other
HI : Hawaii
ID : Idaho
KY : Kentucky
LA : Louisiana
OK : Oklahoma
OR : Oregon
PA : Pennsylvania
PR : Puerto Rico
TX : Texas
VA : Virginia
WA : Washington

REENTRY INTERVAL ABBREVIATIONS
h   : hour(s)

UNIT DESCRIPTIONS
A   : acre
lb   : pound

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of TERBACIL

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-2A	Start. Mat. & Mnfg. Process	ALL	42199001, 00012366, 00142302
61-2B	Formation of Impurities	ALL	42199001, 00012366
62-1	Preliminary Analysis	ALL	00012364, 00067336, 00142302
63-2	Color	ALL	00011958
63-3	Physical State	ALL	00011958
63-4	Odor	ALL	00011958
63-5	Melting Point	ALL	00011958
63-7	Density	ALL	42335302, 00011958
63-8	Solubility	ALL	00011958
63-9	Vapor Pressure	ALL	42335303, 00011958
63-11	Octanol/Water Partition	ALL	00125692
63-12	pH	ALL	42335302
63-13	Stability	ALL	42335301
63-17	Storage stability	ALL	42335301
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	00157177
71-2A	Avian Dietary - Quail	ALL	00012346, 00012347, 241146
72-1A	Fish Toxicity Bluegill	ALL	00390019, 00025224
72-1C	Fish Toxicity Rainbow Trout	ALL	00390017, 00025223, 44150201
72-2A	Invertebrate Toxicity	ALL	00390018, 249455, 125705
72-3A	Estuarine/Marine Toxicity - Fish	AB	41896101, 41896100

Data Supporting Guideline Requirements for the Reregistration of TERBACIL

REQUIREMENT		USE PATTERN	CITATION(S)
72-3B	**Estuarine/Marine Toxicity - Mollusk**	**AB**	**00012332, 00012333**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	**AB**	**00012332**
123-1A	**Seed Germination/Seedling Emergence**	**ALL**	**43895801, 42336701**
123-1B	**Vegetative Vigor**	**ALL**	**43895801, 42336701**
123-2	**Aquatic Plant Growth**	**ALL**	**43929802, 43909802, 42306101, 43929801**
141-1	**Honey Bee Acute Contact**	**AB**	**00018842**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	**ALL**	**00150946, 114693, 24955**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**ALL**	**00130945, 114693, 24955**
81-3	**Acute Inhalation Toxicity - Rat**	**ALL**	**00125700**
81-4	**Primary Eye Irritation - Rabbit**	**ALL**	**00157179**
81-6	**Dermal Sensitization - Guinea Pig**	**ALL**	**00157180**
82-1A	**90-Day Feeding - Rodent**	**ALL**	**00068035, 00039009**
82-1B	**90-Day Feeding - Non-rodent**	**ALL**	**00060851**
82-2	**21-Day Dermal - Rabbit/Rat**	**ALL**	**00125785, 00148006**
83-1A	**Chronic Feeding Toxicity - Rodent**	**AB**	**42987601**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	**AB**	**00060851**
83-2A	**Oncogenicity - Rat**	**AB**	**42987601**

Data Supporting Guideline Requirements for the Reregistration of TERBACIL

REQUIREMENT		USE PATTERN	CITATION(S)
83-2B	**Oncogenicity - Mouse**	**AB**	**42031601, 00126770**
83-3A	**Developmental Toxicity - Rat**	**ALL**	**00050467, 00039001**
83-3B	**Developmental Toxicity - Rabbit**	**ALL**	**00150945**
83-4	**2-Generation Reproduction - Rat**	**ALL**	**00060852**
84-2A	**Gene Mutation (Ames Test)**	**ALL**	**00155103, 00150943**
84-2B	**Structural Chromosomal Aberration**	**ALL**	**00157181, 00150944**
84-4	**Other Genotoxic Effects**	**ALL**	**00150939, 00155103**
85-1	**General Metabolism**	**AB**	**40104702**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	**ALL**	**0001946, 41136301**
161-2	**Photodegradation - Water**	**ALL**	**00011946**
161-3	**Photodegradation - Soil**	**ALL**	**001600235**
162-1	**Aerobic Soil Metabolism**	**ALL**	**05024336, 05013204, 05016176, 42369901**
162-2	**Anaerobic Soil Metabolism**	**ALL**	**42370001, 05024336, 05013204, 05016176**
163-1	**Leaching/Adsorption/Desorption**	**ALL**	**05013202, 42335401, 00155104, 05014424, 05008371, 05014175**
164-1	**Terrestrial Field Dissipation**	**ALL**	**43585500, 05017062, 05014421**
165-2	**Field Rotational Crop**	**AB**	**42369901**
165-4	**Bioaccumulation in Fish**	**ALL**	**00011947**

Data Supporting Guideline Requirements for the Reregistration of TERBACIL

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	ALL	44080101, 43909801, 00011965, 00012014, 05002415, 05013194, 05013216, 05013598
171-4B	Nature of Residue - Livestock	ALL	42809401, 42717101, 00011950, 00011957
171-4C	Residue Analytical Method - Plants	ALL	42740301, 42740302, 42740303, 42740304, 42465202
171-4E	Storage Stability	ALL	00011952,00150369, 42885201
	Nongrass Animal Feeds		
	-Alfalfa forage & hay	AB	00011959, 00130415, 00144089, 00149202, 42335601
	Pome Fruits Group		
	-Apples	AB	44048901, 00070784, 00012015, 00012402, 00149184, 00157178
	Miscillaneous Commodities		
	-Asparagus	AB	00028524, 42465201
	-Mint hay/Peppermint	AB	00012067, 00012103, 42335501
	-Surgarcane	AB	00012179, 00012180, 00157178, 44048903
	Berries Group		
	-Blueberries	AB	00012039, 05013352, 44177101
	-Caneberries	AB	05015405, 00390015, 44177102
	-Strawberries	AB	00012097
	Stone Fruits		
	-Peaches	AB	00012402, 00128574, 00149184

Data Supporting Guideline Requirements for the Reregistration of TERBACIL

REQUIREMENT		USE PATTERN	CITATION(S)
	Grass Grown Soley for Seed		
	-Grass Forage/Fodder/Hay	**AB**	**42692501**
171-4L	**Processed Food**		
	-Apples	**AB**	**00012067, 44048902**
	-Mint	**AB**	**00012067, 00012103, 42345201**
	-Sugarcane	**AB**	**00012179, 00012180, 44048904**

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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MRID	CITATION
00003401	Gessert, R. (EPA Memorandum to R. Taylor) re: upgrading of data from 3-generation rat reproductive study. January 20, 1983.
00011946	Rhodes, R.C. (1975) Biodegradation Studies with 2-14C-Terbacil in Water and Soil. (Unpublished study received Nov 25, 1975 under 4F1428; prepared in cooperation with Univ. of Delaware, College of Agricultural Sciences, submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-A)
00011947	Rhodes, R.C. (1969?) Four Week Residue Studies with 2-14C-Terbacil and Bluegill Sunfish. (Unpublished study received Nov 25, 1975 under 4F1428; prepared in cooperation with Cannon Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-B)
00011950	Han, J.C. (1973?) 2-14C-Terbacil Goat Metabolism Study. (Unpublished study received Oct 1, 1974 under 4F1428, submitted by E. I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093805-B)
00011965	Rhodes, R.C. (1964?) Studies with 14C-Labeled Terbacil in Alfalfa. (Unpublished study received Aug 30, 1973 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093806-J)
00012015	E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. (Unpublished study received Dec 13, 1966 under 6F0510; CDL:090603-N)
00012039	IR-4 Project at Rutgers, the State University (1973) Results of Tests on the Amount of Residue Remaining on Treated Blueberries: (Terbacil). (Unpublished study received Dec 19, 1975 under 6E1719; prepared in cooperation with DuPont Co.; CDL:095364-A)
00012067	E.I. du Pont de Nemours & Company (1975) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. (Unpublished study received Dec 3, 1975 under 6F1713; CDL:095184-C)
00012097	IR-4 Project at Rutgers, the State University (1972) Analytical Residues: (Terbacil). (Unpublished study received Mar 14, 1977 under 7E1936; CDL:097354-A)

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MRID	CITATION
00012103	E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: [Terbacil]. (Unpublished study received Nov 16, 1966 under 7F0549; CDL:092838-B)
00012179	E.I. du Pont de Nemours and Company (1966) Sinbar Weed Killer Residue Data--Sugar Cane: Supplemental Information. (Unpublished study received Apr 13, 1966 under unknown admin. no.; CDL:124198-A)
00012180	E.I. du Pont de Nemours and Company (1966) Sinbar Weed Killer (3- ~ µtertµ ~ -Butyl-5-chloro-6-methyluracil) Residue Data--Sugar Cane. (Unpublished study received Feb 9, 1966 under unknown admin. no.; CDL:124200-A)
00012332	Bentley, R.E. (1973) Bioassay Report Submitted to E.I. du Pont de Nemours & Co.: Sinbar Terbacil Weed Killer, 80% Wettable Powder: Acute Toxicity of H-8309 to Grass Shrimp (µ ~ Palaemonetes vul ~ µ-µ ~ garisµ ~) and Fiddler Crab (µ ~ Uca pugilatorµ ~). (Unpublished study received Apr 11, 1974 under 352-17; prepared by Bionomics, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:129203-B)
00012333	Bentley, R.E. (1973) Bioassay Report Submitted to E.I. du Pont de Nemours & Company, Newark, Delaware: Sinbar Terbacil Weed Killer, 80% Wettable Powder: Acute Toxicity of H-8309 to Atlantic Oyster (µ ~ Crassostrea virginicaµ ~). (Unpublished study received Apr 11, 1974 under 352-317; prepared by Bionomics, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:129203-C)
00012346	Wazeter, F.X.; Buller, R.H.; Geil, R.G. (1966) Acute Toxicity in Wildfowl (Pheasant Chick). (Unpublished study received on Jan 11, 1978 under 352-317; prepared by International Research and Development Corp., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:096709-B)
00012347	Wazeter, F.X.; Buller, R.H.; Geil, R.G. (1966) Acute Toxicity in Wildfowl (Pekin Duckling). (Unpublished study received on Jan 11, 1978 under 352-317; prepared by International Research and Development Corp., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:096709-C)

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MRID	CITATION
00012364	E.I. du Pont de Nemours and Company (19??) Composition of Technical Terbacil: Active Ingredient in Sinbar Weed Killer. (Unpublished study received Nov 7, 1978 under 352-317; CDL:235690-A)
00012366	E.I. duPont de Nemours and Company (19??) Purity of Starting and Intermediate Materials Used in the Terbacil Manufacturing Process. (Unpublished study received Nov 7, 1978 under 352-317; CDL: 235690-C)
00012402	E.I. du Pont de Nemours & Company (1973) Data Supporting the Use of Zobar® Weed Killer in Established Apples and Peaches. Summary of studies 026721-B through 026721-Y. (Unpublished study received Oct 17, 1973 under 352-374; CDL:026721-A)
00013286	Yamane, G.M. (1968) Crop Tolerance for Hyvar X, DuPont 732, and DuPont 767 Experimental Herbicides. (Unpublished study received Mar 24, 1970 under 352-287; prepared by Pineapple Research Institute, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:00 E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:026721-X)
00012424	Ratto, D.B. (1972) To Test Zobar I & Zobar 21 for Weed Control in Apples. (Unpublished study received Oct 17, 1973 under 352-374; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:026721-Y)
00013287	Yamane, G.M. (1968) Crop Tolerance for Hyvar X, DuPont 732, and DuPont 767 Experimental Herbicides. (Unpublished study including incomplete letter dated Jan 4, 1967 from G.M. Yamane to Wayne D. Grogg and letter dated Jul 29, 1968 from M.F. O'Brien to Don L. Burgoyne, received Mar 24, 1970 under 352-287; prepared by Pineapple Research Institute in cooperation with Dole Co. and Hawaiian Fruitpackers, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:002922-I)
00013288	Yamane, G.M. (1968) Soil Persistency of Hyvar X. Rev. (Unpublished study including letter dated May 3, 1968 from D.L. Burgoyne to H.L. Pease, received Mar 24, 1970 under 352-287; prepared by Pineapple Research Institute, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:002922-K)

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MRID	CITATION
00017711	Liu, L.C.; Cibes-Viade, H.R.; Gonzalez-Ibanez, J. (19??) Persistence of several herbicides in a soil cropped to sugarcane. Journal of Agriculture of University of Puerto Rico ? (?):147-152. (Also ~ In ~ unpublished submission received Aug 20, 1976 under 39445-1; submitted by American Carbonyl, Inc., Tenafly, N.J.; CDL:228229-Y)
00025223	McCann, J.A.; Pitcher, F. (1972) [Sinbar Terbicil Weed Killer: Toxicity to Rainbow Trout]: Test No. 520. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Agricultural Research Center, Animal Biology Laboratory, unpublished report.)
00025224	McCann, J.A.; Pitcher, F. (1972) [Sinbar Terbacil Weed Killer: Toxicity to Bluegill Fish]: Test No. 515. (U.S Environmental Protection Agency, Pesticides Regulation Div., Agricultural Research Center, Animal Biology Laboratory, unpublished report.)
00028135	Isom, W.H.; Ford, H.P.; Lavalleye, M.P.; et al. (1969) Persistance [sic] of Herbicides in Irrigated soils. (Unpublished study received Aug 20, 1976 under 39445-1; prepared by Sandoz-Wander, Inc., submitted by American Carbonyl, Inc., Tenafly, N.J.; CDL:228229-X)
00028524	Interregional Research Project Number 4 (1976) (Terbacil Residue Data Summary: Asparagus). (Unpublished study received Jun 11, 1980 under 0E2371; CDL:099449-A)
00039001	Haskell Laboratories, Rat Oral Teratology with Terbacil, received February 20, 1980, submitted by E.I. du Pont de Nemours & Company, Inc., Wilmington, Del.
00039009	Haskell Laboratoris, Rat 90-day feeding study in Rats, received June 28, 1965, submitted by E.I. du Pont de Nemours 7 Company, Inc., Wilmington, Del.
00060851	Wazeter, F.X.; Buller, R.H.; Geil, R.G. (1967) Two-Year Feeding Study in the Dog: IRDC No. 125-011. (Unpublished study received Apr 4, 1967 under 6F0510; prepared by International Research and Development Corp., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090602-A; 090600)

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MRID	CITATION

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Reqistrant'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 Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

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

c. Generic Data Exemption -

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

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

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

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

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption

you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form,

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any

other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

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

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

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

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

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

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

Option 5. Upgrading a Study

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

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

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

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the

classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

2. Product Specific Data

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

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

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

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

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its

benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You

should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

TERBACIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 TERBACIL. 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 TERBACIL 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 TERBACIL are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on TERBACIL 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 TERBACIL 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 Karen Jones at (703) 308-8047.

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

Karen Jones
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: **TERBACIL**

TERBACIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Terbacil. 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 TERBACIL 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 Terbacil are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Terbacil are needed. These data are needed to fully complete the reregistration of all eligible Terbacil 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 Emily Mitchell at (703) 308-8583.

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

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

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources

are registered), you may not claim a Generic Data Exemption and you may not select this item.

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.**

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.

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

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.

INTRODUCTION

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

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

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

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

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

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 Reqistrant'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 Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

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

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

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

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

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

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

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

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

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

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

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

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core

minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

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

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

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

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant

EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

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EPA'S BATCHING OF PRODUCTS CONTAINING TERBACIL AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Terbacil (5-Chloro-3-tert-butyl-6-methyl-uracil), the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. The registrant has several options to participate with all or some other registrants, or to deal only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. TRB must approve any new formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or

Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient Terbacil. All active products containing Terbacil were placed into Batch #1.

Table 1.

	Registration Number	Percent Active Ingredient		Form
1	352-317	Terbacil	80%	powder
	ID80000900	Terbacil	80%	powder
	KY81001000	Terbacil	80%	powder
	OK92000900	Terbacil	80%	powder
	OR80002100	Terbacil	80%	powder
	OR92000300	Terbacil	80%	powder
	OR92001600	Terbacil	80%	powder
	PA90000300	Terbacil	80%	powder
	VA90000400	Terbacil	80%	powder
	WA80001000	Terbacil	80%	powder
	WA92002400	Terbacil	80%	powder
	WA93000700	Terbacil	80%	powder

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	**Company Number**

Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	**Date of Offer**

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	**Date**

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires
3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

The following is a list of available documents for TERBACIL that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using WWW (World Wide Web) on WWW.EPA.GOV., or contact Karen Jones at (703)-308-8047.

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 TERBACIL.

The following documents are part of the Administrative Record for TERBACIL and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria