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Environmental Protection
Agency

Pesticides and
Toxic Substances
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EPA

Registration Standard For Pesticide Products Containing TERBACIL As The Active Ingredient

OMB Control No. 2070-0057
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REGISTRATION STANDARD
(SECOND ROUND REVIEW)

FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

TERBACIL

AS THE ACTIVE INGREDIENT

CASE NUMBER

0039

OPP CHEMICAL CODE

012707

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ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
LC50	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 or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than 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.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.

MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued on May 1982, the Agency summarized the available data supporting the registration of the pesticide and its assessment of those data to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has since reviewed the additional data and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment[1] of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

- Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.

- Section III sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, updated based on data submitted to the Agency under the original Registration Standard.

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D,C. 20460.

° Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions. Section IV also describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing use products and statements for end use products.

° Sections V, VI, VII, VIII and IX describe what products are subject to the data and labeling requirements set out in this Registration Standard, and what is required of registrants to comply with the requirements.

° Appendix I contains a series of tables setting out data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain. A Guide to Tables introduces the tables.

° Appendix II is a series of labeling information sheets, setting out general labeling information that must be placed on labeling.

° Appendix III is a bibliography of the data evaluated by the Agency in its assessment. A Guide to Bibliography explains how to read and use the Bibliography.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Terbacil

Chemical name: 3-tert-butyl-5-chloro-6-methyluracil

Other Chemical Nomenclature: 5-chloro-3-(1,1-dimethylethyl)-6-methyl-2,4(1H,3H)-pyrimidinedione

CAS Number: 5902-51-2

OPP (Shaughnessy) Number: 012701

Empirical Formula: $C_9H_{13}ClN_2O_2$

Molecular Weight: 216.7

Trade names: Sinbar[R], DuPont Herbicide 732, and Geonter.

Physical Chemical Properties

Color: White

Physical State: Crystalline solid

Odor: None

Melting Point: 175°-177°C

Boiling Point: N/A substance is a solid at room temperature.

Specific Gravity: 1.34

Solubility:

at 25°C g/100 g solvent	
Dimethylformamide	33.7 ppm
Xylene	6.5 ppm
Water	710 ppm

Vapor Pressure: 4.7×10^{-7} mm Hg at 29.5°C

Octanol/water partitioning: K_{ow}: 81.9

B. USE PROFILE

Type of Pesticide: Herbicide

Pests Controlled: A broad spectrum of broadleaf weeds and grasses.

C. REGISTERED USES

Major Uses:
Sugarcane (37 - 53%)
Mint (16- 31%)
Apples (ca. 20%)
Peaches (ca. 10%)
Alfalfa (ca. 6%)

Minor Uses: Blueberries, caneberries, citrus fruits, mints, pecans, strawberries, and grass seed crops.

Annual Usage: 290,000 - 610,000 pounds active ingredient

Mode of Activity: Photosynthetic inhibitor

Formulation Types Registered: Wettable Powder 80%, and Wettable Powder 40%.

Method(s) of Application:
-Tractor-mounted spray boom application to soil surface and small emerged weeds.
-Aerial application

D. REGISTRATION HISTORY

Year of Initial Registration: 1966

Basic (USA) Producers: E.I. duPont de Nemours Company, Inc.

End-use Registrants: 1

Number of Registrations:

	Single Active	Multiple Active	Total
Sec 3	1	1	2
Sec 24c	21	0	21
Total	22	1	23

III. AGENCY ASSESSMENT

A. Current Status and Summary of the Terbacil Data Base

The Agency has reviewed all data currently supporting the registration of terbacil as of July 1989. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in sections B through D.

1. TOXICOLOGICAL EFFECTS

The acute toxicity data requirements for technical terbacil have been satisfied.

In the 1982 Registration Standard (RS), the Agency required submission of all acute toxicity data for the unregistered technical. In response to the 1982 RS the Agency accepted data submitted on the 80% wettable powder (WP) in lieu of data on the unregistered technical. Based on data submitted on the unregistered technical and the 80% WP, the Agency concludes that terbacil has a low order of acute toxicity by the oral, dermal, and inhalation routes (Toxicity Category III). The technical material produces slight eye irritation, no skin irritation, and no allergic reactions when tested.

In the 1982 RS, the Agency required additional data to complete its evaluation of the subchronic effects of terbacil. In that review, the Agency required additional data on a 21-day dermal study and waived the requirements for a 90-day non-rodent feeding study. Data submitted previously for a 90-day rat feeding study was reviewed in the 1982 RS and found to be acceptable.

The subchronic toxicity data requirements for technical terbacil have been satisfied. Refer to section B.2 for study reviews.

In the 1982 RS, the subchronic data base for terbacil was essentially complete except for a 21-day dermal study. The Agency had classified this study as supplemental and required additional data to address deficiencies.

The 1989 Reregistration Document accepted the data submitted to address deficiencies in the 21-day dermal study and upgraded this study to core minimum. The Agency did not require a 90-day inhalation, or dermal irritation study for terbacil due to its use patterns. Neurotoxicity testing was not required because this compound is not an organophosphate nor was there any evidence of neurotoxicity in a mammalian species.

The chronic toxicity data requirements for technical terbacil have not been satisfied. Additional data are required for the following studies: Oncogenicity rat and mouse, and chronic oral rat study.

In the 1982 RS, the following chronic studies were reviewed and found to be acceptable: 2-year rat feeding study, and a 2-year dog feeding study. A rat teratology and a rat 3-generation reproduction study were initially reviewed in the 1982 RS and found to be supplemental but repairable. No data were available to assess the oncogenicity, mutagenicity, or the metabolism of terbacil.

The 1989 Reregistration Document reevaluated all chronic data available for terbacil. In this review, the following studies were found to be acceptable: 2-year dog feeding study, teratology (rat and rabbit), reproduction (rat), and two of the three required mutagenicity studies (a gene mutation study was reviewed and classified as supplemental). Refer to section B.3 for study reviews.

The mouse oncogenicity study submitted in response to the 1982 RS was initially reviewed in 1983 and was classified as core minimum. This study was re-reviewed for the 1989 Reregistration Document and was reclassified as core supplemental but repairable (refer to Section B.3 for study deficiencies and review).

The rat chronic/oncogenicity study had been deemed acceptable in the 1982 RS, but was reclassified as invalid and unrepairable in the 1989 Reregistration Document. This study was considered inadequate to satisfy the Agency 1984 Health Assessment Guidelines for a rat chronic/oncogenicity study (refer to Section B.2 for study deficiencies and review).

The rat metabolism study required in the 1982 RS is currently under review.

Based on acceptable data, the following scientific conclusions can be made on the chronic effects of terbacil:

. A chronic (2-year) feeding study in dogs, resulted in a systemic NOEL of 1.25 mg/kg/day (lowest dose tested). This NOEL was based on an increase in thyroid weights in dogs fed greater than 6.25 mg/kg/day. A Provisional Acceptable Daily Intake (PADI) of 0.013 mg/kg/day, with a 100 uncertainty factor, was established based on the NOEL for dogs.

. Terbacil did not produce any teratogenic effects in rats or in rabbits tested.

. Results of a 3-generation reproduction study in rats, indicated terbacil did not produce any reproductive effects at the highest dose tested 250 ppm (approximately to 62.5 mg/kg/day).

. Terbacil did not induce mutagenic effects in assays tested (Unscheduled DNA Synthesis and in vivo bone marrow chromosome study).

. The oncogenicity potential of terbacil has not been defined.

2.TOLERANCE REASSESSMENT

Tolerances have been established for residues of Terbacil in or on the following raw agricultural commodities: alfalfa, apples, asparagus, blueberries, caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries), citrus fruits (including grapefruit, lemons, and oranges), grasses grown for seed, mint (peppermint and spearmint), pecans, peaches, strawberries, and sugarcane. Tolerances for residues of Terbacil are currently expressed as residues of terbacil per se (40 CFR 180.209 (a)) and terbacil and its metabolites A, B, and C (40 CFR 180.209 (b)).

The available data indicate that the established tolerances for residues of terbacil and its metabolites A, B, and C (calculated as terbacil) in or on alfalfa forage, blueberries, and strawberries are adequate. However, this conclusion cannot be finalized until all required plant metabolism and storage stability data have been reviewed and accepted.

Additional data are required regarding residues of terbacil in or on citrus fruits, apples, caneberries, pecans, alfalfa hay, asparagus, mint, sugarcane and grass forage, hay, seed, and seed screenings and straw.

Processing studies are required to determine the need for food/feed additive tolerances for terbacil residues in or on citrus fruits, apples, mint, and sugarcane. In lieu of processing data for spent hay, a feeding restriction may be proposed.

3. AVERAGE DAILY INTAKE REASSESSMENT

The Provisional Average Daily Intake (PADI) was derived from a verified reference dose (RfD) of 0.013 mg/kg/day based on a NOEL of 1.25 mg/kg/day from a two year dog feeding study with an uncertainty factor of 100.

Dietary exposure to terbacil was calculated using the published tolerances in 40 CFR 180.209(a) and 40 CFR 180.209 (b). The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population is estimated to be 0.001594 mg/kg/day, which occupies approximately 12% of the ADI. The two most highly exposed subgroups are non-nursing infants, less than 1 year old (TMRC= 0.008122 mg/kg/day or 62% of the ADI), and children , 1- 6 years of age (TMRC= 0.004361 mg/kg/day or 34% of the ADI).

4. ECOLOGICAL EFFECTS

In the 1982 Terbacil Registration Standard (RS), data were available to characterize the effects of terbacil on avian species (practically non-toxic), freshwater invertebrates (slightly toxic), coldwater fish (slightly toxic), warmwater fish (practically non-toxic), and honey bees (practically non-toxic).

Information reviewed in response to the 1982 RS indicated that terbacil was moderately toxic to oysters and practically non-toxic to birds on an acute oral basis and that additional studies were needed to fully evaluate the risk to marine fish.

In addition, due to aerial application and the use of terbacil near aquatic habitats Nontarget Area Phytotoxicity studies are now required.

5. ENVIRONMENTAL FATE

In the 1982 RS, data were insufficient to fully characterize the environmental fate of terbacil. Data from the 1982 RS indicated that: terbacil is stable to hydrolysis and photo-degrades slowly in water (half-life: 12 weeks). It has a potential to contaminate ground water particularly in areas with sandy soil surfaces. It leaches slower in fine textured soils and also in soils having higher organic contents. It does not accumulate to significant levels in bluegill sunfish, and phytotoxic residues resulting from multiple applications of terbacil persisted for 2 years following the final application.

In response to the 1982 RS, six studies were required: aerobic and anaerobic soil metabolism, long-term terrestrial field dissipation, photodegradation on soil, leaching-adsorption/desorption, and hydrolysis. These studies were reviewed and only three of the six studies were found to be acceptable; hydrolysis, photodegradation, and the unaged portion of the leaching adsorption-desorption study (refer to section E for study reviews).

Based on preliminary data, terbacil appears to be a potential leacher. Preliminary data indicate that terbacil is persistent in soils with a half-life of 520 days under aerobic conditions and 178 days under anaerobic conditions. Rotational crops studies demonstrate that terbacil can persist in soil and is available for uptake by crops 2-years following application.

B. HEALTH EFFECTS

The following is an assessment of the human health risks associated with the herbicide terbacil based on data submitted in response to the 1982 Registration Standard (RS) and data previously reviewed and determined to be acceptable to support the reregistration of products containing terbacil.

1. Acute Toxicities and Irritation Studies:

Manufacturing Use Products

Acute Oral and Dermal Toxicity

No data were submitted to evaluate the acute oral or dermal toxicities of the unregistered technical; however, data submitted for the 80% wettable powder satisfies these data requirements. Refer to "End-Use Formulation" toxicity discussion.

Acute Inhalation

Sufficient data are available to indicate that terbacil has a low degree of acute inhalation toxicity (Toxicity Category III) with a LC50 >4.4 mg/L.

Primary Eye Irritation

Sufficient data are available to indicate that terbacil has a low degree of ocular irritation (Toxicity Category III), causing slight eye irritation (conjunctiva) that cleared 3 days after exposure.

Primary Dermal Irritation

No primary dermal irritation study is available on terbacil; however, an acceptable 21-day dermal study indicated that no dermal irritation effects were observed. No additional data are required.

Dermal Sensitization

Sufficient data are available to indicate that terbacil is not an dermal sensitizer.

End-Use Formulations

Acute Oral Toxicity

Sufficient data are available to indicate that the 80% wettable powder formulation of terbacil demonstrates a low order of oral toxicity with a LD50 value > 5000 mg/kg (Toxicity Category IV).

Acute Dermal Toxicity

Sufficient data are available to indicate that the 80% wettable powder formulation of terbacil demonstrates a low order of acute dermal toxicity with a LD50 value of >5000 mg/kg (Toxicity Category III).

2. Subchronic Testing

Acceptable data are available on the oral and dermal subchronic toxicities of terbacil.

90-Day Feeding-Rodent

A 90-day oral rat feeding study was reviewed in the 1982 RS. In this study male and female rats were fed diets containing 100, 500, and 5000 ppm of terbacil (80% active ingredient). The NOEL was 100 ppm (approximately 5 mg/kg/day) based on increase in liver weights and enlargement of liver parenchymal cells in males in and females rats administered 500 ppm.

21-Day Dermal

A 21-day dermal study on rabbits was reviewed in the 1982 RS and considered supplemental, additional data were submitted in response to the 1982 RS and the classification of this study was upgraded to core-minimum. In this study, 5000 mg/kg of terbacil (80% wettable powder) was applied to abraded skin sites daily for three weeks (5 hours per day, and 5 days per week). No subchronic toxicities were observed. Mild scaliness and staining were detected at the test sites.

No data are available on the 90-day subchronic oral toxicity of terbacil in non-rodents. Additional studies are not required since an acceptable 2-year chronic study in the dog satisfies this data requirement.

No data are available on the subchronic neurotoxicity of terbacil. Since an acute neurotoxicity study is not required and there is no evidence of terbacil neurotoxicity in mammalian species, no testing is required.

3. Chronic Toxicity Testing

Chronic Non-Rodent (Dog):

An acceptable non-rodent study was reviewed in the 1982 RS. In this study, terbacil (80% active ingredient) was administered in the diet to beagle dogs (4/sex/group) at levels of 50, 250, 2500, and 10000 ppm (approximately 1.25, 6.25, 62.5, and 250 mg/kg/day respectively) for 2 years. No adverse effects were observed with respect to food consumption, weight gain, gross or microscopic changes, or biochemical changes. The NOEL was 50 ppm (approximately 1.25 mg/kg/day), lowest dose tested (LDT), based on an increase in thyroid weight in dogs administered >250 ppm (approximately 6.25 mg/kg day) of terbacil in the diet.

Chronic Rodent (Rat):

In an older (1967) study previously reviewed (for the 1982 RS), Charles River CD rats were fed terbacil (80% active ingredient) at levels of 0, 50, 250, 2500, and 10000 ppm (approximately 2.5, 12.5, 125, and 500 mg/kg/day, respectively) for two years, with a NOEL of 250 ppm (approximately 125 mg/kg/day).

Although initially judged acceptable in the 1982 RS, this study is considered inadequate to satisfy current guideline requirements for a chronic and/ or oncogenicity testing in a rodent species for the following reasons: a) an insufficient number of animals was used at the start of the study (36/sex/group), b) an intercurrent infection was present in the animal colony, c) an insufficient number of animals survived the study (the highest survival rate was 16 in the high dose females), d) only terminally sacrificed control and high dose animals were examined microscopically, and e) biochemical determinations were incomplete and were done on only six animals/sex/group. A new study is required.

Oncogenicity

No acceptable data are available on the oncogenicity of terbacil. The rat chronic/oncogenicity study has been classified as invalid and unrepairable due to deficiencies outlined in the discussion above.

A rat oncogenicity study is required.

A mouse chronic/oncogenicity study was submitted in response to the 1982 RS and accepted in 1983. This study was re-evaluated as part of the SRR using the current 1984 Health Assessment Guidelines and determined to be inadequate to satisfy the requirement for oncogenicity testing in mice. The interpretation of findings presented by the study researchers, increased incidence of hyperplastic nodules in the liver of high dose males when compared to the controls, are considered by the Agency to be questionable. The Agency's interpretation of neoplastic nodules (including hyperplastic nodules and nodular hyperplasia) is that these lesions are benign neoplasias.

Pending evaluation and acceptance of additional data; reexamination of liver slides to determine the type of lesion, and information pertaining to the concentration, homogeneity, and stability of the test diet, this study is reclassified as supplemental.

Additional data to address the above mentioned deficiencies are required or submission of a new study.

Developmental Toxicity (Teratogenicity)

Sufficient data are available to satisfy the data requirements for teratogenicity studies in two species.

In the 1982 RS, a rat teratology study had been reviewed and classified as supplemental due to concerns in dosing procedures, and adverse effects seen (i.e. increased post implantation loss in the treated dams, and statistically significant increases in hydronephrosis (collection of urine in pelvis of kidney) in fetuses from the treated dams). These concerns were addressed in responses to the 1982 RS and the study was re-classified to core minimum. The NOEL for developmental effects was > 5000 ppm (approximately 250 mg/kg/day). The maternal NOEL was 250 ppm (approximately 12.5 mg/kg/day) based on decreased body weight at 1250 ppm (approximately 62.5 mg/kg/day) and above. The requirement for a rat teratology study has been satisfied.

A rabbit teratology study was submitted in response to the 1982 RS. In this study, terbacil was administered to pregnant New Zealand rabbits at daily oral doses of 0, 30, 200, and 600 mg/kg. Mean live fetal weights were significantly reduced in the

HDT. There was no significant increase in malformed fetuses in the treated animals when compared to the control groups. The NOEL for developmental effects was 600 mg/kg/day (HDT). The NOEL for maternal toxicity and embryotoxicity was 200 mg/kg/day.

Reproduction

In the 1982 RS, a three-generation rat reproduction study had been reviewed and classified as supplemental due to concerns in study design (only two dose levels; 50 and 250 ppm), and the use of antibiotics to control a respiratory illness in the laboratory. These concerns were addressed in responses to the 1982 RS and the study was re-classified to core minimum. In this study terbacil (80% wettable powder) was administered to 10 male and 20 female Charles River rats at dietary levels of 50 and 250 ppm (approximately 2.5 and 62.5 mg/kg/day, respectively). Body weight gains were significantly reduced in male but not in female rats at the HDT. No reproductive effects were seen at the HDT.

The NOEL for reproductive effects was >250 ppm (62.5 mg/kg/day). The systemic NOEL was < 50 ppm (2.5 mg/kg/day) based on reduction of body weight gain in the male seen at the HDT.

Mutagenicity

Adequate mutagenicity studies in all generic categories were lacking when the 1982 RS was issued. Two of the three required studies have been accepted. These studies indicate that terbacil was not mutagenic when tested in the following assays: Unscheduled DNA Synthesis and in vivo bone marrow chromosome study.

A gene mutation study was reviewed and found to be supplemental due to submission flaws (e.g., missing pages and tables). This study is repairable.

C. ECOLOGICAL EFFECTS

In the 1982 Terbacil Registration Standard (RS), data were available to characterize the effects of terbacil on avian species (practically non-toxic), freshwater invertebrates (slightly toxic), coldwater fish (slightly toxic), warmwater fish (practically non-toxic), and honey bees (practically non-toxic). Information reviewed in response to the 1982 RS indicated that terbacil was moderately toxic to oysters and practically non-toxic to birds on an acute oral basis and that additional studies were needed to fully evaluate the risk to marine fish. In addition, due to aerial application and the use of terbacil near aquatic habitats Nontarget Area Phytotoxicity studies are now required.

1. Avian Species

Based on acceptable laboratory data, terbacil is characterized as practically non-toxic to avian species on both an acute oral and dietary basis. Data are summarized below;

Species	%ai	Study Type	Toxicity Value
Bobwhite Quail	96	Acute Oral	LD50 >2250 mg/kg
Mallard Duck	96	Dietary	LC50 >5000 ppm
Mallard Duck	80	Dietary	LC50 >5000 ppm
Pheasant	80	Dietary	LC50 >5000 ppm

2. Aquatic Organisms

Based on acceptable laboratory data, terbacil was characterized for acute toxicity in the following freshwater aquatic organisms:

Freshwater Invertebrates:

Species	%ai	LC50 (ppm)	Toxicity Characterized
Daphnia magna	95	65	Slightly Toxic

Freshwater Fish:

Species	%ai	LC50 (ppm)	Toxicity Characterized
Rainbow trout	96.6	46.2	Slightly Toxic
Rainbow trout	80.0	79.0	Slightly Toxic
Bluegill sunfish	96.6	102.9	Practically Non-Toxic
Bluegill sunfish	80.0	123.0	Practically Non-Toxic

Estuarine and Marine Organisms

Species	%ai	LC50 (ppm)	Toxicity Characterized
Oyster	84.7	>4.9	Moderately Toxic
Shrimp	84.7	49	Slightly Toxic

3. Non-Target Insects

Terbacil was determined to be practically non-toxic to honey bees in a laboratory acute contact toxicity test with a LD50 value > 193 micrograms/bee. No additional testing is required.

D. ECOLOGICAL RISK ASSESSMENT

Birds

The available data indicate that terbacil is practically non-toxic to birds on an acute oral (LD50 > 2250 mg/kg) and on a dietary basis (LC50 >5000 ppm). Using a maximum application rate of 8 lbs a.i./Acre for citrus use, the maximum expected residues that could be expected to occur on a variety of terrestrial wildlife dietary food items immediately after one application were:

Dietary Food Items	Maximum Expected Residues (ppm)
Short grass	1900
Long grass	900
Leafy crops	1000
Forage, small insects	450
Pods, large insects	950
Fruits	60

These residue levels when compared to the acute oral and dietary values for avian species tested are not expected to cause adverse effects.

Avian reproduction studies were not required in the 1982 RS nor are they required under this Registration Standard. An assessment of the acute oral, dietary, and residue data indicated that chronic and reproductive adverse effects are unlikely to occur.

Aquatic Organisms

Terbacil has no currently registered uses that would involve direct application to water. Terbacil can enter aquatic systems through spray drift and runoff from treated sites adjacent to streams, ponds, or other bodies of water.

The terbacil's maximum application rate is 8 lbs a.i./Acre. Based on the theoretical calculations, available ecological data, and its low toxicity to aquatic organisms, terbacil is not expected to cause unreasonable adverse effects to aquatic species. However, an additional study is needed to fully evaluate the risk to marine fish.

Endangered Species

The registered uses of terbacil do not represent a potential hazard to endangered terrestrial or aquatic organisms on an acute or chronic basis.

E. ENVIRONMENTAL FATE

In the 1982 RS, data were insufficient to fully characterize the environmental fate of terbacil. Data from the 1982 RS indicated that: terbacil is stable to hydrolysis and photodegrades slowly in water (half-life: 12 weeks). It has a potential to contaminate ground water particularly in areas with sandy soil surfaces. It leaches slower in fine textured soils and also in soils having higher organic contents. It does not accumulate to significant levels in bluegill sunfish, and phytotoxic residues resulting from multiple applications of terbacil persisted for 2 years following the final application.

In response to the 1982 RS, six studies were required: aerobic and anaerobic soil metabolism, long-term terrestrial field dissipation, photodegradation on soil, leaching-adsorption/desorption, and hydrolysis.

1. Hydrolysis

Terbacil was stable in aqueous hydrochloric acid and sodium hydroxide solutions at pH's 4 to 10 at 25°C. No additional testing is required.

2. Photodegradation on Soil

Carbonyl-labeled [2-^{14}C] terbacil (purity >99%), at 1.2 lb/A, degraded with a half-life of >15 days on silty clay loam soil when continuously irradiated with a lamp at 25-26°C. The calculated half-life was 61 days, based on continuous irradiation. No additional studies are required.

3. Leaching and Adsorption/Desorption

Based on acceptable batch equilibrium studies, [^{14}C]terbacil was very mobile in two sandy loam and two silt loam soils when equilibrated at 25°C in 1:1 soil:calcium sulfate solution slurries that contained 0.2-6.0 ppm of carbonyl-labeled [2-^{14}C] terbacil (purity >99%). Freundlich K_{ads} values were 0.39-0.71 for sandy loam soils and 1.2-1.3 for silt loam soils. Adsorption of terbacil was highly correlated with the percentage of soil organic matter.

Based on acceptable soil TLC studies, [2-^{14}C] terbacil, was mobile (R_f0.27-0.28) in silt loam soil, and silt soil and mobile to very mobile (R_f0.36-0.54) in sandy loam soils.

An aged leaching-adsorption/desorption study is required.

4. Soil Metabolism Studies

Studies submitted in response to the 1982 RS were reviewed and found to be unacceptable. Preliminary data indicates that terbacil is extremely persistent (half-life: 520 days aerobically and 178 days anaerobically). These studies were deemed unacceptable due to design flaws and reporting deficiencies and are unrepairable. Aerobic and anaerobic soil metabolism studies and a long-term soil field terrestrial dissipation study are required.

5. Confined Rotational Crop Study

Two studies reviewed in the 1982 RS indicated that beets (roots and tops), sunflower seeds, and cabbage grown in a greenhouse in silt loam soil contained no detectable residues of terbacil (<0.04 ppm). Terbacil was detected in cabbage grown in muck soil sampled 2 years after the last application (1-2 lb ai/Acre), but was not detected in beets or sunflower seeds.

Due to the degree of persistence, a rotational crop interval of one year or less could not be set and the confined rotational crop requirement was waived in the 1982 RS. Rotational crop tolerances are required for all crops rotated in fields treated with terbacil.

F. GROUND WATER ASSESSMENT

Limited monitoring has been conducted for terbacil in ground water. No detections have been found in 12 wells sampled in a statewide survey in Louisiana by the Louisiana Department of Agriculture and Forestry. Although pesticide use was a criteria in designing the study, the extent to which terbacil had been used in the vicinity of all sampled wells is unknown.

Very little is known about the degradation products of terbacil due to terbacil's persistence. The physicochemical properties (e.g., persistence and mobility) of the degradates, and their relative proportions to the parent compound have not been adequately identified. Insufficient data exists to predict concentrations of the parent and/or its degradation products in ground water under typical application rates and use areas. A small scale retrospective ground water monitoring study is reserved pending evaluation of the long-term soil field dissipation study.

G. WORKER EXPOSURE/REENTRY ASSESSMENT

The current application practices for terbacil (pre-emergent and dormant application) would present minimum exposure to fieldworkers entering sites treated. Available acute and chronic toxicological data do not demonstrate a risk to workers exposed to terbacil during handling, mixing, and application. The Agency believes that the updated protective clothing statements required under this Standard will adequately protect individuals against any potential hazard.

H. TOLERANCE REASSESSMENT

Tolerances have been established for residues of Terbacil in or on the following raw agricultural commodities: alfalfa, apples, asparagus, blueberries, caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries), citrus fruits (including grapefruit, lemons, and oranges), grasses grown for seed, mint (peppermint and spearmint), pecans, peaches, strawberries, and sugarcane. Tolerances for residues of Terbacil are currently expressed as residues of terbacil per se (40 CFR 180.209 (a)) and terbacil and its metabolites A, B, and C (40 CFR 180.209 (b)). EPA has evaluated the residue and toxicology data supporting these tolerances. The following were considered during this evaluation:

o Whether the tolerances are adequate to protect the public health, including that of sensitive subpopulations.

o Whether the current tolerances and food/feed additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA sec. 24(c).

o Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

o Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

o Whether the tolerances are expressed accurately and in current terminology.

The regulatory determinations resulting from EPA's review are set out in Section IV.A., Regulatory Positions and Rationales.

1. Residue Data

a. Nature of the Residue in Plants

In the 1982 Registration Standard, the nature of the residue in plants was considered to be adequately understood based solely on data pertaining to the metabolism of [^{14}C]terbacil in field-treated alfalfa. The metabolites of terbacil in alfalfa forage are illustrated in Table 1. Other metabolism studies on orange seedlings, peppermint, and sugarcane failed to characterize radioactivity residues following [^{14}C] terbacil treatment. These studies are no longer considered to be adequate to characterize the qualitative nature of terbacil in plants. Additional studies on apples and sugarcane which characterize terbacil residues in plants are needed.

Presently, terbacil and its metabolites, A, B, and C are the residues of concern; however, it should be noted that if the additional required metabolism studies indicate additional residues of concern, the established tolerance definition, as stated in 40 CFR 180.209(b), may need to be revised.

Table 1. Terbacil and its metabolites in plants and animals

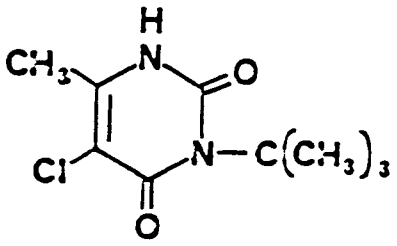
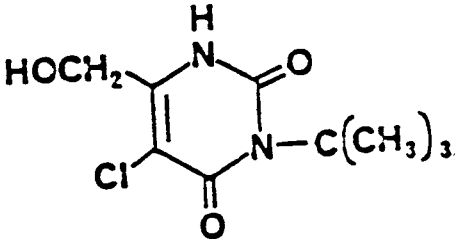
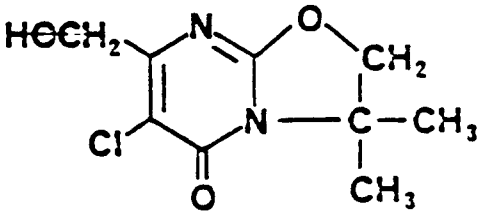
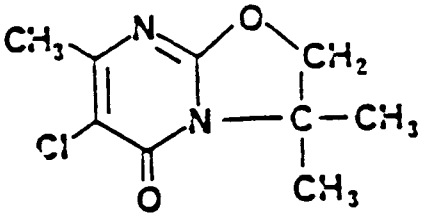
Code	Chemical name Structure	Substrate
I.	3-tert-butyl-5-chloro-6-methyluracil **(Terbacil)** 	Alfalfa Forage Orange seedlings Peppermint Sugarcane Goat, kidney, liver, and muscle.
II.	3-tert-butyl-5-chloro-6-hydroxymethyluracil **(Metabolite A)** 	Alfalfa forage

Table 1 (continued).

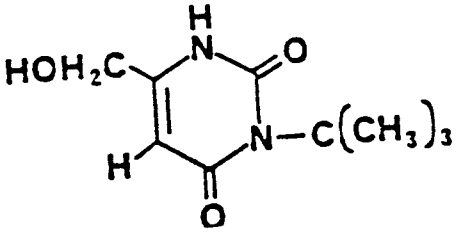
Code	Chemical name Structure	Substrate
III.	6-chloro-2,3-dihydro-7-(hydroxymethyl)-3,3 -dimethyl-5H-oxazolo [3,2-a]pyrimidin-5-one **(Metabolite B)**	Alfalfa forage



IV.	6-chloro-2,3-dihydro-7-methyl-3,3-dimethyl-5H-oxazolo [3,2-a]pyrimidin-5-one **(Metabolite C)**	Alfalfa forage



V.	3-tert-butyl-6-hydroxymethyluracil **(Metabolite D)**	**Alfalfa forage**



b. Nature of the Residues in Animals

The 1982 RS for terbacil concluded that the nature of the residue in animals was adequately understood. Although residues were characterized in milk, the studies reviewed in the 1982 RS failed to adequately characterize residues in tissue even though feeding studies indicate that total terbacil equivalent ^{14}C-residues were 0.06-0.07 ppm in liver, 0.12-0.14 ppm in kidney, and 0.01 ppm in muscle of a single lactating goat following ingestion of [^{14}C] terbacil. Metabolism data are required in livestock and in poultry.

c. Residue Analytical Methods

The 1982 RS concluded that adequate analytical methods were available for data collection and tolerance enforcement pertaining to residues of terbacil per se in or on plant commodities and to the combined residues of terbacil and its metabolites A,B, C, (calculated as terbacil) in or on plant and animal commodities. However, the nature of the residue in plants and animals has not been adequately described. Therefore, the adequacy of the available analytical methods cannot be determined.

Enforcement method I in the PAM, Vol. II is a gas-liquid/microcoulometric (GLC/MC) method for determination of residues of terbacil per se in or on apples, citrus fruits, peaches, pears, and sugarcane. This method has undergone a successful Agency validation study on oranges and peaches.

The 1982 RS also concluded that the GLC/MC method (Method II in the PAM, Vol II) which determines residues of terbacil and its three metabolites A, B, and C as silyl derivatives in or on plant and animal commodities was adequate for data collection and enforcement. This method underwent a successful validation study conducted on alfalfa hay and milk. A confirmatory procedure for this method is listed in the PAM, Vol. II as Method A.

Residues of terbacil per se are completely recovered (>80%) by PAM Vol. I method 232.4 (multiresidue protocol II), and poorly recovered (13-30%) by method 252 (multiresidue protocol I). No data are available concerning recovery of the terbacil metabolites by any of the multiresidue protocols I-IV. These data are required.

d. Storage Stability Data

Data on storage stability of terbacil in or on plant commodities were not required in the 1982 RS. In 1987, a Position Document (NTIS PB 88112362/AS) was published by the Agency in which storage stability requirements were expanded. The Agency now requires that storage intervals and sample storage conditions must be reported for all residue data submitted in support of tolerances or otherwise required by the Agency, and that the residue data be accompanied by data depicting the stability of all residues of concern in storage.

e. Magnitude of the Residues in Raw Agricultural Commodities and Food and Feed Items

The available data indicate that the established tolerances for residues of terbacil and its metabolites A, B, and C (calculated as terbacil) in or on alfalfa forage, blueberries, and strawberries are adequate. However, this conclusion cannot be finalized until all required plant metabolism and storage stability data have been reviewed and accepted.

Additional data are required regarding residues of terbacil in or on citrus fruits, apples, caneberries, pecans, alfalfa hay, asparagus, mint, sugarcane and grass forage, hay, seed, and seed screenings and straw.

Processing studies are required to determine the need for food/feed additive tolerances for terbacil residues in or on citrus fruits, apples, mint, and sugarcane. In lieu of processing data for spent hay, a feeding restriction may be proposed.

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

The 1982 RS concluded that data were adequate to support the established tolerances for residues in fat, meat byproducts, and meat in cattle, goats, hogs, horses, and sheep. However, the qualitative nature of the residue in ruminants is not adequately understood. Also, numerous data gaps exist in determining the magnitude of the residue in feed items of animals. Accurate theoretical dietary exposure for beef cattle and swine cannot be calculated until the required residue data for all feed items have been submitted and accepted.

There are no established tolerances for residues of terbacil in eggs and the fat, meat and meat byproducts of poultry. No data have been submitted pertaining to the metabolism of terbacil in poultry. The need for tolerances for residues in poultry products will be determined following review and acceptance of animal and plant metabolism data, storage stability data, and data regarding the magnitude of the residue in plants.

2. Tolerances Issued

Codex MRL's or Mexican tolerances have not been established for any terbacil commodities. Canadian tolerances have been established for some terbacil commodities but not all. Compatibility of these tolerances to that of the U.S. tolerances cannot be determined until all additional metabolism and residue studies have been evaluated and accepted.

3. ADI Reassessment

The ADI was derived from a verified reference dose (RfD) of 0.013 mg/kg/day based on a NOEL of 1.25 mg/kg/day from a two year dog feeding study with an uncertainty factor (UF) of 100. This ADI has been down graded to a Provisional Acceptable Daily Intake (PADI).

The Agency's verified ADI was based on a two year chronic feeding study in the dog. Other studies considered in the established of the ADI were: oncogenicity (two species), chronic oral (two species), reproduction, and teratogenicity. These studies were reviewed and the chronic rodent, and the oncogenicity studies were found to be unacceptable. Therefore, the ADI was changed to an PADI, however, based on available data it was not considered necessary to increase the UF.

Dietary exposure to terbacil was calculated using the published tolerances in 40 CFR 180.209(a) and 40 CFR 180.209 (b). The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population is estimated to be 0.001594 mg/kg/day, which occupies approximately 12% of the PADI. The two most highly exposed subgroups are non-nursing infants, less than 1 year old (TMRC= 0.008122 mg/kg/day or 62% of the PADI), and children , 1- 6 years of age (TMRC= 0.004361 mg/kg/day or 34% of the PADI).

IV. REGULATORY POSITION RATIONALE

A. REGULATORY POSITIONS

Based on review and evaluation of all available data and other relevant information on terbacil, the Agency has made the following determinations:

1. **Special Review**

Terbacil will not be placed in Special Review at this time.

Rationale: Based on available data terbacil does not meet or exceed the criteria for Special Review as specified in 40 CFR 154.7.

2. **Groundwater Concerns**

The Agency will impose a ground water contamination advisory statement to reduce point source contamination. Refer to section IV.D for specific wording.

Rationale: Based on available data, terbacil is stable to hydrolysis and photodegrades slowly in water (half life: 12 weeks) and on soil (half life: 17 weeks). Terbacil also shows a potential to leach into ground water particularly in areas with sandy soil surfaces, it leaches slower in fine textured soils and in soils having high organic contents. Preliminary data indicate that terbacil is extremely persistent in soil with half-lives of 520 days under aerobic conditions and 178 days under anaerobic conditions.

4. **End-Use Data Requirements**

The Agency is requiring the following testing on terbacil end-use products: acute oral, acute dermal, primary eye, primary skin, dermal sensitization, and acute inhalation if appropriate.

Rationale: These tests are necessary to ensure that end-use products are properly labeled with respect to human hazard, signal word, and precautionary statements because available data does not adequately characterize the toxicity profile of terbacil end-use products.

5. **Reentry Requirements**

The Agency will not establish a reentry interval for terbacil beyond the minimum reentry interval (sprays have dried, dusts have settled and vapors have dispersed).

Rationale: Based on current use practices, relatively low acute toxicity (Toxicity Category III for acute oral, dermal, and inhalation routes of exposure), and no validated toxicological evidence showing that terbacil causes adverse effects to persons entering treated fields, the Agency has determined that a reentry interval beyond the minimum (sprays have dried, dusts have settled and vapors have dispersed) is not warranted at this time.

6. **Protective Clothing Requirements**

The Agency will require updated worker safety and protective equipment statements for end-use products containing terbacil. Refer to section IV.D for specific wording.

Rationale: Current protective clothing and equipment requirements for terbacil are not adequate to minimize exposure to agricultural workers.

7. **Rotational Crop Tolerances**

The Agency is requiring a rotational crop statement on all terbacil labels which may involve rotation to crops other than those currently registered (refer to section IV.D for specific wording). In addition residue data are required for representative crops from any crop group which could be rotated from alfalfa, sainfoin, asparagus, and mint.

Rationale: Terbacil is registered for use on a wide variety of fruit crops. These crops do not present rotational crop concerns. The following registered uses of terbacil: grasses grown for seed, alfalfa, asparagus, and mint, do present rotational crop concerns because it may not be practical to rotate from these crops to crops already listed on the product label.

Environmental fate data demonstrate that for at least 2 years following application of terbacil at >1 lb ai/Acre, organic soils may retain phytotoxic residual terbacil that is available for uptake by rotational crops. Given this degree of persistence, a rotational crop interval of one year or less could not be set. Tolerances must be established for all crops to be rotated in fields treated with terbacil.

8. **Tolerance Revocation**

The Agency will revoke tolerances associated with the commodities sainfoin (hay), sainfoin (forage), and pears.

Rationale: Terbacil is no longer registered for use on the above mentioned crops. Therefore, the Agency intends to revoke the tolerances for these commodities.

9. **Tolerance Definition**

Existing Tolerance Terbacil per se should be amended to include metabolites A,B, and C, as specified in 40 CFR 180.209 (b).

Rationale: Currently tolerances for terbacil are established in 40 CFR 180.209 (a) for residues of terbacil per se and in 40 CFR 180.209 (b) for combined residues of terbacil and its metabolites A,B, and C. (calculated as terbacil). The Agency has determined that additional residue data are needed for the crops listed in 40 CFR 180.209 (a). These data should reflect analysis for terbacil and all metabolites of concern. At such time as the required metabolism and residue studies are submitted and reviewed the Agency will combine the crops in 40 CFR 180.209 (a) with the crops in 40 CFR 180.209 (b).

10. **Tolerance Revisions**

The Agency will revise the tolerance for residues in or on peaches to 0.2 ppm for combined residues of terbacil and its metabolites.

Rationale: The current tolerance expression for peaches (0.1 ppm) is for terbacil per se only. Data submitted in response to the 1982 RS, indicated that the combined residues of terbacil and its metabolites A, B, and C (calculated as terbacil) will not exceed 0.2 ppm in or on peaches following terbacil application according to the maximum registered use pattern. Therefore unless the required storage stability data indicate that these data are invalid or additional residues of concern are identified the tolerance will be revised.

11. **Grazing/Feeding Restriction**

The Agency will impose label restrictions against the feeding and grazing of sugarcane forage and spent hay to livestock, or require the development and submission of data in support of tolerances for residues in or on sugarcane forage and spent hay. The registrant must inform the Agency within 90 days as to whether he will propose tolerances or adopt the grazing/feeding restrictions. If the registrant selects the label restrictions, labeling submitted at the 9 month deadline must include the grazing/feeding prohibitions. Refer to section IV.D for specific wording.

Rationale: Since sugarcane forage and spent hay are raw agricultural commodities used for livestock, a tolerance and a pregrazing interval must be proposed. A label restriction prohibiting grazing/feeding of sugarcane forage and spent hay to livestock will be accepted in lieu of additional data requested.

12. **Food Use Classification**

The Agency has determined that grasses grown for seed is a food use. Therefore, data depicting residues of terbacil in or on members of the grass forage, fodder and hay group are required.

Rationale: The Agency believes that cuttings for hay will be taken and forage will be grazed regardless of label restrictions. Also the grower will have no control over seed, seed screenings and straw (from seed processing) diverted for livestock feed.

13. **Group Tolerances**

The Agency will not propose group tolerances for terbacil.

Rationale: Appropriate residue data must be submitted for representative crops in each crop group.

14. **Food/Feed Tolerances**[2]

The Agency will not grant any significant new food or feed uses for terbacil until the required residue chemistry and toxicology studies have been submitted and reviewed.

Rationale: The Agency needs additional residue data, plant and animal metabolism data, storage stability data, and chronic toxicity data to reassess the tolerances for terbacil.

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[2]New Uses is defined in 40 CFR 152.3 (p). In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

15. **Studies that will Receive Immediate Review**

The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Section 158.340 Toxicology

83-1 Chronic Oral Feeding (Rat)
83-2 Oncogenicity (Rat and Mouse)

Section 158.290 Environmental Fate

162-1 Aerobic Soil Metabolism
162-2 Anaerobic Soil Metabolism
163-1 Leaching Adsorption/Desorption
164-5 Soil, Long Term (field)

Section 158.490 Wildlife and Aquatic Organisms

72-3 Estuarine and Marine Testing (Fish)
122-1 Tier I Nontarget Area Phytotoxicity

Section 158.240 Residue Chemistry

171-4 Metabolism in Plants & Livestock

15. **Continuation of Registration**

While data are being filled, currently registered manufacturing use products (MPs) and end-use products (EPs) containing terbacil may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain terbacil, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent, except for those impurities of toxicological importance of which upper certified limits of less than 0.1% may be indicated.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacturing-use products, and end-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed in the EPA Compendium of Acceptable Uses (for availability see page 1). The Compendium lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing TERBACIL may be released for shipment by the registrant after **August 31, 1990** unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing Terbacil may be distributed or sold after **August 31, 1991**, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the label in order for products to remain in compliance with FIFRA:

1. Ingredient Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT
Terbacil ..... %

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in the EPA Compendium of Acceptable Uses (for availability see page 1). However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

STATEMENTS FOR MANUFACTURING-USE PRODUCTS

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

STATEMENTS FOR END-USE PRODUCTS

A. Groundwater Advisory Statements

Terbacil can travel (seep or leach) to ground water that is used for drinking water. Users are advised to be careful in mixing and handling terbacil to avoid spills.

Terbacil must not be mixed/loaded, or used within 50 feet of sink holes or wells, including abandoned wells and drainage wells.

Terbacil must not be applied more frequently than once per year.

B. Environmental Hazards Statement

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment wash waters."

C. Personal Protective Clothing and Equipment Statement

"Pesticide handlers are to wear the following personal protective clothing and equipment: long pants, long sleeved shirt, shoes, socks. Chemical-resistant gloves are to be worn during mixing, loading and application."

D. Reentry Statement

"Do not enter or allow entry into treated areas until [sprays have dried/dusts have settled/vapors have dispersed as applicable] to perform hand labor tasks. A person may enter the area only if the person is wearing the personal protective clothing and equipment listed on the label for a pesticide handler."

E. Feeding and/or Grazing Restrictions

All End-Use products allowing for use on sugarcane, spent hay, and orchard crops must bear the following restriction (in the absence of supporting residue chemistry data on sugarcane forage, and spent hay):

"Do not graze or feed treated forage to livestock"

F. Rotational Crop Statement

All End-Use products allowing for use on food or feed crops:

"Treated areas may only be replanted with a crop specified on this label."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[3]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[3]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[4]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

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[4]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

2. If eligible for the generic data exemption[5], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[5]If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the regis-tration of products containing this active ingredient.[6]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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 registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[6]Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. <u>You will submit the data yourself.</u>

2. <u>You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data</u>, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also

require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. <u>You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI</u>. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit 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 in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. <u>You request that EPA amend your registration by deleting the uses for which the data are needed</u>. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 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 (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with 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 Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of 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 or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Document Processing Desk (RS-**0039**)
Office of Pesticide Programs - H7504C
U. S. Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3),if applicable.

b. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

c. Confidential Statement of Formula (EPA Form 8570-4)

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

c. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table B, you must submit all product specific data.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3),if applicable.

b. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

c. Confidential Statement of Formula (EPA Form 8570-4)

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months of receipt of this document, you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

c. Product Specific Data Report (EPA Form 8580-4).

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the time frames set forth in Table B, you must submit all product specific data.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable,

b. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1), if Table C lists required product-specific data.

c. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable.

b. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1), if Table C lists required product-specific data.

c. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to 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 out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). 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 Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Terbacil

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
Part 158, Subpart C, Product Chemistry					
Product Composition					
61-2 - Beginning Materials and Production Process	TGAI	Partially	00142302,00012366	Yes[1/]	12 Months
61-3 - Formation of Impurities	TGAI	Partially	00012366	Yes[2/]	12 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	Partially	00142302,00012364, 00067336	Yes[3/]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Yes	00011958	No	
63-3 - Physical State	TGAI	Yes	00011958	No	
63-4 - Odor	TGAI	Yes	00011958	No	
63-5 - Melting Point	TGAI	Yes	00011958	No	
63-6 - Boiling Point	TGAI	N/A[4/]		No	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	00011958	Yes[5/]	12 Months
63-8 - Solubility	TGAI and PAI	Yes	00011958	No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
Part 158, Subpart C, Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-9 - Vapor Pressure	TGAI or PAI	Partially	00011958	Yes[6/]	12 Months
63-10 - Dissociation Constant	TGAI or PAI	N/A[7/]		No	
63-11 - Octanol/Water Partition Coefficient	PAI	Partially	00125692	Yes[8/]	12 Months
63-12 - pH	TGAI	No		Yes	12 Months
63-13 - Stability	TGAI	No		Yes	12 Months
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A		No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes

1/ Information must be submitted on the production process for the unregistered technical concerning: (i) a general characterization of the process (e.g., batch or continuous) used; (ii) the relative amounts of beginning materials, and the order in which they are added; (iii) a description of the equipment used; (iv) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (v) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). In addition, a flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, the duration of each step of the process and of the entire process, and a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced) are required.

2/ A discussion regarding the origin of potential impurities in the unregistered 95% T must be provided: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur during production, the possible degradation of ingredients after production, postproduction reactions between the ingredients, the possible carry over of contaminants from use of production equipment previously used to produce other products or substances, possible contamination from packaging materials, and process control, purification and quality control measures.

3/Statements of the precision and accuracy of the analytical methods used for sample analysis must be submitted.

4/Data on boiling point are not required because the TGAI is a solid at room temperature.

5/Data are required concerning the measurement temperature and the method of determination of specific gravity.

6/The method of determination must be supplied.

7/Data concerning dissociation constant are not required since the technical product is neither a strong acid nor a strong base.

8/Data are required concerning the measurement temperature at which the octanol/water partition coefficient was determined.

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.240 Residue Chemistry					
171-2 - Chemical Identity[1]					
171-3 - Directions for Use		(See Index)			
171-4 - Nature of the Residue (Metabolism) - Plants	PAIRA & Plant Metabolites	Partially	00011965,00012014 05002415,05013194 05013216,05013598	Yes[2]	24 Months
171-4 - Nature of the Residue (Metabolism)	PAIRA & Plant Metabolites	Partially	00011950,00011957	Yes[3]	24 Months
- Livestock					
171-4 - Residue Analytical Methods	TGAI and Metabolites	Partially	00011949,00011953, 00011960,00011961, 00012035,00012181, 05012979,05015405, 05013352,05014422	Yes[4,5]	24 Months
171-4 - Storage Stability	TEP and Metabolites	Partially	00011952,00150369	Yes[6]	24 Months
171-4 - Magnitude of Residue in Plants					
Citrus Fruits	TEP	Partially	00012015,00012232,	Yes[7]	24 Months
- Dried pulp, molasses, oil, and orange juice			00013205,00145897, 00149184.	Yes[8]	24 Months

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.240 Residue Chemistry					
171-4 - Magnitude of Residue in Plants (cont'd)					
Pome Fruits					
- Apples	TEP	Partially	00070784,00012015,	Yes[9/]	24 Months
- Dry apple pomace and juice			00012402,00149184, 00157178	Yes[10/]	24 Months
Stone Fruits					
- Peaches	TEP	Yes	00012402,00128574, 00149184	Reserved[11/]	
Small Fruits					
- Blueberries	TEP	Yes	00012039	Reserved[12/]	
- Caneberries	TEP	Partially	05015405	Yes[13/]	24 Months
- Strawberries	TEP	Yes	00012097	Reserved[14/]	
Tree Nuts					
- Pecans	TEP	Partially	00012348	Yes[15/]	24 Months

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.240 Residue Chemistry					
171-4 - Magnitude of Residue in Plants (cont'd)					
Nongrass Animal Feeds					
- Alfalfa forage/hay	TEP	Partially	00011959,00130415, 00144089,00149202	Yes[16/]	24 Months
Miscellaneous Commodities					
- Asparagus	TEP	Partially	00028524	Yes[17/]	24 Months
- Mint	TEP	Partially	00012103,00012067	Yes[18/]	24 Months
Spent hay and mint oil				Yes[19/]	24 Months
- Sugarcane	TEP	Partially	00012179,00012180	Yes[20,21/]	24 Months
Molasses, bagasse, and refined sugar			00157178	Yes[22/]	24 Months
Crops Grown Solely for Seed					
- Grass forage/fodder/ hay	TEP	No	N/A	Yes[23/]	24 Months
- Rotational Crops	TEP	No		Yes [24/]	24 Months
171-4 - Magnitude of the Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00011963,00011945	Reserved[25/]	24 Months

Table A
Generic Data Requirements for Terbacil (cont'd)

158.240 Residue Chemistry Footnotes

1/The same chemical identity data are required as under 158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

2/Data depicting the uptake, distribution, and metabolism of ^{14}C-ring-labeled terbacil in or on apples and sugarcane. A completely characterized test substance representative of technical terbacil used in commercial formulations (including impurities) must be used under conditions of normal agricultural practices and at rates sufficiently high to permit characterization of ^{14}C-residues. The identities of residues in mature plant parts must be determined and confirmed in order to elucidate terminal residues. Quantitative data must also be provided. Representative samples from the required metabolism studies must also be analyzed using Method II in the PAM, Vol. II to ascertain that the method will adequately recover and quantify all metabolites of concern. The registrant is urged to complete and submit all required plant metabolism studies prior to initiating field trials and processing studies.

3/Metabolism studies characterizing the total terminal residue of terbacil in ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with uniformly ring-labeled [^{14}C]terbacil fed in the diet at a level sufficient to make residue identification and quantification possible. Eggs and milk must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined and confirmed in eggs, milk, liver, kidney (except poultry), muscle, and fat. Representative samples from these studies must be analyzed using Method II in the PAM, Vol. II to ascertain that the method is capable of adequately recovering and identifying all residues of concern. Data depicting the nature of terbacil residues in swine will be required if the required metabolism studies with ruminants and poultry reveal that the metabolism of terbacil differs from that in the rats.

4/Representative plant and animal tissue samples bearing residues of terbacil and its metabolites A, B, and C must be subjected to analysis by multiresidue protocols I and III from PAM Volume I. Multiresidue protocols I through IV are available from the National Technical Information Service (NTIS) under Order No. PB 203734/AS.

5/The nature of the residue in plants and animals is not adequately understood. If the metabolism studies requested in the sections "Qualitative Nature of the Residues in Plants" and "Qualitative Nature of the Residue in Animals" reveal the presence of additional metabolites of concern, additional validation methods for data collection and tolerance enforcement will be required.

6/The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of terbacil residues of concern in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with terbacil residues of concern and fortified meat and milk samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable unforseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field weathered samples are

Table A
Generic Data Requirements for Terbacil (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the Registrant is referred to an August 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order No. PB 88112362/AS.

7/Data depicting terbacil residues of concern in or on lemons, oranges, and grapefruits harvested at regular intervals following a single directed spray soil application of the 80% WP formulation at 6.4 lb ai/A conducted in California and at 8 lb ai/A conducted in Texas (no lemon data required from Texas). Also, data must be submitted for oranges, grapefruit, and lemons grown in Florida and treated twice at 4 lb ai/A. Data must depict the decline in residues over a suitable range of posttreatment intervals. In addition, the registrant must propose a PHI based on the requested residue data and an appropriate tolerance revision to cover all residues of concern, including metabolites A, B, and C.

8/Data depicting terbacil residues of concern in dried pulp, molasses, oil, and juice from oranges bearing measurable, weathered residues. It is recommended that an exaggerated rate greater than or equal to the highest theoretical concentration factor be used. If residues concentrate in any of these processed commodities, an appropriate food/feed additive tolerance must be proposed.

9/Data depicting terbacil residues of concern in or on apples (early maturing varieties must be included) harvested following a dormant directed spray soil application at 3.2 lb ai/A in 20 gal/A. Tests must be conducted in Washington, New York, Michigan, and California which together represent approximately 70% of the U.S. apple production, if New York represents Pennsylvania (7%) (Agricultural Statistics, USDA, 1986, p. 186). The registrant must propose an appropriate tolerance revision to cover all residues of concern, including metabolites A, B, and C.

10/Data depicting terbacil residues of concern in dry apple pomace and juice processed from apples bearing measurable, weathered residues. It is recommended that an exaggerated rate greater than or equal to the maximum theoretical concentration factor be used. If the data indicate a potential for concentration in either commodity, the registrant must propose an appropriate food/feed additive tolerance.

11/If the required storage stability data invalidate the available data for peaches or additional residues of concern are discovered in the required plant metabolism studies, additional data will be required.

12/If the required storage stability data invalidate the available data for blueberries or additional residues of concern are discovered in the required plant metabolism studies, additional data will be required.

13/Residue data depicting terbacil residues of concern in or on blackberries harvested 70 days following a single application of the 80% WP formulation at 1.6 lb ai/A. Tests must be conducted in California (13%) and Oregon (76%) since these States accounted for approximately 90% of the 1982 U.S. blackberry acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 370).

Table A
Generic Data Requirements for Terbacil (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

14/If the required storage stability data invalidate the available data for strawberries or additional residues of concern are discovered in the required plant metabolism studies, additional data will be required.

15/Data depicting terbacil residues of concern in or on pecans harvested at normal crop maturity following a single broadcast soil application of the 80% WP formulation at 2.4 lb ai/A in 30 gal/A made during the early seedling stage of weed growth. Tests must be conducted in Georgia (41%) and Texas (18%), which accounted for approximately 60% of the 1987 U.S. pecan production (Agricultural Statistics Board, NASS, USDA, Crop Database, January 1988). A PHI must be proposed and reflected in the submitted data.

16/Data depicting terbacil residues of concern in or on alfalfa hay harvested at normal crop maturity following a broadcast soil application of the 80% WP formulation at 0.6 lb ai/A, followed by an additional broadcast soil application made 60 days later at 1.2 lb ai/A. The final application must be made when regrowth or new growth is approximately 2 inches in height. Applications must be made using ground equipment in 20 gal/A. Tests must be conducted in New York or Pennsylvania since these States are representative of the northeastern U.S. where this use is permitted. No additional data are required for alfalfa forage unless the required storage stability data indicate that the available data are invalid or additional residues of concern are discovered in the required plant metabolism studies.

17/Data depicting terbacil residues of concern in or on asparagus harvested 5 days following a single application of the 80% WP formulation at 2.4 lb ai/A. Tests must be conducted in California (49%) or Washington (35%) and Michigan (11%), since these States accounted for approximately 95% of the 1986 U.S. asparagus production (Vegetables, 1986 Summary, Agricultural Statistics Board, NASS, USDA, June 1987, p. 18).

18/Data depicting terbacil residues of concern in or on mint hay harvested 60 days following postemergence broadcast application of the 80% WP formulation at 1.6 lb ai/A in 0.5 to 1 pt of surfactant/25 gal of spray. Tests must be conducted in Oregon, Washington, and Wisconsin which represent the Pacific Northwest and Midwest regions where this use is permitted.

19/A processing study depicting terbacil residues of concern in spent hay and oil processed from mint bearing measurable, weathered residues. It is recommended that an exaggerated rate greater than or equal to the highest theoretical concentration factors for mint hay and mint oil be used. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. In lieu of data for spent hay, the registrant may propose a feeding restriction.

20/Data depicting terbacil residues of concern in or on sugarcane harvested at normal crop maturity following: (i) a single preemergence broadcast application of the 80% WP formulation at 2 lb ai/A (tests must be conducted in Hawaii and Puerto Rico); (ii) a single broadcast application of the 80% WP formulation at 3.2 lb ai/A in the early spring, followed by a single directed spray (layby) application applied immediately after the last cultivation at 0.4 lb ai/A (tests must be conducted in

Table A
Generic Data Requirements for Terbacil (cont'd)

158.240 Residue Chemistry Footnotes (cont'd)

Louisiana); and (iii) a preemergence broadcast application of the 80% WP formulation at 1.6 lb ai/A in the fall followed by a second application in the spring at 1.6 lb ai/A (tests must be conducted in Texas). A PHI must be proposed for the layby use in Louisiana which must be supported by the submitted data. Also, the registrant must propose an appropriate tolerance revision to cover all residues of concern, including metabolites A, B, and C.

21/Since sugarcane forage is a raw agricultural commodity of sugarcane, a tolerance and a pregrazing interval must be proposed for this commodity. Alternatively, the registrant may propose a restriction on the feeding of sugarcane forage to livestock.

22/A processing study depicting the potential for concentration of terbacil residues of concern in molasses, bagasse, and refined sugar processed from sugarcane bearing measurable, weathered residues. It is recommended that an exaggerated rate greater than or equal to the highest theoretical concentration factor be used. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

23/Data depicting terbacil residues of concern in or on grass hay and forage (Bermuda grass, bluegrass, and bromegrass or fescue) harvested following a single broadcast soil application (made after seed harvest) of the 80% WP formulation at 1 lb ai/A. Application must be made by ground equipment in 40 gal/A. A pregrazing interval for forage and a preharvest interval for hay must be proposed and reflected in the submitted data. Also, data for seed, seed screenings and straw (as a byproduct of seed processing) collected at the next seed harvest following treatment must be provided. Tests must be conducted in Oregon which is representative of this use. The registrant must propose appropriate tolerances for terbacil residues of concern in or on the forage, hay, seed, seed screenings, and straw of grass.

24/Data are required for representative crops from any crop groups which could be rotated from alfalfa, sainfoin and mint. These data must reflect an appropriate plant back interval and analysis for all terbacil residues of concern in mature plant parts which may be used for food or feed. In addition, the data should involve the maximum proposed registered uses of typical end-use products on the subject crops as well as adequate geographical representation. Acceptable processing studies may also be required. It is recommended that the registrant(s) submit protocols for these studies for Agency approval prior to initiation of any of the experiments.

25/On receipt of the data requested in the sections entitled "Qualitative Nature of the Residue in Plants and Animals," "Magnitude of the Residue in Plants," and "Storage Stability Data," the need for additional feeding studies will be determined.

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	PAIRA	A	Yes	00011946, 41136301	No	
Photodegradation						
161-2 - In Water	PAIRA	A	Yes	00011946	No	
161-3 - On Soil	PAIRA	A	Yes	00160235	No	
161-4 - In Air	PAIRA	A	No		No[1/]	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	PAIRA	A	No		Yes	24 Months
162-2 - Anaerobic Soil	PAIRA	A	No		Yes	24 Months
162-3 - Anaerobic aquatic	PAIRA	N/A	No		N/A	
162-4 - Aerobic aquatic	PAIRA	N/A	No		N/A	
Mobility Studies						
163-1 - Leaching						
- Adsorption/Desorption	PAIRA	A	Partially	00155104	Yes[2/]	12 Months

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.290 Environmental Fate						
Mobility Studies (cont'd)						
163-2 - Volatility (Lab)	TEP	A	No		No[1/]	
163-3 - Volatility (Field)	TEP	A	No		No[1/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A	No		No[3/]	
164-2 - Aquatic (Sediment)	TEP	N/A	No		N/A	
164-3 - Forestry	TEP	N/A	No		N/A	
164-5 - Soil, Long Term	TEP	A	No		Yes[4/] Protocol Progress Rpt.	48 Months 6 Months 1 Year
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	00011948,00011949	No[5/]	
165-2 - Rotational Crops	TEP	A	No		No	
165-3 - Irrigated Crops	TEP	N/A	No		N/A	
165-4 - In Fish	PAIRA	A	Yes	00011947	No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.290 Environmental Fate						
Accumulation Studies (cont'd)						
165-5 - In Aquatic Nontarget Organisms	TEP	N/A	No		N/A	
158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No		Yes[6/]	12 Months
201-1 - Drift Field Evaluation	TEP	A	No		Yes[6/]	24 Months
158.75 Other Exposure Data						
Ground Water Monitoring Data	TEP	A	No		Reserved[7/]	

1/Terbacil is considered to be nonvolatile.

2/An aged leaching study is required for all major degradates of terbacil, including: 5-chloro-6-methyluracil; 3-tert-butyl-6-methyluracil; 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-ã)-pyrimidine-5-one; 3-tert-butyl-5-chloro-6-hydroxymethyluracil; and 6-chloro-2,3-dihydro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo(3,2-ã)-pyrimidine-5-one.

3/Due to the persistence of terbacil, a short-term study is waived in favor of a long-term soil field dissipation study.

Table A
Generic Data Requirements for Terbacil (cont'd)

158.290 Environmental Fate Footnotes (cont'd)

4/A 3-year study conducted in four different representative sites is required. Site locations must include Louisiana (sugarcane), Texas (sugarcane) and two apple (orchard) sites. Applications must be made at the maximum application rate as specified by the product label. Protocols must be submitted and approved before initiating the study. One year progress reports are required.

5/See footnote # 24 under Section 158.240 Residue Chemistry Table A.

6/Due to the phytotoxic effects of this pesticide, these studies are required to assess the risk of drift to nearby plants.

7/A small-scale retrospective groundwater monitoring study is reserved pending the results of the long-term field dissipation study. This monitoring study may be required in order to evaluate the impact of long-term use of terbacil on groundwater in typical and reasonable worst-case use environments. If the groundwater monitoring study is required, the registrant will also be required to perform Pesticide Root Zone Model (PRZM) model simulations for terbacil to help identify sites for a small-scale retrospective ground water monitoring study. Prior to conducting the study, the registrant must submit a protocol for conducting this study. Sampling should not be initiated without prior Agency approval.

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A	Yes	00150946	No	
81-2 - Acute Dermal	TGAI	A	Yes	00130945	No	
81-3 - Acute Inhalation - Rat	TGAI	A	Yes	00125700	No	
81-4 - Eye Irritation - Rabbit	TGAI	A	Yes	00157179	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A	No		No[1]/	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	Yes	00157180	No	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No		No[2]/	
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A	Yes	00068035	No	
- Nonrodent	TGAI	A	No		No[3]/	
82-2 - 21-Day Dermal	TGAI	A	Yes	00125785,00148066	No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Subchronic Testing (cont'd)						
82-3 - 90-Day Dermal	TGAI	A	No		No[4/]	
82-4 - 90-Day Inhalation	TGAI	A	No		No[4/]	
82-5 - 90-Day Neurotoxicity	TGAI	A	No		No[4/]	
Chronic Testing						
83-1 - Chronic Toxicity						
- Rodent	TGAI	A	No		Yes[5/]	48 Months
- Nonrodent	TGAI	A	Yes	00060851	No	
83-2 - Oncogenicity Study						
- Rat	TGAI	A	No		Yes[5/]	48 Months
- Mouse	TGAI	A	No		Yes	48 Months
83-3 - Teratogenicity						
- Rat	TGAI	A	Yes	00050467	No	
- Rabbit	TGAI	A	Yes	00150945	No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Chronic Testing (cont'd)						
83-4 - Reproduction	TGAI	A	Yes	00060852	No	
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A	No		Yes 6/	12 Months
84-2 - Chromosomal Aberration	TGAI	A	Yes	00150944	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	Yes	00150939,00155103	No	
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A	No		Yes 7/	24 Months

1/Satisfied by 21-day dermal toxicity study.

2/Terbacil is not an organophosphate, and available data at this time do not reveal a neurotoxicological problem.

3/Satisfied by a chronic toxicity study in dogs (MRID# 00060851).

4/These studies are not required at this time.

5/A combined chronic/oncogenicity study may be submitted to satisfy this requirement.

6/A gene mutation study (MRID# 00150943) was reviewed and classified as supplemental. This study was deemed supplemental due to missing study pages and tables identified in the study.

7/A rat metabolism study is currently under review (MRID 40104702).

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.490 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Acute Oral Toxicity	TGAI	A	Yes	00157177	No	
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	A	Yes	00012346	No	
- Waterfowl	TGAI	A	Yes	00012347, 00134343	No	
71-3 - Wild Mammal	TGAI	A	No		No	
71-4 - Avian Reproduction	TGAI	A	No		No[1/]	
71-5 - Actual Field Testing						
- Birds and Mammals	TEP	A	No		No[1/]	
Aquatic Organisms Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	A	Yes	00138467	No	
	TEP	A	Yes	00025224	No	
- Coldwater	TGAI	A	Yes	41197801	No	
	TEP	A	Yes	00025223	No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.490 Wildlife and Aquatic Organisms						
Aquatic Organisms Testing (cont'd)						
72-2 - Freshwater Invertebrate LC_{50}	TGAI	A	Yes	41197802	No	
	TEP	A	No		No	
72-3 - Estuarine and Marine Organisms LC_{50}						
- Mollusk	TGAI	A	No		No[2/]	
	TEP	A	Yes	00012333	No	
- Fish	TGAI	A	No		Yes[3/]	12 Months
	TEP	A	No		Reserved[4/]	
- Crustacean	TGAI	A	No		No[2/]	
	TEP	A	Yes	00012332	No	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater	TGAI	A	No		No	
- Marine/Estuarine	TGAI	A	No		Reserved[5/]	
72-5 - Fish Life Cycle	TGAI	A	No		No	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? Use Patterns	(Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.490 Wildlife and Aquatic Organisms						
Aquatic Organisms Testing (cont'd)						
72-6 - Aquatic Organism Accumulation	TGAI	A	No		No	
72-7 - Simulated or Actual Field Testing						
- Aquatic Organisms	TGAI	A	No		No	

1/Due to the nontoxicity of this pesticide to avian species, this study is not required.

2/Requirement satisfied with formulated product.

3/A study had been submitted in response to 1982 RS and found to be unacceptable. A new study is required.

4/Reserved, pending evaluation of study using technical material.

5/Reserved pending evaluation of Marine/Estuarine Fish LC50 study.

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.540 Plant Protection						
Target Area Phytotoxicity						
121-1 - Target Area Phytotoxicity	TEP	A	No		No	
Nontarget Area Phytotoxicity						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		Yes[1/]	12 Months
122-1 - Vegetative Vigor	TGAI	A	No		Yes[1/]	12 Months
122-2 - Aquatic Plant Growth	TGAI	A	No		Yes[1/]	12 Months
TIER II						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		Reserved[2/]	
122-1 - Vegetative Vigor	TGAI	A	No		Reserved[2/]	
122-2 - Aquatic Plant Growth	TGAI	A	No		Reserved[2/]	

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.540 Plant Protection						
Nontarget Area Phytotoxicity (cont'd)						
TIER III						
124-1 - Terrestrial Field	TGAI	A	No		Reserved[2/]	
124-2 - Aquatic Field	TGAI	A	No		Reserved[2/]	

1/Tier I testing is required due to aerial application.
2/Reserved, pending results of Tier I testing.

Table A
Generic Data Requirements for Terbacil (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
§158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Contact LD50	TGAI	A	Yes	00009181	No	
141-2 - Honey Bee - Toxicity Residues on Foliage	TEP	A	No		No 1/	
141-4 - Honey Bee Subacut Feeding Study	TGAI	A	No		No 1/	
141-5 - Field Testing for pollinators	TEP	A	No		No 1/	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	TEP	A	N/A			
142-2 - Aquatic Insect Life Cycle Study	TEP	A	N/A			
142-3 - Simulated or Actual Field Testing for Aquatic Insects	TEP	A	N/A			
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thur 143-3	TEP	A	N/A			

§158.590 Nontarget Insects

§158.590 - Nontarget Insects Footnotes

1/ Data from the acute contact test indicated low toxicity, no further testing is required at this time.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbacil

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
Part 158, Subpart C, Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity	MP	No[1]		Yes[2]	12 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No[1]		Yes[3]	12 Months
61-3 - Discussion of Formation of Impurities	MP	No[1]		Yes[4]	12 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No[1]		Yes[5]	12 Months
62-2 - Certification of Ingredient Limits	MP	No[1]		Yes[6]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	No[1]		Yes[7]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	MP	No[1]		Yes[8]	12 Months
63-3 - Physical State	MP	No[1]		Yes[8]	12 Months
63-4 - Odor	MP	No[1]		Yes[8]	12 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbacil (cont'd)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
Part 158, Subpart C, Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	No[1]		Yes[8]	12 Months
63-12 - pH	MP	No[1]		Yes[8,9]	12 Months
63-14 - Oxidizing or Reducing Agent	MP	No[1]		Yes[8,10]	12 Months
63-15 - Flammability	MP	No[1]		Yes[8,11]	12 Months
63-16 - Explodability	MP	No[1]		Yes[8,15]	12 Months
63-17 - Storage Stability	MP	No[1]		Yes[8,12]	12 Months
63-18 - Viscosity	MP	No[1]		Yes[8,14]	12 Months
63-19 - Miscibility	MP	No[1]		Yes[8,13]	12 Months
63-20 - Corrosion Characteristics	MP	No[1]		Yes[8]	15 Months
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbacil (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes

1/Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient in each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.

3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/A detailed discussion of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimated based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 8570-4 Rev. 2-85.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbacil (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes (cont'd)

7/Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/Physicochemical characteristics (color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

9/Data required if the test substance is dispersible in water.

10/Data required if the product contains an oxidizing or reducing agent.

11/Data required if the product contains combustible liquids.

12/The test must be conducted with the product in its commercial package. Products must be tested for 1 year under either of the following conditions: (i) at 20 or 25°C, and, if the package is permeable, at a relative humidity of 50%; (ii) under warehouse conditions which reflect the expected storage conditions of the commercial product.

13/Data required if the product is a liquid.

14/Data required if the product is a liquid and is to be diluted with petroleum solvents.

15/Data required if the product is potentially explosive.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	A	Yes	00150946	No	
81-2 - Acute Dermal	MP	A	Yes	00130945	No	
81-3 - Acute Inhalation - Rat	MP	A	Yes	00125700	No	
81-4 - Eye Irritation - Rabbit	MP	A	Yes	00157179	No	
81-5 - Dermal Irritation						
- Rabbit	MP	A	No		No[1/]	
81-6 - Dermal Sensitization						
- Guinea Pig	MP	A	Yes	00157180	No	

1/Study satisfied under 158.135 Guideline Series 82-2 (21-Day Dermal).

Table C
Product-Specific Data Requirements for End-Use Products Containing Terbacil

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
Part 158, Subpart C, Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Composition	EP	No[1]		Yes[2]	12 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	No[1]		Yes[3]	12 Months
61-3 - Discussion of Formation of Impurities	EP	No[1]		Yes[4]	12 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	EP	No[1]		Yes[5]	12 Months
62-2 - Certification of Ingredient Limits	EP	No[1]		Yes[6]	12 Months
Physical and Chemical Characteristics					
63-7 - Density, Bulk Density, or Specific Gravity	EP	No[1]		Yes[7]	12 Months
63-12 - pH	EP	No[1]		Yes[7,8]	12 Months
63-15 - Flammability	EP	No[1]		Yes[7,9]	12 Months

Table C
Product-Specific Data Requirements for End-Use Products Containing Terbacil

Part 158, Subpart C, Product Chemistry Footnotes

1/Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient in each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.

3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. Required for products produced by an integrated system.

6/Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at $\geq 0.1\%$ (w/w) and each "toxicologically significant" impurity present at $< 0.1\%$ (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimates based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 857 Rev. 2-85.

7/Density or specific gravity, pH, and flammability information must be submitted for each product as part of the Confidential Statement of Formula. Other physicochemical characteristics (color, physical state, odor, melting point, solubility, vapor pressure, dissociation constant, partition coefficient, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, are not required at this time.

8/Data required if the test substance is dispersible in water.

9/Data required if the product contains combustible liquids.

Table C
Product-Specific Data Requirements for End-Use Products Containing Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	WP[1/]	A	Yes	00150946	No	
81-2 - Acute Dermal	WP	A	Yes	00130945	No	
81-3 - Acute Inhalation - Rat	WP	A	No		Yes	12 Months
81-4 - Eye Irritation - Rabbit	WP	A	No		Yes	12 Months
81-5 - Dermal Irritation						
- Rabbit	WP	A	No		No[2/]	
81-6 - Dermal Sensitization						
- Guinea Pig	WP	A	No		Yes	12 Months

1/80% wettable powder.

2/Requirement satisfied under 82-2 (21-Day Dermal).

Table C
Product-Specific Data Requirements for End-Use Products Containing Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	WP[1/]	A	No		Yes	12 Months
81-2 - Acute Dermal	WP[1/]	A	No		Yes	12 Months
81-3 - Acute Inhalation - Rat	WP[1/]	A	No		Yes	12 Months
81-4 - Eye Irritation - Rabbit	WP[1/]	A	No		Yes	12 Months
81-5 - Dermal Irritation						
- Rabbit	WP[1/]	A	No		Yes	12 Months
81-6 - Dermal Sensitization						
- Guinea Pig	WP[1/]	A	No		Yes	12 Months

1/Mixture of terbacil (40% active ingredient) and diuron (40% active ingredient).

Table A
Generic Data Requirements for Terbacil

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		No[1/]	
132-2 - Soil Dissipation	TEP	A	No		No[1/]	
132-3 ermal Exposure	TEP	A	No		No[1/]	
132-4 - halation Exposure	TEP	A	No		No[1/]	

1/ Terbacil is applied pre-emergent or during crop dormancy.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper

or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label or labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any Agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed;" and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"; and

(C) "Pollution approved."

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to §162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 degrees F (20 degrees C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishment registration number. The producing establishment registration number preceded by the phrase "EPA Est.," of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard Indicators	Toxicity Categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "Poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "Keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of Label Front Panel in Square Inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity Category	Precautionary Statements by Toxicity Category	
	Oral, Inhalation, or Dermal Toxicity	Skin and Eye Local Effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes, or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.]	[No precautionary statements required.]

(ii) Environmental hazards. Where a hazard exists to nontarget organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flashpoint	Required Text
(A) PRESSURIZED CONTAINERS	
Flashpoint at or below 20 degrees F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
Flashpoint above 20 degrees F and not over 80 degrees F the flame extension is more than 18 inches long at a distance of 6 inches from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20 degrees	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20 degrees F and not over 80 degrees F	Flammable. Keep away from heat and open flame.
Above 80 degrees F and not over 150 degrees F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular"; and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for directions for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information, such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug, and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable

restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the heading "Directions for Use""

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in §162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide

may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of §162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use," and reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification.

(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 CF 28268, July 3, 1975; 40 FR 32329, August 1, 1975; 40 FR 38571, August 21, 1975, as amended at 43 FR 5786, February 9, 1978; amended at 53 FR 15952, May 4, 1988.

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extensionaway is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep from heat, sparks, and flame. Do not puncture or incinerate the container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above °F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area,proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during torage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is aviolation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA RegionalOffice for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. 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, will be 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 attempted also 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 at any time 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 a 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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Registrations Under the Terbacil Standard

MRID	Citation
00009181	Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499. (Unpublished study received Jul 29, 1976 under 352-342; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:224800-C)
00011945	E.I. du Pont de Nemours & Company (19??) Terbacil: Poultry Feeding Study: Residue Data--Tissues and Eggs. (Unpublished study received on unknown date under 4F1428; CDL:098172-A)
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)
00011948	E.I. du Pont de Nemours & Company (1975) Terbacil--Rotational Crop Studies. (Unpublished study received Nov 25, 1975 under 4F1428; CDL:094842-C)
00011949	Holt, R.F.; Pease, H.L. (1971?) Residue Procedure for the Determination of Terbacil and Its Metabolites Using Microcoulometric Gas Chromatography. Undated method. (Unpublished study received Nov 25, 1975 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-D)
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)
00011952	E.I. du Pont de Nemours & Company, Incorporated (1974) Freezer Storage Studies: Terbacil-Metabolites. (Unpublished study received Oct 1, 1974 under 4F1428; CDL:093805-E)

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MRID	Citation
00011953	Pease, H.L. (1971?) Confirmatory Procedure for Residues of Terbacil and Its Metabolites. (Unpublished study received Oct 1, 1974 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093805-F)
00011957	Rhodes, R.C. (1974?) Five-Dose 2-14C-Terbacil Goat Study--Residue Analysis of Meat and Milk. (Unpublished study received Apr 25, 1975 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:095530-A)
00011958	E.I. du Pont de Nemours and Company (1973) Name, Chemical Identity, and Composition: [Terbacil]. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-A)
00011959	E.I. du Pont de Nemours and Company (1973) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. Summary of studies 093806-C through 093806-L. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-B)
00011960	Holt, R.F.; Pease, H.L. (1971?) Residue Procedure for the Determination of Terbacil and Its Metabolites in Alfalfa. Undated method. (Unpublished study received Aug 30, 1973 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093806-C)
00011961	E.I. du Pont de Nemours & Company, Incorporated (19??) Determination of Terbacil and Its Metabolites in Milk and Urine. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-D)
00011963	E.I. du Pont de Nemours and Company (1968?) Terbacil: Livestock Feeding Study--Milk and Meat. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-G)
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)

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MRID	Citation
00012014	Rhodes, R.C.; Weed, M.B. (19??) Distribution of 2-14C-Labeled Terbacil in Sugar Cane Following Injection. (Unpublished study received Dec 13, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090603-M)
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)
00012035	Pease, H.L. (1964?) Determination of Terbacil Residues. Undated method. (Unpublished study received Jun 30, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:092796-K)
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)
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00012097	IR-4 Project at Rutgers, the State University (1972) Analytical Residues: [Terbacil]. (Unpublished study received Mar 14, 1977 under 7E1936; CDL:097354-A)
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-tert-Butyl-5-chloro-6-methyluracil) Residue Data--Sugar Cane. (Unpublished study received Feb 9, 1966 under unknown admin. no.; CDL:124200-A)

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MRID Citation

00012181 Pease, H.L. (19??) The Determination of Herbicide 732 Residues in Citrus. Undated method. (Unpublished study received Feb 9, 1966 under unknown admin. no.; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:124200-B)

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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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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.)
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00128574	E.I. du Pont de Nemours & Co., Inc. (1983) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. (Compilation; unpublished study received May 25, 1983 under 352-317; CDL:071628-A)

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00130945	Hood, D. (1965) Acute Skin Absorption Toxicity: [3-tert-Butyl-5-chloro-6-methyluracil: Rabbits]: Haskell Laboratory Report No. 76-65. (Unpublished study received May 1, 1981 under unknown admin. no.; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:251081-C)
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00138467	E.I. du Pont de Nemours & Co., Inc. (1979) 96-Hour LC50 to Bluegill Sunfish: [Uracil]: Haskell Laboratory Report No. 701-78. (Unpublished study received Oct 16, 1979 under 352-317; CDL: 241146-A)
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IV. FORMS APPENDICES

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

Form Approved. OMB No. 2070-0057. Expires 11-30-89.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

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

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

EPA	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 158.120 Product Chemistry					
61-1	Identity of Ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto 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.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated_____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic 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 Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:_____
(Signature

Dated: _____ _____
(Typed)

EPA Form 8570-3