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Office of
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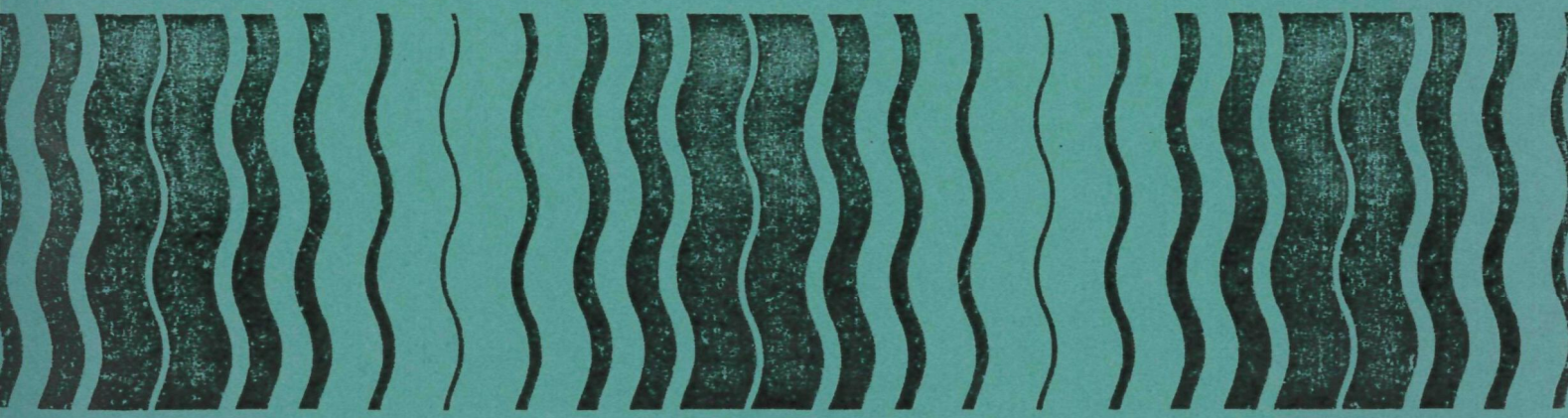
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Terbutryn

as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING TERBUTRYN AS THE ACTIVE INGREDIENT

CASE NUMBER: 085

CAS (DOCKET) NUMBER: 886-50-0

September 1986

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: Acceptable Daily Intake

a.i.: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classifications: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline)

CSF: Confidential Statement of Formula

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

F_0, F_1, F_2 Refers to the generations in a multi-generation study

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50% of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations

MUP: Manufacturing-use product

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level-The maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

Glossary (cont.)

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: Provisional Acceptable Daily Intake

PAI: Pure active ingredient

Q_1*: The mathmatical factor for the potency of a hazard, such as oncogenicity--the Q_1* is a parameter of the linearized multistage extrapolation model. It is used as a multiplier of the estimated exposure (in units of mg/kg/day) to obtain the estimated 95% upper bound on risk. A change in the Q_1* will result in a proportional change in risk.

RPAR: Rebuttable Presumption Against Registration, the term formerly used by the Agency to refer to the interim administrative review which is now called "Special Review". See 40 CFR Part 154.

SAR: Structure/activity relationship

Technical: Active ingredient as manufactured

TMRC: Theoretical Maximum Residue Contribution

ug: microgram

I. INTRODUCTION

The Registration Standards Program

The Environmental Protection Agency (EPA) has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring the product and its labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and are reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies the following:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request, focuses on the pesticide active ingredient. The scientific review presents primarily the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency also looks for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect people and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Part IV, Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include any or all of the following:

1. Submission of data in support of product registration

2. Modification of product labels

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals

5. Modification of uses or formulation types

6. Specification of packaging limitations

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to people or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA section 3(c)(2)(B) to require that registrants submit data to answer questions regarding the toxicological, chemical, and environmental characteristics, and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve concerns about terbutryn. These data are listed in Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA section 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on people or the environment. This requirement continues as long as a product is registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

Common Name	:	Terbutryn
Chemical Name	:	2-(tert-butylamino-4-(ethylamino)-6-(methylthio)-s-triazine
Empirical Formula	:	$C_{10}H_{19}N_5S$
Trade Name	:	Igran, Prebane, Terbutrex, Terbutryne, GS-14260, Clarosan and Short-stop (discontinued)
OPP/Shaugnessy No.	:	080813
CAS Registry No.	:	886-50-0

B. USE PROFILE

Type of Pesticide	:	Herbicide
Pest Controlled	:	Annual broadleaf and grass weeds
Registered Uses	:	Winter wheat, winter barley, grain sorghum, fallow land, and non-crop (including industrial and right-of-way weed control)
Predominant Uses	:	Grain Sorghum (approximately 50%) Winter wheat (approximately 50%)
Acres treated (approximate)	:	Winter wheat--350,000 acres--less than 1.0% of U.S acres planted (420,000 to 770,000 lbs. a.i./yr). Sorghum--350,000 acres--less than 2% of U.S. acres planted (520,000 to 780,000 lbs. a.i./yr)
Method of Application	:	Broadcast or band by ground or aerial equipment, pre-emergence, preplant, or early postemergence
Mode of Activity	:	Inhibition of water photolysis in the photosynthetic process.
Formulation Manufacturing - Use Product	:	95-96% active ingredient (technical)
End-Use Products	:	80% wettable powder and 80% dry flowable formulation

C. HISTORY

Terbutryn was first tested in 1952 in Switzerland by J. R. Geigy (now Ciba-Geigy) under the designation GS-14260. Terbutryn's herbicidal properties were first reported in 1965 by A. Gast, et al. in Paris and J. R. Geigy introduced it to the United States in 1968 (U.S. patent #3,145,208; Swiss patent #393,344; British patents #814,948 and #978,249). It was registered in the United States on July 31, 1969. At the present time, Ciba-Geigy and Gowan Company are the registrants of products containing terbutryn.

Terbutryn was referred as a candidate for the Rebuttable Presumption Against Registration (RPAR, now referred to as Special Review) process in 1980 based on preliminary results of a two-year study indicating that terbutryn is carcinogenic in laboratory rats. A review of the data base was initiated.

In addition to the rat oncogenicity study, the Agency reviewed a mouse oncogenicity study, a three generation study of reproductive effects in rats, and the report of a 1973 lecture by Kalman Szende which suggested that terbutryn may be weakly mutagenic.

The Agency concluded that terbutryn was not shown to be oncogenic in mice, found no evidence that it is mutagenic in mammalian systems, and reported the no observed effect level (NOEL) to be 15 mg/kg/day for reproductive effects in rats.

The Agency also concluded that the two year rat oncogenicity study did demonstrate an increased incidence of tumors in rats, but that the oncogenic risk to humans could be sufficiently reduced by reducing worker exposure. Thus the Agency required that certain changes be made in product labeling in order to reduce worker exposure. These changes require mixers and/or loaders handling terbutryn to wear impermeable gloves, long-sleeved coveralls, and a dust mask capable of trapping particulates 0.6 microns in size.

In its Decision Document of October 8, 1981, the Agency concluded that available data did not support an RPAR under the risk criteria specified in 40 CFR 162.11.

The following data have been required under section 3(c)(2)(B) of FIFRA since the 1981 Decision Document:

Teratogenicity (one species)	Submitted	10/85
Environmental fate studies		
Hydrolysis	"	5/85
Photodegradation in water	"	6/85
Photodegradation in soil	"	3/85
Aerobic soil	"	3/85
Anaerobic soil	"	3/85
Mobility	"	3/85
Field Dissipation in soil	"	3/85
Product Chemistry		
Water solubility	"	4/85
Vapor Pressure	"	4/85
Octanol water partition coefficient	"	4/85

The regulatory conclusions regarding these data and the relationship to the concerns of the 1981 Decision Document are discussed in Part III (Agency Assessments).

III. AGENCY ASSESSMENT

The Agency has conducted a thorough review of the scientific data base on terbutryn. This part of the Standard sets forth the results of that review.

A. SUMMARY OF ASSESSMENT

Based on the review of the data filed in support of the registration of terbutryn, the Agency has reached the following major conclusions. A more detailed discussion of the full assessment appears in Section B.

1. Terbutryn may pose an oncogenic risk from worker exposure. It has been classified as a Group C Oncogen (possible human carcinogen) based on the following:

   In a two-year rat feeding study terbutryn produced 1) a marginal response in a tissue (mammary gland) known to have a high and variable background rate of tumors, and 2) an increase in combined benign and malignant tumors (testicular, thyroid, and liver) with the chemical producing no response in a variety of short-term tests for mutagenicity (limited, but negative mutagenicity data were available).

2. Worker exposure can be reduced to acceptable limits through the classification of products containing terbutryn as restricted use pesticides and through the use of protective equipment, clothing, and gloves.

   Additional data are required to fully assess the quantitative exposure to workers (mixers, loaders, and applicators) and margins of safety. Additional studies have been required. However, estimates have been made using data on other chemicals with similar use patterns, and a risk assessment has been conducted. This is discussed more fully in Section C of this Part.

3. Terbutryn poses a limited oncogenic risk from dietary exposure. The Theoretical Maximum Residue Contribution (TMRC) for terbutryn in the daily diet based on the total tolerances and daily food intake of 1.5 kg is 0.000260 mg/kg/day. Under these conditions 2.6% of the PADI (Provisional Acceptable Daily Intake) has been used.

4. Although no data are available, since it is a relatively non-selective herbicide, terbutryn is expected to be highly toxic to plants. Therefore, interim protective labeling will be required for endangered plant species.

In the course of its review, the Agency has identified data which are necessary to evaluate risks associated with the use of terbutryn. These data must be developed and submitted in order to maintain registrations of products or register new products containing terbutryn. Figure 1 summarizes the data gaps. Please note that this is only a summary, and more details can be obtained by referring to Data Tables A and B in Appendix I.

The Agency has also determined that certain additional or revised label restrictions are necessary. They include:

- Restricted Use Classification
- Protective equipment and clothing
- Grazing and feeding restrictions
- Environmental hazard precautions
- Endangered species warnings

A more detailed discussion of the Agency's assessments follows. In Part IV, the Regulatory Position and Rationale section details the Agency's position regarding the regulation of terbutryn, and Section D of Part IV, Required Labeling, contains the required wording for label revisions.

SUMMARY OF DATA GAPS

PRODUCT CHEMISTRY

Manufacturing process
Identification of suppliers of material
Discussion of impurities
Certification of ingredients
Quantitative methods for impurities

ENVIRONMENTAL FATE

Photodegradation (water, soil)
Anaerobic soil metabolism
Field dissipation study (soil)
Rotational crop study (confined)
Fish accumulation study

FISH AND WILDLIFE

Avian dietary (upland gamebird)
Freshwater fish (warm water, cold water) LC_{50}
Acute estuarine and marine organism LC_{50} studies
Fish early life-stage and aquatic invertebrate life cycle studies
Non-target phytotoxicity (aquatic plant growth, seed germination/seedling emergence and vegetative vigor)

TOXICOLOGY

Acute inhalation (rat)
21-Day dermal
Chronic toxicity (rodent) (special 24-month rat study)
Mutagenicity battery
General metabolism

RESIDUE CHEMISTRY

Metabolism studies (ruminants, poultry)
Uptake, distribution, and metabolism in plants (postemergent application)
Storage stability data
Processed commodity data
Residues of concern on grain and milled products
Residues of concern on green wheat, green barley, wheat straw, and barley straw

Figure 1

B. TOXICOLOGICAL ASSESSMENTS

1. Acute Oral, Dermal and Inhalation Toxicity

Acute toxicity studies show that via the oral, dermal and inhalation routes, terbutryn is relatively non-toxic. An acute oral study with CD rats showed an oral LD_{50} of 1.9 g/kg for males and 2.1 g/kg for females (Toxicity Category III*). An acute dermal study using New Zealand albino rabbits showed a dermal LD_{50} of >20.0 g/kg (Toxicity Category IV*). Acute inhalation studies are not available for technical terbutryn and are being required; however an acute inhalation study using the 80% formulated product with Sprague-Dawley rats resulted in the classification of terbutryn in Toxicity Category III for acute inhalation.

2. Irritation and Sensitization (Eye and Dermal)

Terbutryn caused very slight irritation to the eyes. An eye irritation study with the 80% formulated product with New Zealand White rabbits resulted in placement of terbutryn in Toxicity Category III*.

A primary skin irritation test with New Zealand White rabbits produced no irritation at 72 hours (Toxicity Category IV*).

The dermal sensitization study in male Hartley albino guinea pigs indicated that terbutryn is not a skin sensitizer.

3. Subchronic Toxicity

Valid subchronic oral toxicity studies are not available on technical terbutryn; however, chronic studies in the rat and the dog are available and are discussed below. Subchronic oral toxicity studies are therefore not being required.

Technical terbutryn has not been evaluated in a 21-day subchronic dermal study, and thus the subchronic dermal hazard of the product cannot be evaluated. A 21-day dermal study in the rabbit is required.

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* Toxicity Categories are based on the acute toxicity of the chemical (LD_{50} or LC_{50} values) and are used to determine the appropriate signal word and precautionary language for product labeling. Toxicity Category III requires the signal word CAUTION and precautions against swallowing, inhaling, or contact with the skin and eyes, along with appropriate first aid instructions. Toxicity Category IV also requires the signal word CAUTION, but no precautionary statements are required. See 40 CFR 162.10.

Extended dermal exposure to technical terbutryn is not expected to occur, and thus testing in a 90-day dermal study is not required.

The Agency is reserving its decision on the need for a subchronic inhalation study until the acute LD_{50} has been determined.

Terbutryn is not structurally related to any known group of cholinesterase inhibitors, and no sign of neurotoxicity was seen in subchronic or chronic toxicity tests in rats, mice, and dogs. Thus acute delayed neurotoxicity testing is not required.

4. Chronic Toxicity

The available chronic toxicity studies on terbutryn include a rat study (MRID 00035923) and an acceptable beagle study (MRID 00029152).

In the two year rat feeding study, Charles River CD rats received technical terbutryn in their diet at levels of 0, 2, 300, and 3000 ppm. Decreased body weight gain for both males and females and an increased incidence of focal cytomegaly in livers of female rats was seen at 3000 ppm. Complete hematology and clinical chemistry according to guideline standards were not done in this study and thus a NOEL for these parameters could not be determined.

Because of the deficiencies noted above, a special 24-month study in the same strain of rats is required for reregistration, with emphasis on hematology and clinical chemistry parameters in order to determine a NOEL for these effects. Histopathology and urinalysis are not required for this study.

In the six-month beagle study, dogs received technical terbutryn at levels of 0, 10, 25, and 50 mg/kg/day in the diet. At 25 and 50 mg/kg/day mucosal thickening of various segments of the small intestine and submucosal lymphoid hyperplasia in the pyloric region of the stomach was observed. The NOEL was 10 mg/kg/day. The requirement for chronic toxicity testing in a non-rodent has been satisfied,and the NOEL from this study is used as the basis of the ADI.

5. Teratology and Reproductive Effects

Teratology studies have been conducted on terbutryn in rats (MRID 00152764) and New Zealand White rabbits (MRID 00152763). Terbutryn was not teratogenic to either species. The NOEL for maternal toxicity in the

rabbit was 10 mg/kg and 50 mg/kg for the rat, based upon decreased food consumption, increased food efficiency index (grams of food consumed per kilogram of body weight gained), decreased body weight gain, and stool changes in rabbits at 50 mg/kg and increased mortality, salivation, urine staining, bloody discharge, and weight loss at 500 mg/kg in the rat. The NOEL for fetotoxicity in the rat and rabbit was 50 mg/kg based upon reduced ossification and misalignment of the sternebrae and centrum vertebrae; reduced ossification of the metacarpals, proximal phalanges, phalanges, and distal phalanges of the forepaw; and reduced ossification of the metacarpals and distal phalanges of the hindpaw in rats at 500 mg/kg and reduced ossification of sternebrae in rabbits at 75 mg/kg. Teratogenicity testing requirements have been satisfied.

A three generation reproduction study in Charles River CD rats (MRID 00035659) is also available. Terbutryn was administered in the diet at levels of 2, 300, and 3000 ppm. At 3000 ppm, decreased mean body weights and food consumption values were found for the F_0, F_1, and F_2 parents as well as decreased pup weights in all generations at lactation day 21. This study satisfies the requirements for a reproduction study in rodents. The data from the teratology and reproduction studies do not demonstrate a significant risk to humans.

6. Mutagenicity Data

The requirements for mutagencity testing have not been satisfied. One chromosomal study (in-vivo cytogenetics in Chinese hamsters; MRID 00100654) was acceptable and indicated no mutagenic activity. Terbutryn has also been tested in the nucleus anomaly test (Chinese hamster; MRID 00157846). The nucleus anomaly test was negative but was found to be an unacceptable assay because the methods used to detrmine micronuclei induction were inadequate to detect compound-related effects. Two other tests (host-mediated rat and a mutagenicity chromosome study in germinal epithelium of male mice) were negative for mutagenicity, but were classified as supplementary because of protocol limitations, inadequate reporting of data and lack of positive controls.

The following mutagenicity studies will be required for the registration of terbutryn in order to better define the mechanism of tumor induction of terbutryn in rats:

a. in-vitro mammalian gene mutation assay;
b. unscheduled DNA synthesis assay in rat hepatocytes;
c. a chromosome aberration study in rats; and
d. sister chromatid assay in rats.

These assays are required to provide more information on the mutagenic potential of terbutryn and the mechanism of tumor production in the rat. The additional data may also aid in determining the classification of terbutryn as an oncogen.

7. Metabolism Data

Metabolism studies (MRID 00100640) have been conducted in the rat using both ring and methylthio-^{14}C-labeled terbutryn. Eighty-five percent of the ring-labeled dose was excreted within 72 hours in urine and feces. Sixty-two percent of ^{14}C methylthio-labeled terbutryn was recovered within 72 hours in expired CO_2. The major pathways for metabolism are desulfuration, N-deethylation and S-demethylation.

These studies only partially meet requirements for a metabolism study on terbutryn. A metabolism study that meets present guideline standards (i.e. multiple dosing) is required for the registration of terbutryn.

8. Oncogenicity Data

In a two year carcinogenicity study on Charles River CD-1 mice (MRID 00029153), technical terbutryn was administered in the diet at levels of 0, 3, 1000, and 3000 ppm. No evidence of oncogenicity was observed for terbutryn in this study.

In a two year chronic toxicity study in CD rats (MRID 00035923), the oncogenic potential of technical terbutryn was studied. Levels tested were 0, 2, 300, and 3000 ppm. When administered in the diet to Charles River CD rats at 3000 ppm., terbutryn induced a statistically significant increase in combined mammary tumor-bearing females (adenomas, fibroadenomas and adenocarcinomas) and in combined hepatocellular adenomas and carcinomas in females. In male rats, it induced a statistically significant increase in combined thyroid follicular adenomas and carcinomas and in testicular interstitial cell adenomas.

The incidence of tumors in the animals tested is represented in the chart on the next page.

INCIDENCE OF TUMORS IN RATS

FED TERBUTRYN IN THE DIET FOR TWO YEARS

Organ/Tissue	DOSE (ppm) 0	2	300	3000
	Males			
Thyroid				
follicular cell				
adenoma	1/59	1/59	1/60	6/57
carcinoma	0/59	0/59	1/60	3/57
adenoma + carcinoma	1/59	1/59	1/60	9/57
Testes				
interstitial cell				
adenoma	13/59	11/60	14/60	9/57
	Females			
Liver				
hepatocellular				
adenoma	3/57	2/60	3/59	12/56
carcinoma	2/57	0/60	0/59	4/56
adenoma + carcinoma	5/57	2/60	3/59	16/56
Mammary Gland				
adenoma[1]	6/57	9/58	8/58	13/55
adenocarcinoma[1]	15/57	8/58	7/58	20/55
fibroadenoma[1]	12/57	15/58	20/58	18/58
Total anomals with one or more mammary gland tumors[2]	24/57	29/58	29/58	34/55

[1]These animals could have other types of mammary tumors as well.
[2]There is no duplication of animals in these numbers.

In accordance with EPA's 1984 Proposed Guidelines for Carcinogen Risk Assessment (49 FR 42694, Novembr 23, 1984), the Agency has classified terbutryn as a Group C carcinogen--that is, a possible human carcinogen.

The guidelines categorize the evidence on carcinogenicity of a chemical in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, Group A, ("Human Carcinogen") is reserved for those chemicals for which there is sufficient evidence of carcinogenicity from human epidemiological studies. Group B, ("Probable Human Carcinogen") is divided into subgroups 1 and 2. Group B1 requires some human epidemiological evidence. Since there are no data from human epidemiological studies on terbutryn, there is no reason to classify it under Group A or B1. Group B2 is appropriate if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. "Sufficient evidence" is defined as an increased incidence of malignant (or combined malignant and benign) tumors (1) in multiple species or strains, (2) in multiple experiments, or (3) to an unusual degree with regard to incidence, site or type of tumor, or age at onset.

Group C ("Possible Human Carcinogen") is appropriate if there is "limited evidence" of carcinogenicity in animals in the absense of human data. "Limited evidence" means that the data suggest a carcinogenic effect but are limited because (1) the studies involve a single species, strain, or experiment; or (2) the experiments are restricted by inadequate design or reporting; or (3) an increase [is seen] in the incidence of benign tumors only. Among the types of evidence which may be seen are definite malignant tumor response in a single well-conducted experiment or marginal responses in a tissue known to have a high and variable background rate.

There is also a Group D ("Not Classified") and a Group E, which is reserved for chemicals determined to be non-carcinogenic in animal and/or human studies.

The Agency concluded that terbutryn should be classified as a Group C carcinogen. Based on one study in one strain of one species, the chemical produced 1) a marginal response in a tissue (mammary gland) known to have a high and variable background rate of tumors, and 2) an increase in combined benign and malignant tumors (testicular, thyroid and liver) with terbutryn producing no response in a variety of short-term tests for mutagenicity (limited, but negative mutagenicity data were available).

The Agency also considered a Group B-2 classification for terbutryn since tumors were produced at multiple sites and since positive, but not conclusive, structure activity relationship (SAR) data were available. The Agency reviewed data on two structurally similar compounds, propazine and atrazine. The SAR data was not considered conclusive since, for propazine, historical control data on the mammary tumors seen in the study is still outstanding and, for atrazine, only a preliminary report on the incidence of mammary tumors was available and the final report has not been evaluated. In addition, four thyroid inhibitors which are structurally similar to terbutryn, are known to induce thyroid neoplasia.

On the basis of the foregoing, the Agency finds the Group C classification the most appropriate, but positive information in the area of mutagenicity for terbutryn and/or mutagenicity and oncogenicity for other structurally related triazines could raise terbutryn to the Group B-2 classification. In light of this possibility, it was decided that a quantitative estimation of the oncogenic potential for humans should be developed.

A quantitative estimation of the oncogenic potential in rats has been completed by the Agency as summarized below.

		$[Q_1^*(\text{ppm})^{-1}]$
Females		
Mammary:	adenomas + carcinomas	1.89×10^{-4}
	adenomas + carcinomas + fibroadenomas	2.27×10^{-4}
Liver:	adenomas	1.09×10^{-4}
	adenomas + carcinomas	1.33×10^{-4}
Males		
Thyroid:	adenomas	5.12×10^{-5}
	adenomas + carcinomas	8.70×10^{-5}
Testes:	adenomas	1.68×10^{-4}

The Q_1^* estimate for terbutryn is approximately 10^{-4} $(\text{ppm})^{-}$ in rats which converts (via Lehman's Tables and the surface area correction) to approximately 10^{-2} $(\text{mg/kg/day})^{-1}$ for humans.

The upper 95% confidence limits on the dietary oncogenic risks for terbutryn (possible human oncogen) is 2.6×10^{-6}. This is based on ingestion of barley, sorghum and wheat which had residues at the tolerance levels of 0.1 ppm.

9. Dermal Absorption

In a dermal absorption study with male Harlan Sprague-Dawley rats, (MRID 157844), significant quantities of terbutryn were absorbed dermally at all doses and time intervals. Representative percent absorptions for 10 hours exposure were 22.02%, 4.44%, and 2.25% for doses of 0.05, 0.5, and 5.0 mg/10cm^2. Animals which were washed at ten hours and maintained for an additional 48 hours showed total absorptions of 34.48%, 12.26%, and 8.25% of the respective doses. Further studies on dermal absorption are not required.

C. Worker Exposure Hazard

An assessment of worker exposure to terbutryn which estimated worker exposure during different application techniques was conducted in 1981 for the RPAR Decision Document. The exposure estimates were derived from surrogate data corrected for terbutryn's use rates.

More recently, a worker exposure re-evaluation and dermal exposure risk assessment have been conducted by the Agency. The estimates of risk were determined by using an estimate of the number of man hours associated with various application techniques, estimates of the hourly exposure for workers, and the calculated carcinogenic potency (Q_1*) of terbutryn. The estimated risks associated with various workers are shown on the next page.

Based on the 1982 dermal absorption study (MRID 00157844), calculations were made using the absorption rate of 22% as opposed to a rate of 10% which was used in 1981. It should be noted that, the study indicated that absorption continued after washing up to 34%. However, the Agency chose the 22% absorption figure for its calculations because the 22% figure is more representative of the exposure time estimated for workers in the field. (Use of the 34% absorption rate would have increased risk less than one order of magnitude.)

Since 1981, the Agency has added to its data base of surrogate studies and the methods for estimating worker exposure have been refined. The Agency's current practice is to use all available data which may be applicable for calculations of exposure and risk, including both surrogate data and studies specific to the chemical in question. In this case, an applicator exposure monitoring study submitted by the registrant for terbutryn corroborates the projected exposures in the Agency's current analysis.

YEARLY RISK FROM DERMAL EXPOSURE

	Typical	Range
MIXER/LOADERS (WITH PROTECTIVE CLOTHING--GLOVES ONLY)		
ground wheat/barley		
private	3.6×10^{-6}	$6 \times 10^{-8} - 1 \times 10^{-5}$
commercial	2.9×10^{-5}	$1 \times 10^{-7} - 1 \times 10^{-4}$
aerial wheat/barley		
commercial	1.1×10^{-5}	$3 \times 10^{-7} - 2 \times 10^{-4}$
ground sorghum		
private	2.9×10^{-6}	$8 \times 10^{-8} - 1 \times 10^{-5}$
commercial	8.6×10^{-6}	$1 \times 10^{-7} - 1 \times 10^{-4}$
aerial sorghum		
commercial	1.1×10^{-5}	$1 \times 10^{-7} - 1 \times 10^{-4}$
MIXER/LOADERS (WITHOUT PROTECTIVE CLOTHING)		
ground wheat/barley		
private	1.8×10^{-5}	$3 \times 10^{-7} - 7 \times 10^{-5}$
commercial	1.4×10^{-4}	$7 \times 10^{-7} - 6 \times 10^{-4}$
aerial wheat/barley		
commercial	5.4×10^{-5}	$2 \times 10^{-6} - 1 \times 10^{-3}$
ground sorghum		
private	1.4×10^{-5}	$4 \times 10^{-7} - 9 \times 10^{-5}$
commercial	4.3×10^{-5}	$7 \times 10^{-7} - 9 \times 10^{-4}$
aerial sorghum		
commercial	5.6×10^{-5}	$5 \times 10^{-7} - 1 \times 10^{-3}$
GROUND BOOM APPLICATOR (WITHOUT PROTECTIVE CLOTHING)		
wheat/barley		
private	7.2×10^{-6}	$5 \times 10^{-7} - 2 \times 10^{-5}$
commercial	6.5×10^{-5}	$2 \times 10^{-6} - 1 \times 10^{-4}$
sorghum		
private	5.0×10^{-6}	$5 \times 10^{-7} - 2 \times 10^{-5}$
commercial	1.6×10^{-4}	$5 \times 10^{-7} - 2 \times 10^{-4}$
FLAGGERS		
sorghum	3.1×10^{-6}	$7 \times 10^{-8} - 3 \times 10^{-4}$
PRIVATE APPLICATORS WHO DO THEIR OWN MIXING AND LOADING		
wheat/barley		
without gloves	2.5×10^{-5}	$8 \times 10^{-7} - 9 \times 10^{-5}$
with gloves	1.1×10^{-5}	$5 \times 10^{-7} - 3 \times 10^{-5}$
sorghum		
without gloves	2.0×10^{-5}	$9 \times 10^{-7} - 1 \times 10^{-4}$
with gloves	7.9×10^{-6}	$6 \times 10^{-7} - 3 \times 10^{-5}$

D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of terbutryn in or on barley grain, barley fodder, green barley, barley straw, sorghum grain, wheat grain, wheat fodder, wheat straw, and green wheat at 0.1 ppm (40 CFR 180.265).

1. Residue data

The residue data reviewed in support of these tolerances include:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of terbutryn. Tolerances are set on the parent compound only.

b. Radiological studies on the uptake, translocation, and metabolism of terbutryn in plants show that terbutryn is metabolized in plants.

c. Radiolabeled studies on the metabolism and translocation of terbutryn in ruminants and poultry.

d. Analytical methodology for determining the levels of residues of terbutryn in plants and animals. Such methods have been determined to be suitable for residue determinations and for enforcement of tolerances for the parent compound only.

e. Data on the magnitude and levels of residues in individual raw agricultural commodities.

2. Tolerances

In its evaluation of the data supporting tolerances, EPA reached the following conclusions:

° The available data are inadequate to support the existing tolerances on sorghum forage, fodder, silage, hay, and flour and milled products bearing measurable weathered residues; wheat grain, forage (green wheat), hay straw, and wheat milled products bearing measurable weathered residues; and barley forage, hay, straw, flour, and milled products. Data are required for all the above except the barley products since the data required for wheat can be extrapolated for barley.

- No tolerances exist for terbutryn residues in animal commodities; no analytical methods or supporting data have been submitted for the determination of terbutryn residues in animal commodities. Unless data show that residues do not remain in meat, milk, poultry, and eggs, either tolerances must be obtained or feeding and grazing restrictions must be required.

- If residues in the raw agricultural commodities concentrate as a result of processing, appropriate food additive tolerances must be extablished.

- The following tolerances expressions should be revised to conform with current practices and terminology?

  The designation "N" (negligible) must be deleted from all tolerance entries.

  The term "green barley" should be amended to read " barley forage" and the category "green wheat" should be amended to read "wheat forage."

  The categories "barley fodder" and "wheat fodder" must be deleted.

3. Plant and Animal Residues

Currently tolerances for residues are expressed as terbutryn per se and are given as negligible residues (based on the limits of detection). It has been determined that any metabolite of terbutryn which contains an intact triazine ring is of toxicological concern and should be included in the tolerance expression. Currently the nature, or identity, of metabolites is not adequately understood. Residue data for the terbutryn parent material are adequate for barley and sorghum grain, but residue data on the metabolites are inadequate. Only the tolerance for terbutryn parent material in wheat is not supported. The tolerances for wheat and barley forage, hay and straw are not supported. Additional data are being required.

The Agency has determined that a group tolerance for cereal grains would not be appropriate at this time. A review of Agency files indicates that no data are available and no proposal has been made to establish tolerances for residues of terbutryn in or on corn or rice. Such proposals, with acceptable supporting data, would be necessary to establish a group tolerance for cereal grains. Additional data also would be required for wheat and barley products.

3. Dietary Assessment

The toxicity data considered to establish a Provisional Acceptable Daily Intake (PADI) include the following:

a. A chronic feeding study in rats with an undetermined NOEL is available, but this study was not conducted according to guideline requirements and has been rejected as the basis for the ADI calculation.

b. A six-month feeding study in beagles (MRID 00029152) with a NOEL of 10 mg/kg/day, was selected as the basis for the PADI. A more detailed discussion of this study may be found in Section B, 5 of this Part. Based on this study and a safety factor of 1000, a PADI of 0.100 mg/kg/day was calculated.

The TMRC (Theoretical Maximum Residue Contribution) for terbutryn is 0.000260 mg/kg/day. The TMRC is based on the assumption that the full amount of residues permitted by the published tolerances is present in treated crops. The TMRC for terbutryn constitutes 2.6% of the PADI. Daily dietary exposure to terbutryn is thus substantially less than the calculated provisional acceptable daily intake for humans.

In addition, the TMRC assumes that 100% of the crop is treated. The percentage of food crops actually treated is very limited--less than 1% of the winter wheat and less than 2% of the grain sorghum grown in the U.S. and a negligible amount of barley and fallow land. Because of the limited percentage of crop treated, the resulting dietary risk is actually reduced one hundredfold (from 10^{-6} to 10^{-8}).

E. ENVIRONMENTAL FATE

Available data are insufficient to fully assess the environmental fate of terbutryn.

Terbutryn (unaged) is expected to be relatively immobile in soils ranging in texture from sand to clay loam to peat, based on soil column and batch equilibrium tests. Therefore, the potential for contamination of groundwater appears to be low. However, a metabolite, hydroxy-terbutryn, does appear to have potential to contaminate groundwater, and additional data are being required to evaluate this potential.

Radiolabeled terbutryn (50% WP) residues were relatively immobile in sand, silt loam, and sandy clay loam soil in 30 cm columns leached with 20 cm of water: approximately 80-90% of the applied radiolabeled terbutryn was detected

in the top 8 cm of each soil column (Guth, 0142913). The leachate from all four soils contained less than 0.4% of radiolabeled terbutryn.

Radiolabeled terbutryn (50% WP) residues were detected at maximum depths of 10, 6, and 2 cm in 30 cm columns of sand, silt loam, and sandy clay loam soils, respectively, after eluting with 20 cm of water (Guth, 00038374). Freundlich K values were determined for sand of 1% organic matter (OM)--2.34; for sand of 2.2% OM--4.35; for silt loam (3.6% OM)--9.95; for clay loam (5.6% OM)--20.7; and for peat soils (22.6% OM)--156.6, indicating a positive correlation between adsorption of radiolabeled terbutryn residues and soil organic matter content.

F. HAZARD ASSESSMENT FOR TERRESTRIAL AND AQUATIC ORGANISMS

Aquatic Organisms:

Available acute toxicity data indicate that terbutryn is moderately toxic to warmwater fish and highly toxic to coldwater fish. Minimum data requirements to establish acute toxicity are the results of two 96-hour studies using the technical grade material. In studies using technical material, LC_{50} values of 2.4 ppm in rainbow trout and 4.7 ppm in crucian carp, were reported, but those studies did not satisfy guideline requirements--the trout used were too large and aeration was used and crucian carp is not an acceptable species. Four fish studies using the 80% wettable powder gave the following results:

Rainbow trout (coldwater)	48-hour LC_{50}--3.5 ppm
Rainbow trout "	96-hour LC_{50}--0.82 ppm
Bluegill (warmwater)	96-hour LC_{50}--4.8 ppm
Bluegill "	96-hour LC_{50}--2.7 ppm

One simulated field study with bluegill was conducted for 35 days in miniature ponds. At 5 ppm, 100 percent mortality occurred in 11 days; at 1 ppm and below, no mortality occurred throughout the 35-day study.

Terbutryn is moderately toxic to aquatic invertebrates. A 48-hour study on toxicity to Daphnia magna was evaluated, and the LC_{50} is 2.66 ppm.

No assessment can be made regarding the toxicity to estuarine and marine organisms because no studies have been evaluated. These studies are required for rights-of-way and other non-crop uses.

No assessment can be made regarding the fish early life stage toxicity or the aquatic invertebrates life cycle toxicity because no studies have been evaluated. These studies are required for rights-of way and other non-crop uses and reserved for the sorghum use.

The Agency calculated the levels of residue which could be expected to remain in the top 6 inches and the top 6 feet of water as a result of run-off, drift, and direct application to the water. Except for the direct application to 6 inches of water, the expected residues are all less than one-half of the LC_{50} of the most sensitive aquatic animal species (rainbow trout, LC_{50}=0.82 ppm). Neither the run-off or drift worstcase estimates would exceed the criteria for endangered species concerns. Therefore, the current uses of terbutryn, which do not include direct application to water, are unlikely to result in significant adverse acute ecological effects to aquatic animal species.

Terrestrial Organisms:

There is no evidence to suggest that the use of terbutryn has resulted in kills or has affected mammalian or avian populations.

The data indicate that technical terbutryn is practically nontoxic to waterfowl and upland gamebirds on acute oral and subacute dietary bases. Oral acute toxicity studies indicate LD_{50} values greater than 4,640 mg/kg for very young mallards; greater than 2,000 mg/kg for older mallards; and greater than 2,000 mg/kg for pheasants. These three studies in combination satisfy the data requirement. The avian dietary LC_{50} values are greater than 4,640 ppm for the mallard duck, greater than 20,000 ppm in 7-day exposures and greater than 2,000 ppm in 4-week exposures for Bobwhite quail adults. The avian dietary LC_{50} requirement for waterfowl is satisfied but the requirement for upland gamebirds is not. Therefore, a study is required for upland gamebirds.

No avian reproduction study was available for evaluation; the requirement for a study is being reserved pending review of environmental fate data.

There is sufficient information to characterize terbutryn as relatively nontoxic to honeybees.

Plant Protection

No plant protection studies were reviewed. Tier 1 testing is required on a case-by-case basis to support the registrations of (1) products for which phytotoxicity problems arise, and open literature data are not available and (2)

products that may pose hazards to endangered or threatened species. Since terbutryn has use patterns similar to those chemicals that have jeopardy opinions prepared by OES, the Agency is assuming that use of terbutryn may also pose hazards to endangered plants. The Agency is requiring that Tier 1 testing be performed with terbutryn. Refer to Appendix I for testing requirements.

G. ENDANGERED SPECIES

There are sufficient toxicity and exposure data to indicate that the currently registered uses of terbutryn are unlikely to pose a hazard to endangered aquatic or avian species.

Concerning endangered plants, on October 12, 1983, the Office of Endangered Species (OES) issued a jeopardy opinion for pesticides used on the crop cluster that includes wheat, barley, and sorghum. Solano grass (Orcuttia mucronata) is the only endangered plant that was considered likely to be associated with these uses. In addition, the valley elderberry longhorn beetle (Desmocerus californicus dimorphus) is restricted to elderberry thickets in Central Valley of California. Sorghum and small grains are grown in this vicinity, and OES indicated that herbicides should be prohibited in this area to protect the host elderberry plants and consequently the beetle. See Section D of Part IV for required labeling.

Since terbutryn is a relatively nonselective herbicide registered for the crop uses mentioned in the OES opinions, the Agency concludes that endangered plants in those areas may be adversely affected. The potential for adverse effects is dependent upon the exposure. Additional data are required to evaluate exposure in crop and noncrop areas.

To protect endangered species in noncrop lands, restrictive labeling may be required when the Agency completes its consultation with the OES for the generic cluster of noncrop pesticides. To protect endangered plant species associated with use on sorghum, barley, and wheat, interim labeling is required pending a review of environmental fate data and possibly an OES jeopardy opinion.

H. PRODUCT CHEMISTRY EVALUATION

The Agency has evaluated the available data which identify the ingredients, materials, and manufacturing process and discuss the physical and chemical properties of the technical grade of the active ingredient and of the manufacturing use product. Additional data requirements have been identified and are listed in the data tables.

IV. REGULATORY POSITION

A. REGULATORY POSITIONS AND RATIONALES

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

1. Terbutryn does not meet any of the criteria specified in 40 CFR 154.7; therefore a Special Review is not being initiated at this time.

   Rationale:

   If a pesticide meets or exceeds any of the criteria specified in 40 CFR 154.7, a Special Review of the chemical may be conducted. Although terbutryn has been found to be oncogenic in rats (a Group C oncogen), the Agency does not believe it meets the criterion in 40 CFR 154.7(b)(2) for oncogenic effects requiring Special Review. The regulations provide that the Administrator may conduct a Special Review if a pesticide use "may pose a risk of inducing in humans an oncogenic ...effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk..." (50 FR 49016, November 27, 1985).

   The greatest potential hazard is to workers who mix, load, and apply the pesticide. Having reevaluated exposure to the pesticide and available means of reducing exposure, the Agency has concluded that the risks posed to workers workers by exposure to terbutryn can be reduced significantly by implementation of protective measures through this standard.

   Dietary risk is not considered significant in light of the following facts:

   Actual residues are expected to be lower than the established tolerances of 0.1 ppm.

   Less than 2% of the sorghum and less than 1% of the wheat planted in the United States are treated with terbutryn; other uses of terbutryn are minimal.

2. The Agency is classifying all end-use pesticide products containing terbutryn for "Restricted Use" and requiring appropriate labeling language. The specific language may be found in Section D of this Part.

Rationale:

The oncogenic risk to applicators can only be reduced to an acceptable level if the special precautions which are being required are closely followed. The Agency believes classification of terbutryn as a restricted use pesticide is necessary to avoid unreasonable adverse effects to users due to dermal exposure. Only certified applicators who have received instruction on the safe handling of pesticides, or those under the direct supervision of certified applicators, will be permitted to handle terbutryn products. The Agency believes that, because of their training, certified applicators are more likely to conscienciously follow complex label instructions than are lay pesticide users.

3. In order to remain in compliance with FIFRA, Registrants must place statements on the labels of manufacturing-use and end-use products containing terbutryn requiring protective clothing for mixers and loaders and closed vehicles for flaggers. The specific language required appears in Section D of this Part.

Rationale:

The potential oncogenic risks to workers can be reduced substantially if persons who may come in contact with the chemical wear protective clothing and/or are shielded from the chemical by an enclosed vehicle.

4. In order to remain in compliance with FIFRA, registrants must package all end use products in water soluble bags with appropriate use directions.

Rationale:

The use of water soluble bags will reduce worker exposure to terbutryn by preventing dermal contact with the chemical during mixing.

5. Reentry intervals are not necessary for currently registered uses of terbutryn.

Rationale:

The acute toxicity for terbutryn is low (category III). Terbutryn is a pre-emergence and early postemergence herbicide. Because of cultural practices, it is not anticipated that field workers are likely to come in contact with the wet herbicide after application. Therefore, no reentry interval is required at this time. Following review of additional data, the Agency will give further consideration to this decision.

6. The Agency is not placing a restriction against the planting of crops for which terbutryn is not registered in terbutryn treated fields.

Rationale:

Data currently available indicate that terbutryn does not persist in the soil. "Rotational crop" data have been required, and once those data have been reviewed, the Agency will reassess the need for a restriction.

7. In order to remain in compliance with FIFRA, registrants must do one of the following:

a) amend product labels to incorporate grazing and feeding restrictions for all raw agricultural commodities (i.e., wheat hay, straw, and forage; barley hay, straw, and forage; and sorghum forage, fodder, silage, and hay) if treated with terbutryn;

b) submit data which demonstrate that no residues remain in meat milk, eggs, and poultry as a result of feeding treated commodities; or

c) propose tolerances and provide appropriate supporting data for all food and feed.

Rationale:

Terbutryn residues may be found in the above commodities. If residue-bearing commodities are fed to cattle or poultry, residues may be present in meat, milk, poultry, or eggs (which may be used for human foo). However, no tolerances exist for those foods. In order to avoid unsafe levels of terbutryn residues in human food, grazing and feeding restrictions are necessary unless either (1) it is demonstrated that residues will not be found in human food, or (2) tolerances are established.

8. Additional residue data must be submitted for the following raw agricultural commodities: sorghum forage, fodder, silage, hay, and flour and milled products bearing measurable weathered residues; wheat grain, forage (green wheat), hay, straw, and wheat milled products bearing measurable weathered residues. If residues concentrate in any of the processed products, the appropriate food additive tolerance(s) must be established. Specific data requirements may be found in the Data Tables.

Rationale:

The available data are inadequate to support existing tolerances for these commodities. Previously submitted

barley are not required, since the data to be submitted for wheat can be translated for barley.

9. The Agency is requiring data on plant and animal metabolism as well as storage stability studies. Appropriate validated methodology as well as storage stability and residue data (crops, meat, milk, poultry, and eggs) are required for all plant and animal metabolites of terbutryn which contain an intact triazine ring as identified in the metabolism studies.

Rationale:

Current tolerances are expressed in terms of the parent compound only; however, the Agency has determined that the metabolism in plants and animals is not adequately defined. Metabolites of terbutryn which contain an intact triazine ring are of toxicological concern and should be included in the tolerance expression. In addition, some of the data required are dependent on the results of metabolism studies, and currently available data are inadequate to quantify the metabolites. Storage and stability data are not available and are necessary to ascertain whether residues are stable in plant commodities when stored.

10. The Agency has determined that the following revisions in the tolerances listed in 40 CFR 180.265 are necessary and will initiate actions to effect these changes.

- The designation "N" (negligible) must be deleted from all tolerance entries.
- The term "green barley" should be amended to read "barley forage" and the category "green wheat" should be amended to read "wheat forage."
- The categories "barley fodder" and "wheat fodder" must be deleted.

Rationale:

- The designation "N" for negligible residues is no longer used by the Agency.
- Forage (rather than "green") is the preferred term for the succulent plant material.
- Wheat fodder and barley fodder are not considered raw agricultural commodities of wheat and barley.

11. The Agency is requiring additional field studies to evaluate the potential the metabolites of terbutryn to enter groundwater.

Rationale:

Based on a review of data recently submitted by the registrant, terbutryn demonstrated a low potential to reach groundwater. However, the data showed that hydroxy-terbutryn, the major environmental metabolite, is persistent and mobile in the soil profile. Additional field studies are necessary to further evaluate the persistence and mobility of this and other metabolites.

12. In order to remain in compliance with FIFRA, registrants must amend their labels to incorporate restrictions to protect endangered plant species for all end-use products registered for crop use. Refer to section D of this Part for specific wording of label statements.

Rationale:

Although additional data on phytotoxity and exposure are necessary to evaluate potential adverse effects on endangered plant species, the OES jeopardy opinion of October 1983 indicates that at least one endangered plant species is likely to be associated with the crop uses of terbutryn. In addition to endangered plant species, certain non-target plants may constitute necessary habitat for endangered or threatened insects. Therefore, interim labeling regarding the protection of endangered species is necessary pending review and evaluation of required data.

13. The Agency will not require labeling to protect endangered species for noncrop uses at this time.

Rationale:

The Agency has not yet completed generic consultation for noncrop uses with the OES. Endangered Species labeling for noncrop uses may be required when generic labeling has been completed for noncrop pesticides.

14. While the data gaps are being filled, currently registered manufacturing-use products and end-use products containing terbutryn as the sole active ingredient may be sold, distributed, formulated, and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in Appendix I to maintain existing registrations.

The Agency will issue registrations for substantially similar products. However, new uses will be issued only on a case-by-case basis after considering the effects on the theoretical maximum residue contribution (TMRC), the maximum permissable intake (MPI), and the oncogenic risks.

Rationale:

Section 6 of FIFRA authorizes the Administrator to cancel a pesticide registration if he determines that the pesticide will cause unreasonable adverse effects on the environment. Based on available data, the Administrator has not made such a determination as to terbutryn. The Administrator has authority under FIFRA sections 3(c)(2)(B) and 3(c)(7) to require registrants and applicants for registration to provide data needed to support new or continuing registrations.

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated and the Agency will determine if the data will affect the registration of terbutryn.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain terbutryn as the sole active ingredient; 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 (MUP's) must contain terbutryn as the sole active ingredient. Each MUP formulation proposed for registration or reregistration 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%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing terbutryn 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, technical grade or manufacturing-use products containing terbutryn may be labeled for formulation into end-use products registered only for the uses listed in Appendix III, EPA Index to Pesticide Chemicals--Terbutryn. This Index lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

In order to remain in compliance with FIFRA, all products must bear appropriate labeling as specified in 40 CFR 162.10 in addition to the specific labeling requirements which follow. Appendix II contains information on labeling requirements.

No pesticide product containing terbutryn may be released for shipment by the registrant or producer after June 30, 1987, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing terbutryn may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after June 30, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

After review of data to be submitted under this Standard, the Agency may impose additional labeling requirements.

The following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement shall list the active ingredient as "terbutryn: 2-(tert-butylamino-4-(ethylamino)-6-(methylthio)-s-triazine".

2. Use Pattern Statement

All technical grade and manufacturing-use products shall state that they are intended for formulation into end-use products registered for one or more of the uses listed in the EPA Index to Pesticide Chemicals for Terbutryn, Appendix III. However, no use may be included on the label if the registrant fails to agree to comply with data requirements in Table A for that use pattern, as provided in this Registration Standard.

3. Disposal Statement

The following statement shall appear on manufacturing-use products, "Do not discharge effluent containing technical grade or manufacturing-use products containing terbutryn into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your state Water Board or the Regional Office of EPA."

4. Precautionary Statements

All end-use products shall bear the following restrictions:

a. Restricted Use Classification

"RESTRICTED USE PESTICIDE"

"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."

"The use of this product may be hazadous to your health This product contains terbutryn, which has been determined to cause tumors in laboratory animals."

b. Worker Safety Rules

"Persons mixing and/or loading or otherwise handling this chemical are required to wear impervious gloves, coveralls (or long-sleeved shirt and trousers), face shield, socks, and shoes or boots."

"Flaggers are required to be in enclosed vehicles."

c. Feeding Restriction

"Do not graze or feed livestock treated grain, forage, fodder, hay, silage, or straw to livestock."

d. Environmental Precautions

Terbutryn 80W

"This product is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and run-off from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

Terbutryn DF

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and run-off from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

e. Endangered Species Restrictions (cropland)

"The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify its habitat is a violation of Federal law. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

Before using this pesticide in the following counties you must obtain the EPA Cropland Endangered Species Bulletin. The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The Cropland Bulletin is available from either your county Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the appropriate Regional Office of either the U.S. Fish and Wildlife Service (FWS) or the U.S. Environmental Protection Agency (EPA) indicated below.

THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

Contact FWS in Portland, Oregon
or EPA in San Francisco, California
CALIFORNIA: Solano County (Solano grass), Merced, and Sacramento Counties (critical habitat of Valley Elderberry Longhorn Beetle)"

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 submission 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[2]

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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[2] 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 a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

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

The data requirements listed in Table A.

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.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's 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:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's 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 those data requirements.

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 registration of products containing this active ingredient.[4]

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 § 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 not now eligible for a formulator's 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 Formulator's Exemption Statement form.

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

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

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 submission 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 section 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. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, 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 submission. 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.

3. 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. 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:

1. 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).

2. 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.

4. You request a waiver of the data requirement. 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 timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. 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. Procedures for requesting a change in testing protocol

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either 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 and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. 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. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the 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. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. 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 section 3(c)(2)(B), an existing stocks provision 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 IV. D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV. 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 SUBMISSION 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 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) Containing (name of pesticide) as Sole Active Ingredient

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

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

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

   c. Formulator's Exemption Statement (EPA Form), if applicable.

   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 to the Product Manager:

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

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should 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. The draft label 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.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

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

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

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

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing (name of pesticide) alone or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

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

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

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

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should 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. The 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. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing (name of pesticide) either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

[Insert PM name and number]
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, and B 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.

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 5 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.

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date _____

Guidance Document for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§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				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
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				
§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				

TABLE A

DATA REQUIREMENTS FOR TERBUTRYN 96% TECHNICAL[1] (EPA REGISTRATION NO. 100-540; CIBA-GEIGY CORP.)

Data Requirement	Composition[2]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry				
Product Identity and Composition				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Partially	—[4]	Yes
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00047595,00065588	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	00024668	Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration Jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	No		Yes

TABLE A

DATA REQUIREMENTS FOR TERBUTRYN 96% TECHNICAL[1] (EPA REGISTRATION NO. 100-540; CIBA-GEIGY CORP.)

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (continued)				
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00047595	No
63-3 - Physical State	TGAI	Yes	00047595,00065588	No
63-4 - Odor	TGAI	Yes	00065588,00085203	No
63-5 - Melting Point	TGAI	Yes	00047595	No
63-6 - Boiling Point	TGAI	N/A[5]		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00047595,00065588	No
63-8 - Solubility	TGAI or PAI	Yes	00022855,00047595	No
63-9 - Vapor Pressure	TGAI or PAI	Yes	00022855,00047595	No
63-10 - Dissociation Constant	TGAI or PAI	Yes	00065588	No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Yes	00047595,00065588	No

TABLE A

DATA REQUIREMENTS FOR TERBUTRYN 96% TECHNICAL[1] (EPA REGISTRATION NO. 100-540; CIBA-GEIGY CORP.)

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (continued)				

1. The 96% technical serves as a manufacturing-use product.
2. Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
3. Data must be submitted no later than 8 months from issuance of this Standard.
4. Information obtained from desk references, (THE MERCK INDEX, Ninth edition, 1976; CRC HANDBOOK OF CHEMISTRY AND PHYSICS, 59th edition, 1978-1979; and THE HERBICIDE HANDBOOK, 1986).
5. Not applicable since the technical product is a solid at room temperature.

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.125 Residue Chemistry						
171-2 - Chemical Identity	TGAI	A,B	Yes	Registration File	No	
171-3 - Directions for Use	TGAI	A,B	Yes	Registration File	No	
171-4 - Nature of Residue (metabolism)						
- Plants	PAIRA	A,B	Partially	00103154,00103155 00103156,00103157 00103173,00109755 00109759,00109784	Yes[2]	18 Months
- Livestock	PAIRA & Plant Metabolites	A,B	Partially	00085223,00100640 00100647	Yes[3]	18 Months
171-4 - Residue Analytical Method						
- Plant residues	TGAI & Metabolites	A,B	Partially	00065582,00070872 00109793,00111690 00109784,00109786	Yes[4]	
- Animal residues	TGAI & Metabolites	A,B	No	—	Yes[4,5]	
- Storage stability data	TGAI	A,B	No	—	Yes[6]	15 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.125 Residue Chemistry (continued)						
171-4 - Magnitude of the Residue--residue studies for each food use.						
- Crop Group #1, cereal grains	TGAI	A,B	No	—	No[7]	
- Forage, fodder and straw of cereal grain group			N/A		N/A[7]	
- Barley grain	TGAI	A,B	Yes	00109752	No	
- Barley, forage hay, and straw	TGAI	A,B	Partially	00109752	No[8]	
- Barley flour and milled products	TGAI	A,B	No		No[9]	
- Sorghum (grain)	TGAI	A,B	Yes	00047878,00065582 00070872,00093150 00109784	No	
- Sorghum forage, fodder, silage and hay	TGAI	A,B	No		Yes[10]	15 Months
- Sorghum flour and milled products	TGAI	A,B	No		Yes[11]	24 Months
- Wheat grain	TGAI	A,B	Partially	00029579,00056911 00109759	Yes[12]	15 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.125 Residue Chemistry (continued)						
- Wheat, forage, hay, and straw	TGAI	A,B	Yes	00029579 00109759	Yes[13]	15 Months
- Wheat flour and milled products	TGAI	A,B	No		Yes	24 Months
- Sugarcane	TGAI	A,B	No		No[14]	
- Meat/milk/poultry/ eggs	TGAI or Plant Metabolites	A,B	No		No[15]	

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

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§158.125 Residue Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
2/ The information concerning uptake, distribution, and metabolism of terbutryn in either barley, sorghum, or wheat following postemergence application is required.
3/ Metabolism studies utilizing ruminants and poultry with ring-labeled (^{14}C) terbutryn are required.
4/ Methodology is needed for all plant and/or animal metabolites of terbutryn containing an intact triazine ring.
5/ No tolerances exist for residues of terbutryn in animal commodities at the present time.
6/ The information on storage intervals and conditions of samples used to support all established tolerances for residues of terbutryn must be submitted, as well as storage length and conditions of storage of samples which are analized for all required residue data and are submitted in support of terbutryn tolerances.
7/ This crop group tolerance is not appropriate at this time as there is no proposal for this use and residue data to support uses in corn (fresh sweet and dried field) and rice are required. Also additional data to support existing
8/ Data are insufficient to support tolerances for barley forage, hay and straw. However no data are required because the required wheat data will translate in support of barley.
9/ Data to support tolerances for barley flour and milled products will be translated from wheat data for flour and milled products.
tolerance on wheat are required.
10/ Sorghum forage, fodder, silage and hay tolerance must be proposed and supported by data, or a feeding restriction must be placed on product labeling.
11/ Data are required in a location where sorghum bears measurable weathered residues in sorghum flour and milled products.
12/ Data are required depicting residues of concern following a single postemergence broadcast application of the 80% WP formulation at 2.2 lb ai/A. Applications using aerial and ground equipment must be represented. Note no data on processed products have been submitted.
13/ Data are required depicting terbutryn residues of concern from an application as described in footnote 8, for these commodities as well. Also no data are available for residues in or on wheat.
14/ There is no established or proposed tolerance for residues of terbutryn in or on sugarcane. However Puerto Rico has requested a section 18 exemption for which no action level has been proposed.
15/ Pedding the out come of the required animal metabolism studies.

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	TGAI	A,B	Yes	00045432	No
81-2 - Acute Dermal - Rabbit	TGAI	A,B	Yes	00048742	No
81-3 - Acute Inhalation - Rat	TGAI	A,B	No		Yes
81-4 - Eye Irritation - Rabbit	TGAI	A,B	Yes	00146728	No
81-5 - Dermal Irritation - Rabbit	TGAI	A,B	Yes	00048741	No
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B	Yes	00146730	No
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B	No[4]		No
SUBCHRONIC TESTING:					
81-1 - 90-Day Feeding					
- Rodent	TGAI	A,B	Yes	00035923	No
- Nonrodent	TGAI	A,B	Yes	00029152	No
82-2 - 21-Day Dermal	TGAI	A,B	No		Yes
82-3 - 90-Day Dermal	TGAI	A,B	No[5]		No

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement[1]	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No[4]		No
CHRONIC TESTING:					
82-1 - Chronic Toxicity					
- Rodent	TGAI	A,B	Partially	00035923	Yes[6]
- Nonrodent	TGAI	A,B	Yes	00029152	No
83-2 - Oncogenicity Study					
- Rat	TGAI	A,B	Yes	00035923	No
- Mouse	TGAI	A,B	Yes	00029153	No
83-3 - Teratogenicity					
- Rat	TGAI	A,B	Yes	00152764	No
- Rabbit	TGAI	A,B	Yes	00152763	No
83-4 - Reproduction - Rat	TGAI	A,B	Yes	00035659	No
MUTAGENIC TESTING					
84-2 - Gene Mutation	TGAI	A,B	No		Yes[7]
84-2 - Chromosomal Aberration	TGAI	A,B	Partially	00100654	Yes[8]
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	No		Yes[9]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B	Partially	00100640	Yes[10]
b5-3 - Dermal Absorption	TGAI	A,B	Yes	00157844	No
85-4 - Special Study	TGAI	A,B	No		Yes[6]

1/ Composition: TGAI = Technical grade active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.

3/ Unless otherwise specified data must be submitted no later than 8 months after publication of this Standard.

4/ Terbutryn is not structurally related to a known group of cholinestarase inhibitors, thus neurotoxicity testing is not required.

5/ Extended dermal exposure is not expected to occur, thus subchronic dermal testing is not required.

6/ A special 24-month rat study is required to determine a no-observed-effect level for hematology and clinical chemistry parameters. This study must be submitted 3 years after publication of this Standard.

7/ An in vivo mammallian gene mutation assay is needed; it must be submitted one year after publication of this Standard.

8/ A chromosome aberration assay in rats is needed; it must be submitted one year after publication of this standard.

9/ An unscheduled DNA synthesis assay in rat hepatocytes and a sister chromatid exchange assay in rats are needed. These studies must be submitted 1 year after publication of this Standard.

10/ Additional metabolism information is necessary to meet 1982 EPA Guidelines, i.e., multiple dosing phase. This study must be submitted 1 year after publication of this Standard.

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.130 Environmental Fate						
DEGREDATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00147480	No	
Photodegredation						
161-2 - In Water	TGAI or PAIRA	A,B	No	—	Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No	—	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	—	No[3]	—	No	
METABOLISM STUDIES-LAB						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	00147482	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	—	Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	—	No[3]	—	No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	—	No[3]	—	No	
MOBILITY STUDIES						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	Yes	00147483 00147484 00147485	No	

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.130 Environmental Fate (continued)						
163-2 - Volatility (Lab)	TEP	A,B	Yes[4]	00257857	No	
163-3 - Volatility (Field)	TEP	—	Yes[4]	00257857	No	
DISSIPATION STUDIES - FIELD						
164-1 - Soil	TEP	A,B	Partially	00147482	Yes[5,7]	27 Months
164-2 - Aquatic (Sediment)	TEP	--	No[3]		No	
164-3 - Forestry	TEP		No[3]		No	
164-5 - Soil, Long-Term	TEP	A	Tier (section 165-1)		Tier[6]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (field)	TEP	A	Tier (section 165-1)		Tier[6]	
165-3 - Irrigated Crops	TEP		No[3]		No[3]	

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
§158.130 Environmental Fate (continued)						
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	6 months
1x5-5 - In Aquatic Nontarget Organisms	TEP	A,B	No		No[3]	

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor

3/ Not required by reason of use pattern.

4/ EPA Accession No. 257857: V.P. = 1.3×10^{-6} @ 20 °C.

5/ An additional study on another site to include complete field test data per section 164-1.

6/ May be required, depending upon results of confined accumulation studies (165-1).

7/ In order to resolve the groundwater contamination questions associated with the use of this chemical, the following data are required in addition to the soil dissipation study required in Subpart N:
In at least one soil of the High Plains area, (West Texas), and one type in the Northwest U.S. where terbutryn is used: a) At least three soil core sites shall be examined for background terbutryn/hydroxy-terbutryn before pesticide application; b) A conservative water tracer such as bromide ion shall be added (100-200 pounds per acre), to the field on the same day the pesticide is used; c) All soil cores shall be taken and analyzed in continuous six-inch segments until the maximum leaching zone is established; d) Soil cores shall be taken and examined until terbutryn hydroxide has dissipated; e) Terbutryn residues at the zone of maximum leaching shall be speciated as well as quantified. You should contact EPA for further guidance prior to study protocol submission.

8/ Octanol/H_2O participation coefficient: pK = 4.3 @ 20°C.

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Single Dose Oral LD_{50}	TGAI	A,B	Yes[3]	GS0144012 00073006	No	
71-2 - Avian Dietary LC_{50}						
A. Upland Game Bird	TGAI	A,B	No		Yes	9 Months
B. Waterfowl	TGAI	A,B	Yes	00103995	No	
71-4 - Avian Reproduction						
A. Upland Game Bird	TGAI	A,B	No		Reserved[4]	
B. Waterfowl	TGAI	A,B	No		Reserved[4]	
AQUATIC ORGANISMS TESTING						
72-1 - Freshwater Fish LC_{50}						
A. Warmwater	TGAI	A,B	No		Yes	9 Months
	TEP	A,B	Yes	GS1440012 00140836	No	
B. Coldwater	TGAI	A,B	No		Yes	9 Months
	TEP	A,B	Yes	GS1440012	No	

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	
§158.145 Wildlife and Aquatic Organisms (continued)						
72-2 - Acute LC_{50} Aquatic Invertebrates	TGAI	A,B	Yes	00139440	No	
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B	No		Yes[5]	9 Months
72-4 - Fish and Early Life-Stage and Aquatic Invertebrate Life Cycle	TGAI	A,B	No		Yes[6]	12 Months

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor

3/ None of the three studies in the two documents fulfills the requirement individually, but the combination of all three studies does fulfill the requirement.

4/ Reserved pending receipt and evaluation of fate data.

5/ Required to support rights-of-way and other noncrop uses associated with coastal counties.

6/ Required to support rights-of-way and other noncrop use. Reserved for other uses pending receipt and evaluation of additional fate data.

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
NONTARGET AREA PHYTOTOXICITY					
Tier I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B	No		Yes[3] 9 Months
122-1 - Vegetative Vigor	TGAI	A,B	No		Yes[3] 9 Months
122-2 - Aquatic Plant Growth	TGAI	A,B	No		Yes[3] 9 Months
Tier II					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,D,	No		Reserved[4]
123-1 - Vegetative Vigor	TGAI	A,B,D	No		Reserved[4]
123-2 - Aquatic Plant Growth	TGAI	A,B,D	No		Reserved[4]
Tier III					
124-1 - Terrestrial Field	TEP	A,B	No		Reserved[5]
124-2 - Aquatic Field	TEP	D	No		Reserved[5]

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

§158.150 Plant Protection (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor
3/ These studies are required because data on the extent of phytotoxicity are not available and because the use of this product may pose hazards to endangered or threatened species.
4/ Reserved pending results of Tier I phytotoxicity tests.
5/ Reserved pending results of Tier II phytotoxicity tests.

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS					
141-1 - Honeybee Acute Contact LD_{50}	TGAI	A,B	Yes	00018842	No
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	A,B	No	—	No[3]
141-4 - Honeybee Subacute	TEP	A,B	No	—	Reserved[4]
141-5 - Field Testing for Pollinators	TEP	A,B	No	—	No[3]
NONTARGET INSECT TESTING - AQUATIC INSECTS					
142-1 - Acute Toxicity to Aquatic Insects	TEP	A,B	No	—	Reserved[5]
142-2 - Aquatic Insect Life Cycle Study	TEP	A,B	No	—	Reserved[5]
142-3 - Simulated or Actual Field Testing for Aquatic Insects	TEP	A,B	No	—	Reserved[5]
143-1 thru 143-3 - NONTARGET INSECT TESTING PREDATORS AND PARASITES	TEP	A,B	No	—	Reserved[5]

TABLE A

GENERIC DATA REQUIREMENTS FOR TERBUTRYN

§158.155 Nontarget Insect (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor
3/ As data from the acute contact study show very low toxicity to honeybees, no further testing is required.
4/ Reserved pending development of test methodology.
5/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

DATA REQUIREMENTS FOR TERBUTRYN 95% TECHNICAL[1] (EPA REGISTRATION NO. 46386-3; VEROLIT CHEMICAL MANUFACTURING CO., LTD.

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Partially	4/	Yes
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	Registration File	Yes[6]
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration File	Yes[6]
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	Registration File	Yes[6]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No		Yes
63-3 - Physical State	TGAI	No		Yes

TABLE B

DATA REQUIREMENTS FOR TERBUTRYN 95% TECHNICAL[1] (EPA REGISTRATION NO. 46386-3; VEROLIT CHEMICAL MANUFACTURING CO., LTD.

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (continued)				
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	TGAI	No		No[5]
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes
63-8 - Solubility	TGAI or PAI	No		Yes
63-9 - Vapor Pressure	TGAI or PAI	No		Yes
63-10 - Dissociation Constant	TGAI or PAI	No		Yes
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	No		Yes

TABLE B

DATA REQUIREMENTS FOR TERBUTRYN 95% TECHNICAL[1] (EPA REGISTRATION NO. 46386-3; VEROLIT CHEMICAL MANUFACTURING CO., LTD.

§158.120 Product Chemistry (continued)

1. The 95% technical serves as a manufacturing-use product.
2. Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
3. Data must be submitted no later than 8 months from issuance of this Standard.
4. Information obtained from desk references, (THE MERCK INDEX, Ninth edition, 1976; CRC HANDBOOK OF CHEMISTRY AND PHYSICS, 59th edition, 1978-1979; and THE HERBICIDE HANDBOOK, 1986).
5. Not applicable since the technical product is a solid at room temperature.
6. Updated information required by this standard or certification from registrants that EPA has current information on file.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TERBUTRYN

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology				
81-1 - Acute Oral - Rat	MP	Yes	00146725	No
81-2 - Acute Dermal	MP	Yes	00146726	No
81-3 - Acute Inhalation - Rat	MP	Yes	00146727	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00146729	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00146728	No
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	00146730	No

1/ Composition: MP = Manufacturing-use product.

LABEL CONTENTS

40 CFR 162.10 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 text. 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 162.10(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 162.10(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 162.10(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 162.10(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 162.10(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. [40 CFR 162.10 (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 162.10(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 162.10(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 162.10(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 162.10(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 162.10(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 162.10(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 162.10(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 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. [40 CFR 162.10]

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.

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 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.

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 panelM	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 the 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.

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 wordM
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 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

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 extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate 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 130°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."

Ttorage 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 storage 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 (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, 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 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."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) 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."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #
[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-D æthyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Daethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Danitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (SNTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl githiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

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II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichloro-phenoxy) ethyl ethec	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Pltassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Dasodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Pbtassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (A_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dapropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Pltassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether estec	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Poopylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)]	RCRA #	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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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[1]
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.

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)80813

TERBUTRYN*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
Tech (95%, 96%)
WP (80%)
DF (80%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. For retail sale to and use only by Certified Applicators or persons under their supervision and only for those uses covered by the Certified Applicator's certification. A selective herbicide for control of annual broadleaf weeds and grasses in winter wheat, winter barley, grain sorghum and non-crop land areas. When applied preemergence to weeds, the chemical will enter weeds through the roots after germination. When applied to emerged weeds, the chemical provides foliar knockdown of existing weeds and residual control of late germination weeds.
Terbutryn is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Drift and run-off from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.
Persons mixing and/or loading or otherwise handling this chemical are required to wear impervious gloves, coveralls (or long-sleeved shirt and trousers), face shield, socks, and shoes or boots. If flaggers are to be used during application, they are required to be in enclosed vehicles.
Do not graze or feed treated grain, forage, fodder, hay, silage, or straw to livestock.
Refer to labeling for appropriate ENDANGERED SPECIES LIMITATIONS.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits the Hill reaction in photosynthesis.

BROADLEAF WEEDS CONTROLLED:

ZAAABP	Annual groundcherry	
ZAAAAF	Annual thistle	
EMADAA	Bedstraw	
BKAKBA	Blue mustard	(a)
EUAEAA	Bluelips	
EHAGBJ	Bur buttercup	
ADABBA	Carpetweed	
EMADBA	Catchweed bedstraw	
AZAAAC	Chickweed	
ARABBB	Coast fiddleneck	
BFDQAA	Cocklebur	

*2-(tert-butylamino)-4-(ethylamino)-6-(methylthio)-s-triazine

BROADLEAF WEEDS CONTROLLED (continued)

0BB	Common chickweed	
JBA	Corn gromwell	
MBA	Corn spurry	
PBA	Cowcockle	
AHA	Dock (seedling)	
IBB	Dogfennel	
GAA	Falseflax	
BAA	Fiddleneck	
FBA	Field pennycress	
JAA	Gromwell	
FBA	Henbit	
ABK	Jacob's ladder	
IBA	Kochia	
EAB	Lambsquarter	
HBB	Mayweed	
CBA	Minerslettuce	
AAB	Morningglory	
AIAA	Nightshade	
AWAA	Pepperweed	
AABI	Pigweed	
CKBB	Pineappleweed	
CEBF	Prickly lettuce	
AJBF	Prickly sida	
AGBD	Prostrate knotweed	
AFBB	Puncturevine	
AABP	Purslane	
AEAA	Ragweed	
ABBB	Redstem filaree	
AKBA	Russian thistle	
AHBA	Shepherdspurse	
AGAD	Smartweed	
AACA	Snow weed	
APAA	Speedwell	
AEBA	Springbeauty	
BDBA	Tumble mustard	(a)
AACG	Tumbleweed	
AGBA	Umbrella spurry	
ABBB	Velvetleaf	
BJBA	White sweetclover	
AGBH	Wild buckwheat	(b)
BKBB	Wild mustard	

(a) Controls early germinating seedlings only.
(b) Partial control.

GRASSES AND OTHER MONOCOTS CONTROLLED:

CABZBA	Annual ryegrass	(b)
CABHBB	Barnyardgrass	
CAATBK	Cheat	(b)
CABFAA	Crabgrass	
CAATBM	Downy brome	(b)
CACUAA	Foxtail	
CACUBF	Green foxtail	(b)
CABHBA	Junglerice	
CAAFBC	Pacific meadow foxtail	

(b) Partial control.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
TERRESTRIAL FOOD CROP	
(Agricultural Crops)	
24001AA Barley (winter)	0.1 ppm (N) (fodder, grain, green barley, straw) Do not make more than 1 application per crop cycle. Do not plant any crops except wheat or barley until 9 months after application. General Information: Do not use on sand or loamy sand soils. Treatments made prior to the development of the secondary root system may result in increased winter injury during severe weather conditions. Do not make postemergence applications after temperatures exceed 70 F (21.1 C), as crop injury may occur. Apply in a minimum of 20 gallons of water per acre by ground or 5 gallons by air.
1.2-1.8 (80% DF) 000100-00655	Use limited to WA, west of the Cascades. Preemergence. Broadcast. Apply after planting and before crop emergence.
1.2-1.8 (80% WP)	Use limited to ID, OR, and WA. Postemergence. Apply as soon as the crop has a well developed root system, as indicated by the development of secondary roots. If this stage of development is not reached in the fall, an application may be made in early spring. For effective weed control, apply before weed rosettes have a 3 inch diameter

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Barley (winter) (continued)	
	or exceed 4 inches in height. Do not apply in liquid fertilizer solutions, as injury may occur.
Sorghum (grain)	0.1 ppm (N) (grain) General Information: Use ground equipment for preplant applications. Preplant applications should be made within 2 weeks of planting, and should be incorporated to a depth of 1 to 2 inches. For sorghum planted in beds, apply and incorporate after bed formation. In case of planting failures, sorghum may be replanted into soil previously treated with this chemical. Do not make a second broadcast application, as injury may occur. Rainfall or irrigation is necessary to move the chemical into the soil. If irrigation is used, irrigate during the first 36 hours after planting or wait until the sorghum is at least 2 inches in height. Apply only on sorghum planted after the minimum soil temperature has reached 60 F (15.6 C) or more for at least 3 consecutive days. Do not wait more than 2 days after planting to apply. Rainfall or overhead irrigation at the time of sorghum emergence until the sorghum is 2 inches in height may cause crop injury. Do not apply to millets, sudan-sorghum hybrids or sorghum breeding stocks. Applications may result in crop injury when made to sorghum growing on alkali soils, caliche outcroppings or where cuts, fills or erosion has exposed calcareous subsoils. To avoid concentration of herbicide in the seed furrow, do not make a broadcast application to sorghum planted in furrow deeper than 2 inches. Width of the band should not exceed the width of the bottom of the furrow. Do not make a second application to the same crop. Terbutryn applied alone in sorghum stubble should be plowed prior to planting the next crop. Rotational crops may be planted as follows: 4 months after application for winter wheat; 7 months or longer for all other crops, following normal agricultural practices and planting dates. Use the following guidelines for crop rotation after an application of terbutryn and atrazine or terbutryn and paraquat: do not plant to any crop except corn or sorghum until the following year if applied after June 10. Injury

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Sorghum (grain) (continued)	
	General Information (continued)
	may occur to soybeans planted in north central and northwest IA, south central and southwest MN, southeast SD, and northeast NE the year following an application on soils having a calcareous surface layer. Do not plant sugar beets, tobacco, vegetables (including dry beans, spring-seeded legumes or grasses) the year following treatment.
1.6-2.4 (80% WP) 000100-00496 (80% DF) 000100-00655	Use limited to eastern CO, IA, IL, KS, MN, MO, NE, and SD. Preplant or preemergence. Broadcast or band. Apply preplant with shallow incorporation, at planting, or immediately after planting. Use the lower dosage on loamy sand soils and the higher dosage on silt loam to clay soils.
1.6-2.4 (80% WP) (80% DF)	Use limited to all sorghum growing regions except eastern CO, IA, IL, KS, MN, MO, NE, and SD. Preplant or preemergence. Broadcast or band. Apply preplant with shallow incorporation, at planting or immediately after planting. Use the lower dosage on sandy loams and loam soils and the higher dosage on silt and clay loam soils. Do not use on sand or loamy sand soils.
0.8-1.6 (80% WP) (80% DF)	Use limited to the desert regions of AZ and CA, KS, NM, OK, and TX. Preplant or preemergence. Broadcast or band. Apply preplant with shallow incorporation, at planting or immediately after planting. Use the lower dosage on sandy soils and loam soils and the higher dosage on all other soils.
0.6-0.8 (80% DF)	Use limited to the Gulf Coast and Blacklands of TX. Preplant. Broadcast. For control of winter weeds. Apply in the fall or winter to fall-bedded land to be planted to sorghum the following spring. Add a surfactant, emulsifiable oil, or oil concentrate.
1.6 (80% WP) (80% DF)	Use limited to IA, IL, eastern KS, MN, MO, eastern and central NE, and SD. Preplant or preemergence. Broadcast or band. Tank mix with propazine. Apply preplant with shallow incorporation, at planting or immediately after planting. Use on sandy loam soils only.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Sorghum (grain) (continued)	
1.6-2.0 (80% WP) (80% DF)	Use limited to IA, IL, eastern KS, MN, MO, eastern and central NE, and SD. Preplant or preemergence. Broadcast or band. Tank mix with atrazine. Apply preplant with shallow incorporation, at planting or immediately after planting. Use on loam or finer textured soils. Do not use on sand, loamy sand, or sandy loam soils.
1.6-2.0 (80% WP) (80% DF)	Use limited to central KS, western NE, OK, and TX. Preplant or preemergence. Broadcast or band. Tank mix with propazine. Apply preplant with shallow incorporation, at planting or immediately after planting. Use the lower dosage on sandy loam soils and the higher dosage on loam or finer textured soils. Do not use on sand or loamy sand soils.
1.6 (80% WP) (80% DF)	Use limited to eastern CO and western KS. Preplant or preemergence. Broadcast or band. Tank mix with propazine. Apply preplant with shallow incorporation, at planting or immediately after planting. Use on sandy loam and finer textured soils. Do not use on sand or loamy sand soils.
1.6-2.0 (80% DF)	Preplant or preemergence. Broadcast or band. Tank mix with atrazine and paraquat. Apply preplant with shallow incorporation, at planting, or immediately after planting. Apply in 20 to 40 gallons of finished spray per acre. Add a nonionic surfactant. Use only water or nitrogen solutions as a carrier. Use the lower dosage on loam and silt soils and the higher dosage on silty and sandy clay loam soils, and sandy and silty clay soils.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
4007AA	Wheat (winter)	0.1 ppm (N) (fodder, grain, green wheat, straw) Do not make more than 1 application per crop cycle. Do not plant any crops except wheat or barley for 9 months after application. General Information: Do not use on sand or loamy sand soils. Do not make postemergence applications after temperatures exceed 70 F (21.1 C), as crop injury may occur. Treatments made prior to the development of the secondary root system may result in increased winter injury during severe weather conditions. For effective weed control, apply before weed rosettes are 3 inches in diameter or exceed 4 inches in height. Apply in a minimum of 5 gallons of water per acre by air, or in a minimum of 20 gallons of water or nonpressurized fertilizer solution per acre by ground.
	1.2-2.2 (80% DF) 000100-00655	Use limited to WA, west of the Cascades. Preemergence. Broadcast. Apply after planting and before crop emergence.
	1.2-2.2 (80% WP) 000100-00496	Use limited to ID, OR, UT, and WA. Postemergence. Broadcast. Apply as soon as the crop has a well developed root system, as indicated by the development of secondary roots. If this stage of development is not reached in the fall, an application may be made in early spring.
	0.6-0.8 (80% WP)	Use limited to ID, OR, and WA. Postemergence. Broadcast. Tank mix with chlorbromuron.
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)	
660020A	Fallowland	General Information: Apply only once during the fallow period. Apply in 20 to 60 gallons of water and a surfactant per acre. Use the higher dosage if weeds are 4 to 6 inches in height.
	1.6-2.0 (80% WP) 000100-00496 (80% DF) 000100-00655	Use limited to CO, KS, MT, NE, ND, SD, and WY. Postharvest application to wheat fallow to be planted to wheat. Apply July or August following wheat harvest. Tank mix with atrazine. May be tank mixed with metribuzin in CO, KS, MT, NE, and WY. Make 1 application of terbutryn by itself during the same fallow period. Plant wheat no

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Fallowland (continued)	
	sooner than 4 months after application of terbutryn alone and no sooner than 12 months after the tank mix application.
1.6-2.0 (80% WP) (80% DF)	Use limited to KS and NE. Postharvest application to wheat fallow to be planted to corn grown under minimum tillage. Apply July or August following wheat harvest. Tank mix with atrazine.
1.6-2.0 (80% DF)	Use limited to the Great Plains, including KS, OK, and northern TX. Preemergence or postemergence to wheat fallow to be planted to wheat, or to sorghum fallow to be planted to wheat. Broadcast or band. Apply in the spring at the start of the fallow period. In the Great Plains, do not plant wheat sooner than 4 months after application, in KS, OK, and northern TX do not plant wheat sooner than 2 months after application. May be tank mixed with paraquat, DMA, and cyanazine on wheat fallow to be planted to wheat.
1.6-2.0 (80% WP) (80% DF)	Postharvest application to wheat fallow to be planted to sorghum grown under minimum tillage. Apply in July or August following wheat harvest. Tank mix with atrazine.

TERRESTRIAL NON-FOOD CROP

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

Uncultivated Non-Agricultural Areas	General Information: This site includes railroad rights-of-way, and other noncrop sites.
2.0-2.4 (80% WP) 000100-00496 (80% DF) 000100-00655	Broadcast. Apply to actively growing weeds not more than 6 inches in height. Apply in at least 20 gallons of water per acre. May be tank mixed with atrazine and simazine.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	AERIAL AND TANK MIX APPLICATIONS	
001500 AAAAAA	Aerial Application	
	—	Refer to TERRESTRIAL FOOD CROPS (Agricultural Crops) Barley (winter), Sorghum (grain), Wheat (winter) (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Fallowland
900300 AAAAAA	Tank Mix	
	—	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Sorghum (grain), Wheat (winter) (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Fallowland TERRESTRIAL NON-FOOD CROP (Noncrop, Wide Area and General Indoor/Outdoor Treatments) Uncultivated Non-Agricultural Areas

TERBUTRYN

Listing of Registered Pesticide Products by Formulation

,0002 95% formulation intermediate
terbutryn (080813)
046386-00003

,0002 96% formulation intermediate
terbutryn (080813)
000100-00540

,0006 80% wettable powder
terbutryn (080813)
000100-00496

,0011 80% water dispersable granules
terbutryn (080813)
000100-00655

999 State Label Registrations

AZ Reg. No.
010163-06402

CA Reg. No.
000100-04282

ID Reg. No.
000100-04305

UT Reg. No.
000100-04262

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
101101	metribuzin	4-amino-6-(1,1dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one
080803	—	atrazine
090701	chlorbromuron (ANSI)	3-(4-bromo-3-chlorophenyl)-1-methoxy-1-methylurea
100101	cyanazine (ISO)	2-[[4-chloro-6-(ethylamino)-S-triazin-2-yl]-amino]-2-methyl propionitrile
030019	DMA	2,4-dichlorophenoxyacetic acid, dimethylamine salt
061601	paraquat	paraquat dichloride
080808	—	propazine
080807	—	simazine

— Use EPA Acceptable Common/Chemical Name

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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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
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MRID	CITATION
00146730	Maedgen, J. (1984) Guinea Pig Sensitization--Igran 80 WDG: Project No. 3307-84. Unpublished study prepared by Stillmeadow, Inc. 14 p.
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00147483	Franklin, L.; Cranor, W. (1982) Determination of Adsorption/Desorption Constant of Terbutryn: ABC Report No. 27959. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 113 p.
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FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

T NAME

NT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

pect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced ce 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:

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.)

ANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

OMB Approval No. 2000-0468

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

ualify, certify ALL four items)

im duly authorized to represent the following firm(s) who are subject to the require- :nts of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

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

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

/ 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 und 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 the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

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

/ *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 ve agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement es not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

110

D NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 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				

ATTACHMENT A
FORMULATOR'S EXEMPTION STATEMENT

EPA File Symbol/Reg. No. _____ Product Name _____

Applicant's Name and Address _____

_____

_____

As an authorized representative of the applicant for registation of the product identified above, I hereby certify that:

(1) Our product is an end use product, and it contains the active ingredient(s): _____

_____

_____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling the appropriate text which paragraph applies--(A) or (B):

(A) An accurate Confidential Statement of Formula 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 active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active Ingredient	Source: Product Name and Reg. No.
_____	_____
_____	_____
_____	_____

Signature: _____

Typed name: _____

Dated: _____