United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-95-005
March 1995

Reregistration Eligibility Decision (RED)

Terbuthylazine

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative C.P. Moran at (703) 308-8590.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the

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

e. **Certification With Respect to Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**

Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

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

By U.S. Mail:

Document Processing Desk **(RED-SRRD-2646)***
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

***** 2645 = the case code for the RED (see front cover of RED)

By express:

Document Processing Desk **(RED-SRRD-2645)***
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

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

REREGISTRATION ELIGIBILITY DECISION

TERBUTHYLAZINE

LIST B

CASE 2645

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

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for refernce dose (RfD).
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs

GLOSSARY OF TERMS AND ABBREVIATIONS

PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Agency has completed its review of the target database for terbuthylazine and has concluded that terbuthylazine products labeled and used as specified in this Reregistration Eligibility Decision will not cause unreasonable risk to humans or the environment and that terbuthylazine uses are eligible for reregistration.

Terbuthylazine is an algicide, a microbicide and microbistat used to control algae and slime-forming algae, fungi, and bacteria. It is formulated as a flowable concentrate. It is labeled for aquatic non-food industrial, commercial, and residential uses. Industrial and commercial uses are for ornamental fountains, ponds, and for water cooling systems, including evaporative condensers, heat-exchange systems, and commercial and industrial cooling towers. Residential uses are for ornamental ponds/aquaria. Applications are made as continuous feed or intermittent slug treatments. Previous to this reregistration decision, application was allowed either by the open-pouring method or by closed system such as a metering pump.

The Agency's assessment found unacceptable risk from short and intermediate-term exposure to workers who use the open-pouring method of application for commercial uses. Therefore this application method is no longer being allowed. Rather, the Agency is restricting product application to closed systems and the use of certain personal protection equipment to reduce exposure and risk to acceptable levels for commercial uses. Risks associated with residential uses are acceptable and no restrictions are necessary.

Also, risk to aquatic plants is of concern. Phytotoxicity data addressing this concern recently have been called-in so that the Agency can evaluate the potential environmental impact of discharges of terbuthylazine under the permitting process of the National Pollutant Discharge Elimination System.

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Terbuthylazine
- **Chemical Name:** 2-(tert-butylamino)-4-chloro-6-(ethylamino)-s-triazine
- **Chemical Family:** triazines
- **CAS Registry Number:** 5915-41-3
- **OPP Chemical Code:** 080814
- **Empirical Formula:** $C_9H_{16}ClN_5$
- **Trade and Other Names:** Gardoprim, Primatol M, Primatol M80, Sorgoprim, Bellacide 325, and Bellacide 329
- **Basic Manufacturer:** FMC Corporation

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of terbuthylazine appears in Appendix A.

Type of Pesticide: Algicide, microbicide/microbistat (slime-forming algae, fungi, and bacteria).

Use Sites: Aquatic Non-food Industrial - recirculating commercial/industrial water cooling systems, recirculating evaporative condenser water systems, recirculating heat exchanger water systems, lakes/ponds/reservoirs (without human or wildlife use) [e.g. wastewater ponds].

Aquatic Non-food Residential - ornamental ponds/aquaria.

Aquatic Non-Food Outdoor - Aquatic areas/water (e.g. aquatic noncrop use products).

Target Pests: slime-forming algae, fungi and bacteria

Formulation Types Registered:

Soluble Concentrate/Liquid - 4 % - 44.7%
Technical Grade - 96%

Method and Rates of Application:

Equipment - unspecified

Method and Rate - Recirculating water system treatment: continuous or intermittent (slug) treatment; open pouring or closed system pump application.

Rates and Timing for Terbuthylazine Application in Chlorinated or Brominated Recirculating Industrial Water Cooling Systems

Application Timing	Continuous Feed	Slug Application
Initial	1 ppm	1-2 ppm
Subsequent	1-9 ppm	1-9 ppm

For non-chlorinated or non-brominated systems for both continuous feed and slug treatments, initial application is made at 3 ppm and subsequent applications at 3-9 ppm. Applications to recycled cooling water ponds is made at 2 ppm by weight.

Use Practice Limitations:

Preclean systems before applying the pesticide.

Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority.

Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction.)

Do not use where treated water will come into contact with lawns, trees, shrubs, or other desirable plants, since injury may result.

Do not use water from treated systems for irrigation or spraying of agricultural crops, lawns, or ornamental plants, or for watering cattle, goats, hogs, horses, poultry or sheep, or for human consumption.

C. Estimated Usage of Pesticide

According to the manufacturer annual production of terbuthylazine for the years 1992 and 1993 was less than 100,000 pounds. A portion of this production was exported, no terbuthylazine was imported. It is not known what portion of the production is used for each of the two sites of use: commercial and industrial water cooling towers systems and ornamental ponds, fountains and aquaria.

D. Regulatory History

Terbuthylazine was registered in the United States in 1975. Tolerances were established for terbuthylazine in or on corn fodder and forage, corn grain (including popcorn grain), and sorghum forage and grain (40 CFR 180.333). However, since no end-use products were registered for use of terbuthylazine as a herbicide these tolerances were revoked in 1992 (53 FR 4860, 56 FR 14471, and 57 FR 30132). Products formulated for end-use were registered as algicide and microbicides/microbistats starting in 1986. Currently, five products containing terbuthylazine are registered to a total of three companies.

A Data Call-In for data required to support the reregistration of terbuthylazine was issued in 1991. Certain chemical, toxicological, and environmental fate data were required. Three additional data call-ins were issued: one requiring worker exposure information, and another requiring specific manufacturing information with respect to dioxin formation, and a third requiring aquatic plant testing data.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color: Off-white.

Physical State: Powdery solid, waxy and globular.

Odor: Rancid, putrid.

Melting Point: 178 to 179.3EC

Specific Gravity: 22.04 lb/ft^3

Solubility at 25EC:
Water……11.5 ppm
Acetone…….4.13 g/100 ml
Ethanol…….1.50 g/100 ml
Toluene…….1.04 g/100 ml
n-Octanol……..1.25 g/100 ml
Ethylene glycol..0.236 g/100 ml

Vapor Pressure: 5.8 X 10-7 mm Hg at 25°C

Dissociation Constant: $pK_b = 1.9 \pm 0.1$ at 21°C

Octanol/Water Partition Coefficient: 1.6×10^3

pH: 6.6 to 7.8 at 25EC

Stability: Not sensitive to metals, metal ions; stable at elevated temperature, not sensitive to sunlight.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on terbuthylazine is adequate and will support reregistration eligibility.

a. Acute Toxicity

The table below summarizes the results of acute toxicity studies on terbuthylazine and the toxicity categories for the different routes of exposure.

ACUTE TOXICITY DATA FOR TERBUTHYLAZINE

TEST	RESULT	CATEGORY
Oral LD50 in rat (MRID 41907702)	LD_{50} 1000 - 1590 mg/kg (males); 1503 mg/kg (females)	III
4 hr inhalation LC50 in rat (MRID 41603305)	LC_{50} > 5.3 mg/L	III
Dermal LD50 in rat (MRID 41907703)	LD_{50} > 2000 mg/kg	III
Eye irritation in rabbit (MRID 41907704)*	Mildly-to-moderately irritating	III
Dermal irritation in rabbit (MRID 41907705)*	Slightly irritating	III
Dermal sensitization in Guinea pig (MRID 41907706)*	Not a sensitizer	N/A

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

Treatment-related clinical signs reported following acute oral or inhalation exposure included piloerection, dyspnea, reduced locomotor activity and/or diarrhea.

Slightly different results were obtained in two acute toxicity studies not reported above. In an acute oral toxicity study (MRID 41603304) in rats, an LD_{50} of > 2000 mg/kg was determined (Toxicity Category III). In an ocular irritation study in rabbits (MRID 41603306), terbuthylazine caused minimal eye irritation (Toxicity Category IV). The

more sensitive studies (listed in the above table) are used for regulatory purposes.

b. Subchronic Toxicity

Subchronic oral toxicity:

In a 28-day oral toxicity study (MRID 00161104), terbuthylazine (technical, 99.8% a.i.) was administered to male and female RAI (SPF) rats in the diet at concentrations of 0, 25, 75, 250 or 750 ppm (corresponding to doses of 0, 2.4, 7.7, 26.6 or 68.7 mg/kg/day in males and 0, 2.3, 8.1, 27.9 or 63.4 mg/kg/day in females).

At 25 ppm (2.4 mg/kg/day) and higher, dose-related, statistically significant decreases in mean body weight gain compared to controls were observed in males (at termination body weight gain was 12, 18, 22 and 35% less than controls, low to high dose, respectively). Relative thymic weight was reduced (-17%, decreasing to -36% at 750 ppm) and slight decrease in absolute 1 week kidney weight was also observed (-4%, decreasing to -25% at 750 ppm). In females, both absolute liver weights and liver:brain weights were decreased at 25 ppm (2.3 mg/kg/day) and higher (reductions ranged from about -20% to about -30% at 750 ppm). At 250 and 750 ppm, mean body weights of females were statistically significantly reduced in females (-25 and -41%, respectively). The LEL is 25 ppm (2.3 mg/kg/day) based on decreased body weight gain, relative thymic weight and absolute kidney weight in males and possibly decreased liver weight in females. The NOEL is less than 25 ppm (lowest dose tested).

Subchronic dermal toxicity:

In a repeated dose dermal toxicity study (MRIDs 40514802 and 42059804), terbuthylazine (technical, 97.1% a.i.) was applied daily to the intact skin of 5 male and 5 female New Zealand White rabbits for 29 consecutive days. Test material was moistened with distilled water and 0 (distilled water), 0.05, 0.5 or 500 mg/kg/day were applied for 6 hrs/day under occlusive wrap.

At 500 mg/kg/day, reduced body weight gain compared to controls at day 28 was observed in males (-36%) and females (-39%). Food consumption was also decreased (-76% and -89% of controls during week 1 in males and females; between -11% to -54% of controls at other times). Reduced fecal output was observed sporadically among both sexes. Mortality occurred in one female, preceded by cachexia,

hypothermia and muscle wasting. The LEL of 500 mg/kg/day is based on decreased body weight gain and food consumption in males and females and, in one female, hypothermia, cachexia and mortality. The NOEL is 0.5 mg/kg/day.

The following dermal toxicity study was classified as Core-supplementary due to several study deficiencies (NOEL not determined, less than 10 animals/dose and some information lacking in study report) but was considered in determination of appropriate toxicity endpoints for short- and intermediate-term occupational and residential risk assessment.

In a subchronic dermal toxicity study (MRID 00151622), male and female New Zealand White rabbits were dermally exposed to terbuthylazine (technical, 99.8% a.i.) at 0, 5, 50 or 500 mg/kg/day (10 animals/sex at 500 mg/kg/day; (5 animals/sex at all other dose levels). Doses were administered in an aqueous vehicle of 0.1% polysorbate/0.5% carboxymethylcellulose. Animals were exposed for 6 hrs/day, 5 days/week. Five high dose animals/sex were sacrificed at 29 days and 5 after a 2-week recovery period.

At 5.0 mg/kg/day, several clinical signs classified as minimal were observed among males and females. During the first 7 days of the study, clinical signs were observed only in 1 male (dyspnea, piloerection, sedation) and 1 female (curved body position). Thereafter, all animals developed dyspnea, piloerection, sedation and curved body posture, a few developed tremors (1 male, 2 females), and 1 female had ataxia. Dermal irritation was also observed in treated animals. At 50 and 500 mg/kg/day, clinical signs occurred earlier and with greater severity (classified as moderate). At 500 mg/kg/day, body weight gain was decreased compared to controls (-87% for males and -73% for females) and food consumption was decreased compared to controls during weeks 1 and 2 (- 2% to - 71% for males; 23% -37% for females). The LEL of 5.0 mg/kg/day is based on clinical signs in males and females. The NOEL is less than 5.0 mg/kg/day.

c. Chronic toxicity and carcinogenicity

Mouse:

In a 2-year chronic feeding/carcinogenicity study (MRID 00156487), terbuthylazine (technical, 98% a.i.) was administered in the diet to 50/sex/dose Tif:MAGF (SPF) mice at dose levels of 0, 30, 150

or 750 ppm (males: 0, 3.28, 16.99 or 86.76 mg/kg/day; females - 0, 3.22, 16.66 or 88.54 mg/kg/day).

Percent body weight gain of males in the 750 ppm group was decreased by approximately 10%, while in females it decreased by approximately 23% throughout most of the study. Food consumption in males at 750 ppm was decreased by approximately 20% throughout most of the study. The LEL for systemic toxicity is 750 ppm based on decreased body weight in females and a possible decrease in food consumption in males. The NOEL for systemic toxicity is 150 ppm. There was no evidence that administration of terbuthylazine was associated with an increase in tumors.

Rat:

In a 2- year chronic feeding/carcinogenicity study (MRID 00156486), terbuthylazine (technical, 96.8% a.i.) was administered for 24 months to a total of 80/sex/dose Tif:RAIF(SPF) rats at dose levels of 0, 30, 150 or 750 ppm (males: 0, 1.24, 6.97 or 41.47 mg/kg/day; females: 0, 1.37, 7.81 or 52.80 mg/kg/day). Twenty sex/dose of these were sacrificed at 24 months and 10/sex/dose at 12 months. The remaining animals received terbuthylazine for 24 months and were then placed on untreated diet until terminal sacrifice at weeks 112 (males) or 122 (females).

At 30 ppm and above, decreased body weight gain was observed in males (10%, 28% and 49% less than controls at week 54, low to high dose) and females (12%, 32% and 47% at week 54, low to high dose). At 30 ppm and above, food consumption was decreased in males (9%, 14% and 25% at 54 weeks) while in females only at 150 ppm and above (10% at 54 weeks). At 150 ppm and above in females, BUN and urinary specific gravity were increased while urinary volume and pH were decreased. These changes were noted in males at 750 ppm only. At 750 ppm, there were increased lesions observed in males compared to controls, including macroscopic hepatic cysts, Leydig cell nodular hyperplasia of the testes (27% vs 9% in the controls) and increases in benign interstitial cell tumors of the testes (13% vs. 4% in the controls). In females at the 750 mg/kg/day dose there were increased lesions including macro- and microscopic hepatic cysts and mammary gland carcinomas (18% vs. 5%, controls). The LEL for systemic toxicity is 30 ppm (1.24-1.37 mg/kg/day) based on decreased body weight gain in males and females and food consumption in males. The NOEL is less than 30 ppm. Terbuthylazine was associated with increased incidence of testicular interstitial cell tumors in males and mammary gland

carcinomas in females, but only at a dose at which excessive systemic toxicity was also observed. The Office of Pesticide Program's Health Effects Division (HED) Carcinogenicity Peer Review committee considered the systemic toxicity observed at 750 ppm to be excessive (exceeding the maximum tolerated dose or MTD) and the slight increases in tumor incidence to be of uncertain relevance to human cancer risk assessment (see "Carcinogenicity", below).

In a second 2-year chronic feeding/carcinogenicity study designed to determine a NOEL for chronic systemic toxicity (MRID 00157342), terbuthylazine (technical, 98% a.i.) was administered to 80/sex/dose Tif:RAIF(SPF) rats at dose levels of 0, 6 or 30 ppm (males - 0, 0.35 or 1.6 mg/kg/day; females - 0, 0.36 or 1.6 mg/kg/day). Animals fed for 98 weeks were placed on diets lacking the test material until final sacrifice at week 118 (males) and 121 weeks (females).

At 30 ppm there were decreases in percent body weight gain in males (7% less) and females (12% less) as well as decreases in food consumption in males (6% less than controls) and females (11% less) as compared to controls. The LEL for systemic toxicity is 30 ppm based on transient decreases in body weight and food consumption consistent with another study. The NOEL for systemic toxicity is 6 ppm. Terbuthylazine administration was not associated with an increase in tumors at the doses tested.

On May 25, 1994 (Peer Review Document dated August 24, 1994), the Agency's Carcinogenicity Peer Review Committee classified terbuthylazine as a Group D Carcinogen (inadequate evidence to determine carcinogenicity in humans). The incidence of benign interstitial tumors in testes of male rats and of mammary gland carcinoma in female rats was increased, but the increase was only observed at a dose at which excessive toxicity was observed (750 ppm). The classification was assigned because although terbuthylazine is structurally related to other s-triazines that induce similar types of tumors, tumors were only observed at a dose that exceeded the MTD and were only seen in one species.

d. Developmental Toxicity

Rabbit:

In a rabbit developmental toxicity study (MRID 00130744), female New Zealand White rabbits were dosed by gavage from days 7 through 19 of gestation with terbuthylazine (technical, 98.5% a.i.) in

1% methylcellulose at 0, 0.5, 1.5 or 4.5 mg/kg/day. Animals were sacrificed on day 29 of gestation.

No signs of maternal toxicity were observed at any dose tested (in a preliminary study, body weight loss was observed at 12.5 mg/kg/day but not at 5 mg/kg/day in the rabbit). The maternal toxicity LEL is greater than 4.5 mg/kg/day. The maternal toxicity NOEL is equal to or greater than 4.5 mg/kg/day. No signs of developmental toxicity were observed in the rabbit at any dose tested. The NOEL for developmental toxicity is equal to or greater than 4.5 mg/kg/day. The LEL for developmental toxicity is greater than 4.5 mg/kg/day. Although an LEL for developmental toxicity was not established, this study is considered adequate for regulatory purposes since (1) the data indicate that the rabbit is not more sensitive than the rat for developmental toxicity since the NOEL is not significantly lower in the rat (4.5 mg/kg/day vs. 5.0 mg/kg/day, respectively), as described below, and (2) the rabbit preliminary study indicated that maternal toxicity was observed at 12.5 mg/kg/day.

Rat:

In a rat developmental toxicity study (MRID 41962701), female Tif:RAI (SPF) rats were administered 0, 1, 5 or 30, mg/kg/day terbuthylazine (technical, 96.4% a.i.) by gavage in an aqueous 3% corn starch vehicle (10 ml/kg) on days 6 through 15 of gestation, inclusive. Animals were sacrificed on day 19 of gestation.

Maternal toxicity was observed at 30 mg/kg/day as significantly reduced body weight gain (60% less than controls) during the treatment period compared to controls and food intake was also reduced (18%). The maternal toxicity LEL is 30 mg/kg/day based on decreased body weight gain and food intake. The maternal toxicity NOEL is 5 mg/kg/day. Developmental toxicity was also observed at 30 mg/kg/day based on a dose-related increased incidence of absent ossification of the posterior phalanx of anterior digit 2 (30% litter incidence vs. 10% of the controls). The developmental toxicity LEL is 30 mg/kg/day based on absent ossification in anterior digit 2. The developmental toxicity NOEL is 5 mg/kg/day.

e. Reproductive Toxicity

Acceptable data on reproductive toxicity is not available to the Agency at this time. However, a 2-generation reproduction study in the rat is not required to support reregistration of terbuthylazine and its

current uses. In the future if food uses are proposed a 2-generation reproduction study will be required to support registration.

f. Mutagenicity

Terbuthylazine was negative for reverse gene mutation in Salmonella typhimurium strains in assays when tested with or without metabolic activation up to limits of solubility (5 mg/ml) in two independently conducted studies (MRIDs 00108817 and 00140816; MRID 41634001).

In a mouse L5178T/TK +/- assay, terbuthylazine did not cause increased mutation frequency with or without metabolic activation when tested up to 1 mg/ml (MRID 00151618).

In a mouse micronucleus assay, terbuthylazine did not cause increased micronuclei formation in bone marrow following administration to mice up to the limit dose of 5000 mg/kg (MRIDs 41418102 and 42059805).

Terbuthylazine did not induce unscheduled DNA repair in cultured rat hepatocytes at test concentrations up to 125 Fg/ml or 1000 Fg/ml in two independently performed studies (MRIDs 41391801 and 42059806; MRID 00151619). Terbuthylazine was also negative when tested for unscheduled DNA repair at concentrations of up to 125 Fg/ml in cultured human fibroblasts (MRID 00151620).

g. Metabolism

Although a guideline metabolism study has not been required (or submitted) for the nonfood uses, adequate information is available from two published metabolism studies to provide a general characterization of metabolism of terbuthylazine in rats. Metabolism of terbuthylazine in rats is similar to other chloro-s-triazine herbicides. The major routes of metabolism are hydrolysis of the chlorine moiety and mono- or didealkylation. Hydroxylation of one or both of the dealkylated amine groups may also occur (MRID 00055672).

In a rat metabolism study (MRID 00038018), ^{14}C-terbuthylazine (3.6 mg) was administered orally to Wistar rats. Terbuthylazine was rapidly (50% excreted by 16-17 hrs) and completely metabolized and did not accumulate in tissues. Radioactivity was excreted equally in urine and feces in males, but in females about 66% of the radiolabel was

excreted in the urine. Urine and feces contained up to 25 and 15 identified metabolites, respectively, most of which were polar. Degradation of the triazine ring did not occur. Ammeline and ammelide, 2 dechlorinated and dealkylated/hydroxylated metabolites common to all triazines, were identified in low amounts in the feces.

h. Reference Dose

The Agency's Office of Pesticide Program's HED RfD/Peer Review Committee recommended establishing an RfD of 0.00035 mg/kg/day for terbuthylazine. This was based on an NOEL of 0.35 mg/kg/day from the chronic toxicity study in rats, where effects on body weight and food consumption were observed in males and females at 1.6 mg/kg/day. An uncertainty factor of 100 was used to account for inter- and intra-species variability, with an additional factor of 10 to compensate for lack of non-rodent chronic toxicity data and reproductive toxicity data. A reference dose is used in assessing risk from food treated with a pesticide registered with the Agency. Before registering uses of terbuthylazine the Agency's RfD Committee would need to approve the RfD.

2. Exposure Assessment

a. Dietary Exposure

No dietary exposure is expected since there are no pesticidal products with food uses currently registered.

b. Occupational and Residential Exposure

The Agency requires an occupational and/or residential exposure assessment for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to mixers, loaders, or applicators during use or to persons entering sites after application is complete. The Agency has determined that an exposure assessment is required for terbuthylazine, since it triggers the toxicological criteria (systemic toxicity in the developmental toxicity study) and the normal use-patterns identified for terbuthylazine products potentially expose persons associated with its use.

The Agency has identified potential for exposure to loaders and applicators during commercial/industrial applications of terbuthylazine. The Agency also has identified potential for post-application exposure to persons cleaning or maintaining water cooling towers and to persons,

especially children, wading or swimming in commercial or residential fountains or ornamental ponds. Assessments of these exposures are described below.

Mixer/Loader/Applicator (Handler) Exposure:

Toxicological data submitted to support reregistration indicate that short and intermediate-term exposures to terbuthylazine may cause health effects, and therefore, an occupational and/or residential exposure assessment is warranted. No exposure data specific to terbuthylazine are available. However, surrogate exposure data from the Chemical Manufacturers Association's Antimicrobial Exposure Assessment Study (MRIDs 41412201, 41742601, and 42587501) is considered by the Agency to be appropriate for use in estimating human exposure to most uses of antimicrobials, including those of terbuthylazine.

The Agency conducted exposure assessments for applicators of a typical product used in industrial water cooling tower systems and commercial and residential/homeowner ornamental fountains for control of algae. Use practices for a typical industrial use product, Belclene 329® (EPA Registration Number #279-3137), containing 44.7% terbuthylazine, were used in the analysis. (Another formulation containing 4.0% terbuthylazine is registered but due to low concentration of terbuthylazine in this formulation lower exposure would be expected during its use.) The Agency assumes the quantity of active ingredient used in ornamental fountains is less than one-tenth of that used in typical industrial sites based on smaller volumes of water at ornamental fountains.

I. Open-Pouring Application Method

Belclene 329®, is applied by open pouring where there is good mixing with the water such as in the cooling tower sump near the recirculating pump or near the fountain recirculatory pump. Eight fluid ounces of Belclene 329® are applied into 10,000 gallons of water in industrial/commercial systems (this results in a concentration of 3 ppm of active ingredient). This assessment assumes no use of personal protective equipment since no such requirement is specified on labels. Assuming one gallon of Belclene 329 is equivalent to 11 pounds, a total amount of product equal to 0.31 lb of a.i. is added into 10,000 gallons of water in industrial/commercial systems each application time (or one-tenth as much to ornamental fountain).

Estimates for daily exposure can be calculated as (MCS X lb ai used ai) / BW, where the Maximum Credible Sum (MCS) is assumed to be the amount of a.i. the applicator is exposed to from each pound of a.i. applied and the applicator is an adult female of average body weight (BW). Based on these assumptions for open-pouring of a terbuthylazine product, the Agency estimates daily exposure to be 140.17 Fg/kg/day for the industrial/commercial uses or 14.02 Fg/kg/day for the residential use. Exposure from open pouring would be greater in larger systems -- increasing with the volume of water treated. It would also be expected to increase with a higher frequency of application, for example during the initial charging of the system until a maintenance level was obtained.

OPEN POURING LIQUID				
Site of Use	MCS[1] (ug/lb ai)	lb ai/used	BW[2] (kg)	Daily Exposure[3] (Fg/kg/d)
Cooling Tower & Commercial Ornamental Fountain	27130	0.31	60	140.17
Residential Ornamental Fountain	27130	0.03	60	14.02

[1] MCS = Maximum Credible Sum, or the unit exposure, derived from the CMA Study.
[2] BW = Body Weight
[3] Daily exposure = the estimated exposure during a single application of the chemical.

II. Metering-Pump Application Method

Based on the use of a metering pump application method and an estimate for exposure (MCS) from the CMA study, the Agency estimates daily exposures to be 4.81 ug/kg/day for exposure to commercial applicators and 0.0048 mg/kg/day to homeowner users. Unlike the open-pouring application where applicators could potentially be exposed during each application, exposure to workers using a closed application system is expected to be lower since exposure would occur less frequently during handling when bulk containers are coupled to and uncoupled from the closed application system. For this reason the size of the system treated is expected to have a negligible effect on exposure to workers. In addition, a higher frequency of application as in the initial charging of the system until a maintenance level is obtained is also not expected to increase exposure significantly.

METERING-PUMP LIQUID				
Site of Use	MCS[1] (Fg/lb ai)	lb ai/used	BW[2] (kg)	Daily Exposure[3] (Fg/kg/d)
Cooling Tower & Commercial Fountain	930	0.31	60	4.81
Residential Ornamental Fountain	930	0.03	60	0.48

[1] MCS = Maximum Credible Sum was derived from the CMA Study.
[2] BW = Body Weight
[3] Daily exposure = the estimated exposure during a single application of the chemical.

Post-Application Exposure:

Because of the use patterns and the dilution factors in the water cooling tower systems and ornamental fountains (3 ppm of terbuthylazine), post-application exposure is expected to be minimal. Therefore, the Agency has not required post-application exposure data or attempted to quantify such potential exposure.

3. Risk Assessment

a. Dietary

The Agency did not conduct a dietary risk assessment for terbuthylazine since there are no food or feed uses for this chemical at this time.

b. Occupational and Residential Risk Characterization

Toxicological Endpoints

Short-term occupational exposure (1 - 7 days): The Agency believes the pertinent toxicological endpoint for short-term occupational or residential exposure and risk assessment for the current use patterns of terbuthylazine is the LEL (5.0 mg/kg/day; LDT) from the 28-day rabbit dermal toxicity study (MRID 00151622) described above in Section II; A NOEL was not determined in this study). Although this study has certain deficiencies the LEL of 5.0 mg/kg/day from this study is considered appropriate for risk assessment because 1) exposure was via the dermal route and (2) the summarized daily clinical observation data indicate that during days 1-7 of the study, only marginal clinical signs of toxicity were observed in 1-2 males and females. For short-term exposure, 5.0 mg/kg/day is therefore considered a threshold LEL and an appropriate endpoint for risk assessment. The NOEL of 0.5 mg/kg/day from the other 28-day dermal toxicity study (MRIDs 40514802 and 42059804) was considered not representative of terbuthylazine toxicity due to: 1) the large difference between doses selected for this study -- the 1000-fold difference between the two highest doses -- 0.5 vs. 500 mg/kg/day means the study was not very precise in measuring toxicity and 2) oral toxicity data from both the rabbit and the rat are consistent with this selection (for example the NOEL of 2.4 mg/kg/day in the rat subchronic dermal toxicity study demonstrates toxicity occurs at exposure much closer to 5 mg/kg/day than 0.5 mg/kg/day).

Intermediate-term occupational or residential exposure (1 week-several months): The pertinent toxicological endpoint for intermediate term occupational or residential exposure risk assessment is 1.5 mg/kg/day (mid-dose in the gavage rabbit developmental toxicity study). The duration of the study used as an endpoint to assess occupational or residential risk should be comparable to intermediate-term exposure. Consideration was given to the fact that in the two subchronic dermal toxicity studies, there were no doses tested between 0.5 (NOEL) and 5.0

(LOEL) mg/kg/day. Therefore, the rabbit gavage developmental toxicity (NOEL > 4.5 mg/kg/day) and the rat subchronic oral toxicity (LOEL = 2.3 mg/kg/day) studies were considered in selecting the intermediate exposure endpoint. Because the 4.5 mg/kg/day NOEL was so close to the 5.0 mg/kg/day LOEL observed in the subchronic dermal study, the mid-dose from the rabbit developmental toxicity (1.5 mg/kg/day) was selected as the intermediate-term exposure endpoint.

Although no toxicity was observed in the rabbit developmental toxicity study up to 4.5 mg/kg/day or at 5.0 mg/kg/day in the rat developmental toxicity study, systemic toxicity was observed in a rabbit dermal study at 5.0 mg/kg/day mentioned above, and in the 28-day rabbit feeding study at 2.3 mg/kg/day. A NOEL of 0.5 mg/kg/day was established for rabbit dermal toxicity, but no intermediate doses were tested between 0.5 and 5.0 mg/kg/day. The rabbit developmental study mid-dose (1.5 mg/kg/day) was therefore considered by the Agency to be a more realistic endpoint for risk assessment.

Risk Characterization

Application:

The Agency is concerned for potential risk of toxicity to handlers based on the above two endpoints demonstrating toxicity to laboratory animals and the presumption that handlers will be exposed to terbuthylazine. To provide a quantified comparison between the estimate of the toxicological endpoints and exposure for handlers, the Agency used the following equation for calculating the margin of exposure (MOE):

$$\text{MOE} = \frac{\text{Toxicological endpoint (mg/kg/day)}}{\text{Daily exposure (mg/kg/day)}}$$

Based on the endpoints for short-term occupational or residential exposure (5.0 mg/kg/day) and for intermediate term occupational or residential exposure (1.5 mg/kg/day) the following MOEs are calculated for applying Belclene 329® at typical rates to water cooling towers or ornamental fountains using either an open pouring or a closed pump method.

Margins of Exposure From Typical (3 ppm) Terbuthylazine Application to Industrial and Residential Sites

Exposure Scenario	Margins of Exposure at 3 ppm Rate	
Commercial:	Open Pouring System	Closed Pump System
Short-term	36	1000
Intermediate-term	11	310

One product, Biosperse 288 Algistat (EPA Registration Number 279-3137), may be maintained at up to 9 ppm a.i. (20 ppm of product containing 44.7% a.i.) for the control of algae within the system. This use increases estimates of exposure for the open poring system by a multiple of three (see table below). However, this higher exposure does not alter the Agency's position; risk from open-pouring is unacceptable. With a closed system greater risk from a higher rate of application is not expected because workers are not exposed to the pesticide during application.

Margins of Exposure from High (9 ppm) Terbuthylazine Application to Industrial Sites

Exposure Scenario	Margins of Exposure at 9 ppm Rate	
Commercial:	Open Pouring System	Closed Pump System
Short-term	12	1000
Intermediate-term	4	310

In contrast, the Agency believes there are acceptable margins of exposure from use of the products intended for residential use for both the open pouring and closed system methods of application.

Margins of Exposure from Terbuthylazine Application to Residential Sites

Exposure Scenario	Margins of Exposure	
Residential:	Open Pouring System	Closed Pump System
Short-term	360	> 10,000
Intermediate-term	110	3000

Post-Application:

Because of the use patterns and the dilution factors in the water cooling tower systems and ornamental fountains, MOEs from post-application exposure are expected to be much higher than those presented above for handlers.

C. Environmental Assessment

1. Environmental Fate

At this time, all data requirements in the environmental fate guidelines are fulfilled for the current use pattern of terbuthylazine.

a. Environmental Chemistry, Fate and Transport

Hydrolysis

There are sufficient data available to conclude that terbuthylazine is stable to hydrolysis. Terbuthylazine was stable in sterile aqueous pH 7 and 9 buffer solutions, and relatively stable in pH 5 buffer solutions that were incubated in the dark at 25EC for 50 days. The registrant-calculated half-lives were 73.0 days at pH 5, 204.6 days at pH 7, and 194.0 days at pH 9. In the pH 5 buffered solution, the degradate hydroxy-terbuthylazine was a maximum of 15.6% of the applied radioactivity at 50 days posttreatment. The hydrolysis (161-1) data requirement has been fulfilled (MRID #41907707).

Photodegradation in Water

There are sufficient data available to conclude that terbuthylazine is stable to aqueous photolysis. [^{14}C]-Terbuthylazine (uniformly ring-labeled), at 5 ug/mL, was relatively stable in sterile aqueous buffered pH 7 solutions that were continuously irradiated with artificial light (xenon arc lamp) at 25EC for 30 days. The intensity of the light source was approximately one-half that of natural sunlight. At 30 days posttreatment, terbuthylazine was 95.6-97.7% of the applied radioactivity in the irradiated samples and 94.2-98.3% in the dark control samples.

The degradate 2-tert-butylamino-4-chloro-6-amino-5-triazine (GS-26379) was #3.61% of the applied radioactivity and was present in both the irradiated and the dark control samples. The photodegradation in water (161-2) data requirement has been satisfied (MRID #41994801).

Aerobic Aquatic Metabolism

There are sufficient data to conclude that terbuthylazine degrades very slowly under aerobic aquatic conditions. Terbuthylazine degraded slowly with registrant calculated half-life of 38.8 days in flooded loam sediment that was incubated aerobically in darkness for 30 days at 25EC. The degradate GS 26379 was a maximum of 6.62% of the applied at 22 days. This degradate was also present in the aqueous photolysis study. The degradate GS 23158 was a maximum of 8.07-8.72% of the applied at 30 days. The unextracted [^{14}C] residues increased to 29.70% of the applied at day 30. At day 30 only 0.11% of the applied had been volatilized. The aerobic aquatic metabolism (162-4) data requirement has been fulfilled (MRID#42790001).

b. Environmental Fate Assessment

Based on the results of acceptable studies, it is reasonable to conclude that terbuthylazine will persist under most aquatic conditions.

To aid in the aquatic risk assessment of terbuthylazine from industrial discharge of treated water, the Agency used a screening model. Tier 1C EEC (estimated environmental concentration) calculations were used (Jones) to assess the estimated environmental concentrations of residue levels of terbuthylazine immediately downstream from an industrial discharge site. A tier 1C EEC is a preliminary or lower tier exposure assessment for industrial biocides. The EECs are presented in the following table. This model provides two types of estimates:

High exposure case: This is a reasonable worst case of a high exposure site with a return frequency of 1 in 10 years. The high exposure site represents a site that would be expected to produce larger EEC's than 90% of all sites with the specified use pattern. It would be expected that the EEC would be equaled or exceeded once every 10 years, i.e., there is a 10% chance in any given year that the EEC will be equaled or exceeded.

Typical case: This represents a median site at mean flow concentration. Inspection of the labels of terbuthylazine products shows that it is used in

industrial cooling towers at a maximum application rate of 9 ppm active ingredient. The estimated environmental concentrations (EECs) are presented in the following Table. For the same site, different products have different maximum application rates. For the purpose of EEC calculations these products are placed in different groups (Groups A and B). To calculate the EEC, the concentration in the waste stream was assumed to be the same as the application rate; this assumes that no degradation occurred in the processing stream. The concentration in the receiving body of water, immediately downstream from the discharge site, was estimated. Dilution factors were taken from a compilation of dilution factors compiled for the Agency's Office of Pollution Prevention and Toxic Substances[1].

It is noted that terbuthylazine is also used in decorative and ornamental fountains. Discharges from these sites would probably occur infrequently and would likely be to a waste treatment facility. Therefore, the Agency did not calculate EECs for this use.

Tier 1C EECs for Terbuthylazine

Use site	SIC Code[1]	High exposure case		Typical Exposure Case	
		Appl. Rate	EEC	Appl. Rate	EEC
Industrial cooling towers: Group A[2]	4911	3 ppm	3 ppm	3 ppm	0.005 ppm
Industrial cooling towers: Group B[2]	4911	9 ppm[3]	1.6 ppm	3 ppm	0.005 ppm

[1] SIC is the Standard Industrial Classification

1. Office of Prevention and Toxic Substances. 1992. Summary of Stream Dilution Factor Program (SDFP) Outputs for 40 Industrial Categories (Updated January, 1991, IQ10 & 3Q5 added October, 1992).

2. Groups A or B refer to a group of products with similar application rates for a common use site. The products in each group are as follows: Group A - Bellacide® 325 (Reg. No. 279-3139), and AMA-204 (Reg. No. 9386-34) application rates 3 ppm; Group B - Belclene 329® (Reg. No. 279-3137) application rates 9 ppm.

3. The label for Belclene 329® states a maximum application rate of 9 ppm a.i.. This appears to be the clean-out rate. As it is recommended, the 90% exceedence site, mean flow is used to estimate the high exposure case, as it would be unlikely that a clean-out and a low flow condition would occur simultaneously. A maximum application rate of 3 ppm, which is recommended for maintenance in non-chlorinated (continuous addition) systems, was used to estimate the typical exposure case.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

(a) Avian Toxicity

Results from available studies indicate that terbuthylazine with an LD_{50} > 2,510 mg/kg is practically non-toxic to birds. Results from these studies also indicate that a Level of Concern has not been exceeded for either endangered or non-endangered avian species. The guideline requirement for the avian acute oral LD_{50} study is fulfilled (MRID #129142).

(b) Avian Subacute Dietary Toxicity

Avian Subacute Dietary Toxicity Findings			
Species	**% Test Material**	**LC_{50}** ppm	**Conclusions**
Bobwhite Quail	99.8%	> 5,620	practically non-toxic
Mallard Duck	99.8%	> 5,620	practically non-toxic

On a subacute dietary basis, terbuthylazine is practically non-toxic to birds. Two studies, one on the mallard duck and one on the bobwhite quail produced LC_{50}s > 5,620 ppm. The Level of Concern has not been exceeded for either endangered or non-endangered avian species. The guideline requirement is fulfilled (MRID #s 129144 and 129143).

(c) Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. The use of terbuthylazine in ornamental fountains and cooling towers is not expected to provide significant exposure or risk to birds; therefore, these studies were not required.

(d) Toxicity to Nontarget Mammals

Based on the use pattern no testing is required.

(2) Aquatic Data

(a) Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study, using either a coldwater species (preferably the rainbow trout), or a warmwater species (preferably the bluegill sunfish). For terbuthylazine the Agency has data on both species.

Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	98%	3.4 ppm	moderately toxic
Bluegill sunfish	98%	7.5 ppm	moderately toxic

The results of the 96-hour acute toxicity studies indicate that terbuthylazine is moderately toxic to both cold and warm water fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled (MRID #s 129594 and 129593).

(b) Freshwater Invertebrate Toxicity

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater invertebrate toxicity test, preferably using first instar *Daphnia magna* or an early instar amphipod, stonefly, mayfly, or midge species.

Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**EC_{50}**	**Conclusions**
Daphnia magna	98%	50.9 ppm	slightly toxic

Based on available data there is sufficient information to characterize terbuthylazine as slightly toxic to aquatic invertebrates. The guideline requirement is fulfilled (MRID #129595).

(c) Estuarine/Marine Toxicity

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Although such a study was not required for terbuthylazine's uses, one study was submitted and reviewed.

Estuarine/Marine Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**EC_{50}**	**Conclusions**
Pink Shrimp	99.24%	109.7 ug/l	highly toxic

The submitted study is sufficient to characterize terbuthylazine as highly toxic to estuarine/marine invertebrates from acute exposures. (MRID #0543701)

(3) Non-Target Insects Data

No testing is required for terrestrial non-target insects such as honeybees since significant exposure is unlikely due to the use pattern.

(4) Non-Target Plants Data

No data are currently available. However, data have recently been called in concerning phytotoxicity to aquatic plants. Phytotoxicity can reasonably be expected since terbuthylazine belongs to the triazine chemical family (which include many herbicides), is released to the environment, and does not immediately degrade in the environment.

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Animals

The criterion for the determination of hazard and presumption of unacceptable risk from exposure for acute avian and mammalian species is a value greater than or equal to 0.5 for the quotient of the preliminary estimated environmental concentration (EEC) divided by the lowest LD_{50} value for birds and mammals. This is known as the risk quotient (RQ).

Acute and Dietary RQ = EEC/LD_{50} or EEC/LC_{50} > or = 0.5 for birds and mammals

(a) Avian Acute Oral and Subacute Dietary Effects

No significant risks are expected from terbuthylazine. The results from acceptable studies show that terbuthylazine is practically non-toxic to birds.

Exposure to birds can occur at ponds, aquaria, and waste water ponds. The typical exposure case EEC as estimated above at these sites is 0.005 ppm ai. The high exposure case EEC is estimated to be 3 ppm for certain products applied to industrial cooling towers. The practically non-toxic nature of terbuthylazine to birds when compared to these concentrations suggests that it does not exceed the levels of concern.

Given the use patterns for terbuthylazine, avian and mammalian species are not expected to be significantly exposed to terbuthylazine.

(b) Avian Chronic Effects

No significant risks are expected.

(c) Mammalian Acute Oral and Subacute Dietary Effects

Due to the use pattern the Agency believes exposure of terbuthylazine to mammalian species through dietary residues is not expected to be significant. No significant risks are expected.

(2) Risk to Aquatic Animals

Fresh Water

The available information indicates that terbuthylazine is moderately toxic to fish and slightly toxic to freshwater invertebrates on an acute basis. The Agency screening model (see Section III.C.1.b) estimates the concentration of the chemical in the receiving body of water immediately downstream from the discharge site to range from 0.005 ppm ai (typical case) to 1.6 ppm ai (high exposure case). Based on the typical exposure scenario, freshwater fish and invertebrates are not expected to be at risk (see table below). However, on the basis of a high exposure scenario, the acute levels of concern for high risk, restricted use and endangered species are met or exceeded for freshwater fish and invertebrates (see table below).

Aquatic Acute Risk Quotient and LOC for the high and typical exposure scenarios of Terbuthylazine. (LC50 = 3.4 ppm rainbow trout)

Use Site	App. Rate	High Exposure (HE) EEC	Typical Exposure (TE) EEC	Risk Quotient (EEC/LC50)	Level of Concern
Industrial Cooling Towers - Group A	3 ppm	3 ppm	0.004 ppm	0.882 HE 0.001 TE	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Industrial Cooling Towers - Group B	9 ppm	1.6 ppm	0.004 ppm	0.470 HE 0.001 TE	High Risk $ 0.5 RU $ 0.1 ES $ 0.05

RU = Restricted Use
ES = Endangered Species

Estuarine/Marine

Terbuthylazine is highly toxic to estuarine/marine invertebrates. The typical exposure results in a Risk Quotient of 0.04. No significant risk is expected from the use of terbuthylazine at the typical use rate. For the high exposure scenario the Risk Quotient is 30. However, the Agency believes the presently registered use patterns are not associated in a significant way with estuarine or marine environments. Therefore, although the RQ for the high exposure scenario exceeds the Agency's

LOC, the Agency expects actual risk from current use of terbuthylazine to be insignificant for these species.

(3) Risk to Terrestrial, Semi-Aquatic and Aquatic Plants

No data are available to assess the effects to plants. Phytotoxicity is expected, especially to aquatic plants, since terbuthylazine is a triazine chemical (and chemically similar to the herbicides atrazine, cyanazine, and simazine), is released to waterways, and dissipates slowly in the environment. Certain labels warn against using the product in systems where the treated water would come into contact with lawns, trees, shrubs, or other desirable plants "since injury may result". Because of this possible phytotoxic property, the Agency has required Tier I aquatic plant testing data on the chemical for confirmatory purposes. The Agency has required these data to be submitted by January 1996. These results will be used by the Agency in evaluating the downstream risk aquatic plants from effluents containing the chemical.

(4) Risk to Endangered Species

-

For endangered avian and mammalian species the risk quotient is a value greater than or equal to 0.1. For endangered aquatic vertebrate and invertebrate species, the risk quotient is 0.05.

RQ = EEC/LC_{50} > or = 0.1 for endangered birds and mammals; the

RQ = EEC/LC_{50} > or = 0.05 for endangered aquatic animals; and the

RQ = EEC/EC_{25} and the EEC/EC_{50} > or = 1 for terrestrial, semi-aquatic and aquatic plants.

No significant risk is expected for terrestrial avian endangered species since the level of concern is not exceeded. A risk to endangered freshwater and estuarine/marine organisms is expected from the high exposure scenario. The Level of Concern for the high exposure scenario is exceeded.

Even though no data are available on non-target plants, if exposed, endangered aquatic would presumably be at risk for the reasons presented above. The nature of this chemical and the label warning indicate phytotoxicity.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of terbuthylazine and to determine that terbuthylazine when used as directed in this document can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing terbuthylazine as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

1. Eligibility Decision

Based on the review of the generic data for the active ingredient terbuthylazine, the Agency has sufficient information on the health effects and its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that terbuthylazine products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing terbuthylazine for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of terbuthylazine as specified in this document are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

The Agency did not conduct a tolerance reassessment for terbuthylazine because no tolerances are currently established. Previous tolerances for this chemical were revoked as discussed above in Section III.

2. Potential Discharge to Surface Waters

The Agency has determined that discharge to surface waters of effluent containing terbuthylazine may result from its use as a pesticide. Its use as a pesticide and its potential release to the environment subjects it to the requirements of both FIFRA and the National Pollutant Discharge Elimination System (NPDES) which is administered by the Federal Office of Water (OW) with the states.

By their nature, industrial biocides are often toxic to aquatic organisms. The environmental effects of discharges containing biocides may depend heavily upon the volume, concentration, and other constituents of a particular discharge, as well as the size, nature, and flow rate of waters receiving the discharge. FIFRA permits EPA to require the generation of data on the effects of biocides and to set general limits and conditions of use of a biocide through statements on its labeling. However, because FIFRA regulation is generally national in scope, these mechanisms are not readily adaptable to varied and changing local conditions. Generalized regulation of a pesticide under FIFRA may be insufficiently protective under some local conditions. The NPDES process is designed to take local conditions into account through the issuance of facility- specific permits for the discharge of pollutants to bodies of water. However, historically, specific information about the toxicological and environmental properties of biocides in effluent streams was not always readily available or considered in writing permits.

EPA's Office of Pesticide Programs and Office of Water intend to cooperate in the oversight of biocide uses to take advantage of the strengths of each program while avoiding duplication of regulation. Under FIFRA, OPP will require the submission to the Agency of information that will be used to identify

potential hazards from the discharge of biocides from pesticidal use that may require control measures under either regulatory program. This information will be shared with the Office of Water where it can be made available to NPDES permit writers to address aquatic effects of point source biocide use. In turn, OW will forward to OPP any information that becomes available concerning unanticipated aquatic effects of the use of biocides for OPP's use in national registration decisions for these products. EPA believes this approach will provide adequate environmental safeguards since it allows OPP to control the general approval of the biocide as required by FIFRA, but includes a mechanism for recognizing and regulating potential local unacceptable effects through the NPDES program. Improved limitations on use under FIFRA and more targeted NPDES permitting decisions for industrial biocides may be developed in the future as the information gathering and exchange program between the Offices progresses.

Absent extraordinary concern about the adverse effects of the uses of terbuthylazine from its potential discharge to surface waters, the Agency concludes that the use of terbuthylazine will not cause unreasonable adverse effects if an effluent discharge label statement (requiring that any such discharge is subject to the NPDES process) is required for all products which have a potential for discharge to surface waters.

3. Endangered Species

The Agency is concerned about the exposure of endangered aquatic animal and plant species as discussed above in the science assessment chapter.

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

The Agency plans to publish a description of the Endangered Species Program in 1995 and have enforceable county-specific bulletins available after that time. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under The Endangered Species Protection Program.

4. Labeling Rationale

Risk Mitigation to Handlers

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

> (a) If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines;
>
> (b) If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc).

In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient. These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There is a special toxicological concern for terbuthylazine; systemic toxicity in the rabbit developmental toxicity study. Risk assessment determined that unacceptable risk (i.e. margins of exposure less than 100) occurred during the open pouring application to industrial water systems. This application method may result in exposure to the applicator since the applicator manually pours terbuthylazine into the system. The main concern is for dermal exposure. One-hundred percent absorption is assumed in absence of acceptable dermal absorption data. However, terbuthylazine is not believed to be a respiratory risk because of its low vapor pressure. The Agency considered personal protective equipment but found that exposure is not sufficiently reduced by these measures. For example, requiring applicators to wear chemical resistant gloves doubles the MOE from typical exposure (3 ppm) to approximately 20. Respiratory protection was not considered. However, this MOE is still far away from acceptable. Personal protective equipment does not reduce exposure to

acceptable levels with the open pouring application method. In contrast, the MOEs for closed systems are of an acceptable level.

Therefore the Agency is prohibiting the open-pouring method of application for commercial uses. Instead, a closed-system metering pump system of application will be required for all currently registered uses of terbuthylazine. This decision is based on the unacceptable risk levels to workers applying terbuthylazine as discussed above. No such restriction will be placed on homeowner uses because homeowners are exposed to much less terbuthylazine from typical use of homeowner products.

It is worth noting that developmental toxicity was observed in the rat at 30 mg/kg/day in another developmental toxicity study. As discussed in Section III.B.1.d. developmental toxicity in the fetus and maternal toxicity were observed at the same dose. Therefore it is impossible to separate maternal toxicity from fetal toxicity. However, risk mitigation measures as discussed further in this chapter are based on a risk assessment using the mid level dose from the developmental toxicity study in the rabbit (1.5 mg/kg/day for intermediate-term exposure) and therefore should also mitigate any potential for developmental toxicity.

Personal Protective Equipment

While the assessment for the use of a closed-system suggests the risks to workers is acceptable, the Agency believes it is prudent to have handlers wear certain personal protective equipment to further reduce dermal exposure. This exposure may occur inadvertently during attachment of the metering equipment. Persons using closed systems must wear a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves. A chemical-resistant apron must be immediately available during loading and application and must be worn in case of a leak, spill, or other exposure to the concentrate.

The minimum PPE for professional applicators (non-homeowners) at residential sites who mix, load, or apply terbuthylazine using the open pouring application method is long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves.

Homeowners who mix, load, or apply terbuthylazine using the open pouring application method must wear a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves.

Risk to Aquatic Organisms

Since the Agency has concerns for risk to aquatic organisms, the Agency is requiring an effluent discharge label statement (requiring that any such discharge is subject to the National Pollutant Discharge Elimination System process) when a product has a potential for discharge to surface waters.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of terbuthylazine for the above eligible uses has been reviewed and determined to be substantially complete. However, since exposure and toxicity to aquatic plants can reasonably be expected since terbuthylazine is discharged to waterways and is a member of the triazine herbicide class of chemicals, data measuring the toxicity of terbuthylazine to aquatic plants have recently been required of registrants. These data will be used as necessary by the Agency to confirm the presumed phytotoxicity and to support regulation of discharge of terbuthylazine in effluent.

2. Labeling Requirements for Manufacturing-Use Products

Effluent Discharge Labeling Statements

All manufacturing-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the effluent discharge labeling statements as described in PR Notice 93-10.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

Effluent Discharge Labeling Statements

All manufacturing-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the effluent discharge labeling statements as described in PR Notice 93-10.

Other Labeling Requirements

The Agency is requiring the following statements to be located on all end-use products containing terbuthylazine that are intended primarily for industrial use:

Application Restrictions:

For products intended for industrial uses:

> "Open pouring of this product is prohibited."
>
> "Mixing, loading, and application must be with a closed system (one that prevents the chemical from contacting handlers or other persons) and during handling of the chemical personal protective equipment must be worn. Personal Protective equipment includes a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves. A chemical-resistant apron must be immediately available during loading and application and must be worn in case of a leak, spill, or other exposure to the concentrate."

For products intended for homeowner uses:

> "Persons that mix, load, or apply this product must wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."

User Safety Requirements:

"Follow personal protective equipment manufacturer's instruction for cleaning/maintaining Personal Protective Equipment. If no such instructions for washables exists, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

User Safety Recommendations:

"Users should wash before eating, drinking, chewing gum, using tobacco, or using the toilet"

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

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

C. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Chlorinated system.	FlC	W .96	W .96	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96
	FlC	W .96	W .96	*	NS NS	NS NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 3.1	W 3.1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96
	FlC	W 3.1	W 3.1	*	NS NS	NS NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS NS	NS NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS NS	NS NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Chlorinated system.	FlC	W 9	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96
	FlC	W 9	*	NS	NS	NS	NS	NS	NS	UT			A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 9	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96
	FlC	W 9	*	NS	NS	NS	NS	NS	NS	UT			A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Brominated system	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Chlorinated system.	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-brominated system	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't) Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)													
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Chlorinated system.	FlC	W 1		*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W 1		*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 3		*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W 3		*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Rate @ Max. Dose /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Chlorinated system.	FlC		W 9	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC		W 9	*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Non-chlorinated system.	FlC		W 9	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC		W 9	*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
EVAPORATIVE CONDENSER WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
EVAPORATIVE CONDENSER WATER SYSTEMS (con't)					Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC	W	1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Brominated system	FlC	W	1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Chlorinated system.	FlC	W	1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-brominated system	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
EVAPORATIVE CONDENSER WATER SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)									
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Brominated system	FlC	W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC	W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
HEAT EXCHANGER WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Brominated system	FlC	W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Chlorinated system.	FlC	W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-brominated system	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
HEAT EXCHANGER WATER SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Brominated system	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Brominated system	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Chlorinated system.	FlC	W 1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W 1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
HEAT EXCHANGER WATER SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)										
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
LAKES/PONDS/RESERVOIRS (WITHOUT HUMAN OR WILDLIFE USE)			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment., When needed., Not on label., Not Applicable., Not applicable for this use.	FlC	W 2.6	W 2.6	*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL PONDS/AQUARIA				Use Group: AQUATIC NON-FOOD RESIDENTIAL									
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Chlorinated system.	FlC	W .96	W .96	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W .96	W .96	*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (initial)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 3.1	W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W 3.1	W 3.1	*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
ORNAMENTAL PONDS/AQUARIA (con't)				Use Group: AQUATIC NON-FOOD RESIDENTIAL (con't)										
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Chlorinated system.	FlC	W	9	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96
	FlC	W	9	*	NS	NS	NS	NS	NS	NS	UT			A08, C18, C24, C96
Water treatment (recirculating system)., Continuous feed (subsequent)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W	9	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96
	FlC	W	9	*	NS	NS	NS	NS	NS	NS	UT			A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Brominated system	FlC	W	1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Chlorinated system.	FlC	W	1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-brominated system	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				A08, C18, C24, C96, C97
	FlC	W	3.1	*	NS	NS	NS	NS	NS	NS				C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL PONDS/AQUARIA (con't)			Use Group: AQUATIC NON-FOOD RESIDENTIAL (con't)										
Water treatment (recirculating system)., Intermittent (slug)(initial)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Chlorinated system.	FlC	W 1		*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W 1		*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(initial)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 3		*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96
	FlC	W 3		*	NS	NS	NS	NS	NS	NS	UT		A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Brominated system	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Chlorinated system.	FlC		W 1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-brominated system	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Metering pump., Not Applicable., Non-chlorinated system.	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			A08, C18, C24, C96, C97
	FlC		W 3.1	*	NS	NS	NS	NS	NS	NS			C18, C24, C96, C97

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL PONDS/AQUARIA (con't)			Use Group: AQUATIC NON-FOOD RESIDENTIAL (con't)								
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Chlorinated system.	FlC	W 9	*	NS	NS	NS	NS	NS	NS		A08, C18, C24, C96
	FlC	W 9	*	NS	NS	NS	NS	NS	NS	UT	A08, C18, C24, C96
Water treatment (recirculating system)., Intermittent (slug)(subsequent)., Not on label., Not Applicable., Non-chlorinated system.	FlC	W 9	*	NS	NS	NS	NS	NS	NS		A08, C18, C24, C96
	FlC	W 9	*	NS	NS	NS	NS	NS	NS	UT	A08, C18, C24, C96

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

FlC	: FLOWABLE CONCENTRATE

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
C96 : Do not use where treated water will come into contact with lawns, trees, shrubs, or other desirable plants, since injury may result.
C97 : Water from treated systems may not be used for irrigation or spraying of agricultural crops, lawns, or ornamental plants, or for watering cattle, goats, hogs, horses, poultry or sheep, or for human consumption.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

UT	: Utah

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Terbuthylazine

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	416033-01
61-2A	**Start. Mat. & Mnfg. Process**	ALL	416033-02
61-2B	**Formation of Impurities**	ALL	416033-01
62-1	**Preliminary Analysis**	ALL	416033-02
62-2	**Certification of limits**	ALL	416033-02, 425674-01
62-3	**Analytical Method**	ALL	416033-02, 425674-01
63-2	**Color**	ALL	416033-03
63-3	**Physical State**	ALL	416033-03
63-4	**Odor**	ALL	416033-03
63-5	**Melting Point**	ALL	416033-03
63-6	**Boiling Point**	ALL	WAIVED
63-7	**Density**	ALL	416033-03, 424094-01
63-8	**Solubility**	ALL	416033-03
63-9	**Vapor Pressure**	ALL	416033-03
63-10	**Dissociation Constant**	ALL	416033-03, 425574-01

Data Supporting Guideline Requirements for the Reregistration of Terbuthylazine

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	**Octanol/Water Partition**	ALL	416033-03
63-12	**pH**	ALL	416033-03
63-13	**Stability**	ALL	416033-03, 426774-01
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	E,F,G	00129142
71-2A	**Avian Dietary - Quail**	E,F,G	00129144
71-2B	**Avian Dietary - Duck**	E,F,G	00129143
72-1A	**Fish Toxicity Bluegill**	E,F,G	00129593
72-1C	**Fish Toxicity Rainbow Trout**	E,F,G	00129594
72-2A	**Invertebrate Toxicity**	E,F,G	00129595
72-3C	**Estuarine/Marine Toxicity - Shrimp**	E,F,G	00543701
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	E,F,G	**41603304, 41907702**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	E,F,G	**41907703**
81-3	**Acute Inhalation Toxicity - Rat**	E,F,G	**41603305**
81-4	**Primary Eye Irritation - Rabbit**	E,F,G	**41603306, 41907704**
81-5	**Primary Dermal Irritation - Rabbit**	E,F,G	**41907705**
81-6	**Dermal Sensitization - Guinea Pig**	E,F,G	**41907706**
82-1A	**90-Day Feeding - Rodent**	E,F,G	**00161104**
82-2	**21-Day Dermal - Rabbit/Rat**	E,F,G	**40514802, 42059804**

Data Supporting Guideline Requirements for the Reregistration of Terbuthylazine

REQUIREMENT		USE PATTERN	CITATION(S)
83-1A	**Chronic Feeding Toxicity - Rodent**	E,F,G	**00156487,00156486,00157342**
83-2A	**Oncogenicity - Rat**	E,F,G	**00156486, 00157342**
83-2B	**Oncogenicity - Mouse**	E,F,G	**00156487**
83-3A	**Developmental Toxicity - Rat**	E,F,G	**41962701**
83-3B	**Developmental Toxicity - Rabbit**	E,F,G	**001307044**
84-2A	**Gene Mutation (Ames Test)**	E,F,G	**00108817,00140816, 00151618, 41634001**
84-2B	**Structural Chromosomal Aberration**	E,F,G	**41418102, 42059805**
84-4	**Other Genotoxic Effects**	E,F,G	**00151619, 41391801, 42059806**
85-1	**General Metabolism**	E,F,G	**00055672, 00038018**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
231	**Estimation of Dermal Exposure at Outdoor Sites**	E,F,G	**41412202,41742601, 42587501**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	E,F,G	**41412202,41742601, 42587501**
233	**Estimation of Dermal Exposure at Indoor Sites**	E,F,G	**41412202,41742601, 42587501**
234	**Estimation of Inhalation Exposure at Indoor Sites**	E,F,G	**41412202,41742601, 42587501**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	E,F,G	41907707
161-2	**Photodegradation - Water**	E,F,G	41994801
161-3	**Photodegradation - Soil**		

Data Supporting Guideline Requirements for the Reregistration of Terbuthylazine

REQUIREMENT		USE PATTERN	CITATION(S)
161-4	Photodegradation - Air		
162-1	Aerobic Soil Metabolism		
162-2	Anaerobic Soil Metabolism		
162-3	Anaerobic Aquatic Metabolism		
162-4	Aerobic Aquatic Metabolism		
163-1	Leaching/Adsorption/Desorption		
163-2	Volatility - Lab		
163-3	Volatility - Field		
164-1	Terrestrial Field Dissipation		
164-2	Aquatic Field Dissipation		
164-3	Forest Field Dissipation		
164-5	Long Term Soil Dissipation		
165-1	Confined Rotational Crop		
165-2	Field Rotational Crop		
165-3	Accumulation - Irrigated Crop		
165-4	Bioaccumulation in Fish		
165-5	Bioaccumulation - Aquatic NonTarget		
166-1	Ground Water - Small Prospective		
166-2	Ground Water - Small Retrospective		

REQUIREMENT		USE PATTERN	CITATION(S)
166-3	Ground Water - Irrigated Retrospective		
201-1	Droplet Size Spectrum		
202-1	Drift Field Evaluation		
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants		
171-4B	Nature of Residue - Livestock		
171-4C	Residue Analytical Method - Plants		
171-4D	Residue Analytical Method - Animal		
171-4E	Storage Stability		
171-4F	Magnitude of Residues - Potable H2O		
171-4G	Magnitude of Residues in Fish		
171-4H	Magnitude of Residues - Irrigated Crop		
171-4I	Magnitude of Residues - Food Handling		
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		
171-4K	Crop Field Trials		
171-4L	Processed Food		
171-5	Reduction of Residues		

Data Supporting Guideline Requirements for the Reregistration of Terbuthylazine

REQUIREMENT		USE PATTERN	CITATION(S)
171-6	Proposed Tolerance		
171-7	Support for Tolerance		
171-13	Analtyical Reference Standard		

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Terbuthylazine

BIBLIOGRAPHY

MRID	CITATION

00038018 Marbach, P. (1970) Metabolic Behaviour in Rats of GS 13'529 and Its Plant Metabolites GS 23'158 and GS 28'620. (Unpublished study received Jun 19, 1973 under 3F1409; prepared by J.R. Geigy, S.A., submitted by Ciba-Geigy Corp., Ardsley, N.Y.; CDL:093767-0.

00055672 Ciba-Geigy Chemical Corporation (1971) Metabolism of ~ s ~ -Triazine Herbicides. (Unpublished study including letter dated Dec 29, 1971 from J.R. Forsythe to Harold G. Alford, received Dec 29, 1971 under 100-437; CDL:231915-A)

00108817 Arni, P.; Muller, D. (1977) Salmonella/Mammalian-microsome Mutagenicity Test with GS 13529 (Test for Mutagenic Properties in Bacteria). (Unpublished study received Jun 3, 1982 under 40810-5; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Ardsley, NY; CDL:247619-F)

00129142 Fink, R.; Beavers, J.; Joiner, G.; et al. (1983) Acute Oral LD50: Mallard Duck: Terbuthylazine: Project No. 108-213. Final rept. (Unpublished study received Jul 1, 1983 under 40810-6; prepared by Wildlife International Ltd., submitted by Ciba-Geigy Corp., Ardsley, NY; CDL:250654-E)

00129143 Fink, R.; Beavers, J.; Joiner, G.; et al. (1983) Eight-day Dietary LC50--Mallard Duck: Terbuthylazine: Project No. 108-212. Final rept. (Unpublished study received Jul 1, 1983 under 40810-6; prepared by Wildlife International Ltd., submitted by Ciba-Geigy Corp., Ardsley, NY; CDL:250654-F)

00129144 Fink, R.; Beavers, J.; Joiner, G.; et al. (1983) Eight-day Dietary LC50--Bobwhite Quail: Terbuthylazine: Project No. 108-211. Final rept. (Unpublished study received Jul 1, 1983 under 408106; prepared by Wildlife International Ltd., submitted by CibaGeigy Corp., Ardsley, NY; CDL:250654-G)

00129593 Rufli, H.; Cheron, A.; Kurmann, F.; et al. (1983) Report on the Test for Acute Toxicity of TK 12669/1 to Bluegill: Project No. 83 00 64. (Unpublished study received Jul 27, 1983 under 40810-6; prepared by Ciba-Geigy Ltd., Switz., submitted by CibaGeigy Corp., Ardsley, NY; CDL:250837-E)

00129594 Rufli, H.; Cheron, A.; Kurmann, F.; et al. (1983) Report on the Test for Acute Toxicity of TK 12669/1 to Rainbow Trout: Project No. 83 00 63. (Unpublished study received Jul 27, 1983 under 40810-6; prepared by Ciba-Geigy Ltd., Switz., submitted by CibaGeigy Corp., Ardsley, NY; CDL:250837-F)

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MRID	CITATION
00129595	Rufli, H.; Kurmann, F.; Cheron, A.; et al. (1983) Report on the Test for Acute Toxicity of TK 12 669/1 to Daphnia magna: Project No. 83 00 62. (Unpublished study received Jul 27, 1983 under 40810-6; prepared by Ciba-Geigy Ltd., Switz., submitted by CibaGeigy Corp., Ardsley, NY; CDL:250837-G)
00130744	Bottomley, A.; Mayfield, R.; Clark, R. (1983) Effect of TK 12 669/ 1 on Pregnancy of the New Zealand White Rabbit: CBG 345/341/ 83354. (Unpublished study received Aug 26, 1983 under 408106; prepared by Huntingdon Research Centre, Eng., submitted by by Ciba-Geigy, Ardsley, NY; CDL:251076-A)
00140816	Ciba-Geigy Corporation (1977?) Summary of Human Safety Data. Summary of studies 246364-B through 246364-E. (Unpublished study received Dec 1, 1981 under 40810-6; CDL:246364-A)
00151618	Strasser, F. (1983) L5178Y/TK + /Mouse Lymphoma Mutagenicity Test: GS 13 529: (In vitro Test for Mutagenic Properties of Chemical Substances in Mammalian Cells): Exp. No. 820911. Unpublished study prepared by Ciba-Geigy Limited. 10 p.
00151619	Puri, E. (1984) Autoradiographic DNA Repair Test on Rat Hepatocytes: GS 13'529 Techn: Final Report: Report No. 831174. Unpublished study prepared by Ciba-Geigy Limited. 12 p.
00151620	Puri, E. (1984) Autoradiographic DNA Repair Test on Human Fibro-blasts: GS 13'529: Final Report: Rep. No. 831175. Unpublished study prepared by Ciba-Geigy Limited. 11 p.
00151622	Seifert, G. (1984) 28 Day Repeated Dose Dermal Toxicity Study in Rabbits: GS 13529: Final Rep: Project No. 83 02 87. Unpublished study prepared by Ciba-Geigy, Stein, Switzerland. 249 p.
00156486	Gfeller, W. (1983) Lifetime Carcinogenicity and Chronic Toxicity Study in Rats: GS 13529: Finalised Report: GU Project No. 785196. Unpublished study prepared by Ciba-Geigy Ltd. 1577 p.
00156487	Gfeller, W. (1982) Chronic Toxicity and Carcinogenicity Study in Mice: GS 13529 Techn.: Final Report: GU Project No. 785195. Unpublished study prepared by Ciba-Geigy Ltd. 965 p.
00157342	Gfeller, W. (1983) GS 13529: Lifetime Carcinogenicity and Chronic Toxicity Study in Rats: Finalised Report: GU Project No. 791229. Unpublished study prepared by Ciba-Geigy Ltd. 1384 p.

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MRID	CITATION
00161104	Basler, W. (1984) GS 13529: 28 Days Toxicity Study in Rats: Final Report: GU Project No. 830289. Unpublished study prepared by Ciba-Geigy Ltd. 222 p.
40514801	Schiavo, D.; Hazelette, J.; Green, J. (1987) Terbuthylazine: 28-day Oral Toxicity Study in Rabbits: Toxicology/Pathology Report 86178. Unpublished study prepared by Ciba-Geigy Corp. 192 p.
40514802	Schiavo, D.; Hazelette, J.; Green, J. (1987) Terbuthylazine: 28-day Dermal Toxicity Study in Rabbits: Toxicology/Pathology Report 86143. Unpublished study prepared by Ciba-Geigy Corp. 204 p.
40543701	Ward, G. (1988) Acute Toxicity of Technical Terbuthylazine to Mysid Shrimp (Mysidopsis bahia) Under Static Conditions: Laboratory Project ID 87356-2210-2130. Unpublished study prepared by Environmental Science and Engineering, Inc. 23 p.
41391801	Hertner, T. (1989) Belclene 329: Autoradiographic DNA Repair Test on Rat Hepatocytes (OECD Conform): Lab Project Number: 881606. Unpublished study prepared by Ciba-Geigy Ltd. 105 p.
41418102	Hertner, T. (1989) Belclene 329: Micronucleus Test, Mouse: Lab Project Number: 891393. Unpublished study prepared by Ciba-Geigy Co. 33 p.
41412201	Popendorf, W.; Selim, M.;Kross, B. (1990) Chemical Manufacturers Association Antimicrobial Exposure Assessment Study ID:Q626. Unpublished study prepared by University of Iowa Institute of Agriculutural Medicine and Occupational Health.
41603301	Schwemmer, B. (1990) Terbuthylazine Product Chemistry: Product Identity and Composition. Unpublished study prepared by CibaGeigy Corp. 185 p.
41603302	Schwemmer, B. (1990) Terbuthylazine Product Chemistry: Analysis and Certification of Product Ingredients. Unpublished study prepared by Ciba-Geigy Corp. 114 p.
41603303	Schwemmer, B. (1990) Terbuthylazine Product Chemistry: Physical and Chemical Characteristics: Lab Project Number. Unpublished study prepared by Ciba-Geigy Corp. 132 p.
41603304	Hartmann, H. (1990) Terbuthylazine: Acute Oral Toxicity in the Rat: Report: Lab Project Number: 891215. Unpublished study prepared by Ciba-Geigy Ltd. 17 p.

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MRID	CITATION
41603305	Hartmann, H. (1989) Terbuthylazine: Acute Inhalation Toxicity in the Rat: Report: Lab Project Number: 891219. Unpublished study prepared by Ciba-Geigy Ltd. 22 p.
41603306	Schneider, P. (1989) Terbuthylazine: Acute Eye Irritation/Corrosion Study in the Rabbit: Report: Lab Project Number: 891216. Unpublished study prepared by Ciba-Geigy Ltd. 14 p.
41634001	Ogorek, B. (1987) Salmonella/Mammalian-Microsome Mutagenicity Test (OECD-Conform): Report: Lab Project Number: 874192. Unpublished study prepared by Ciba-Geigy Ltd. 22 p.
41742601	Popendorf, W.; Selim, M.;Kross, B. (1990) Chemical Manufacturers Association Antimicrobial Exposure Assessment Lab project number:Q626. Unpublished study prepared by University of Iowa.
41907702	Mercier, O. (1991) Terbuthylazine: Test to Evaluate the Acute Toxicity Following a Single Oral Administration (LD 50) in the Rat: Lab Project Number: 012333: 904139. Unpublished study prepared by Hazleton France. 45 p.
41907703	Mercier, O. (1991) Terbuthylazine: Test to Evaluate the Acute Toxicity Following a Single Cutaneous Application (Limit Test) in the Rat: Lab Project Number: 012319: 904151. Unpublished study prepared by Hazleton France. 30 p.
41907704	Mercier, O. (1990) Terbuthylazine: Test to Evaluate Acute Ocular Irritation and Reversibility in the Rabbit: Lab Project Number: 904140: 009324. Unpublished study prepared by Hazleton France. 29 p.
41907705	Mercier, O. (1990) Terbuthylazine: Test to Evaluation Acute Primary Cutaneous Irritation and Corrosivity in the Rabbit: Lab Project Number: 008327: 904141. Unpublished study prepared by Hazleton France. 28 p.
41907706	Mercier, O. (1991) Test to Evaluate the Sensitizing Potential in the Guinea-Pig "Guinea-pig Maximization Test": Lab Project No: 101322: 904152. Unpublished study prepared by Hazleton France. 59 p.
41907707	Doyle, R. (1991) Hydrolysis of [carbon 14]-Terbuthylazine: Lab Project Number: IITRI-VTC-9004. Unpublished study prepared by IIT Research Institute. 90 p.

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MRID	CITATION
41962701	Fitzgerald, R. (1990) Developmental Toxicity (Teratogenicity) Study in Rats with GS 13529 Technical (Oral Administration): Final Report: Lab Project Number: 891220. Unpublished study prepared by Ciba-Geigy. 302 p.
41994801	Head, L.; Schmidt, J. (1991) Determination of the Aqeous Photolysis Rate of [Carbon 14]-Bellacide 320: Lab Project Number: 39309. Unpublished study prepared by ABC Labs, Inc. 483 p.
42059804	Verma, M. (1991) 28-Day Dermal Toxicity Study in Rabbits: Purity of the Test Material Used (Batch FL 860558): Terbuthylazine: Lab Project Number: MIN-862131. Unpublished study prepared by CibaGeigy Corp. 5 p.
42059805	Puri, E. (1991) Supplement to Micronucleus Test, Mouse: Terbuthylazine: Lab Project Number: 891393. Unpublished study prepared by Ciba-Geigy Corp. 4 p.
42059806	Puri, E. (1991) Supplement to Autoradiographic DNA Repair Test on Rat Hepatocytes: Terbuthylazine: Lab Project Number: 881606. Unpublished study prepared by Ciba-Geigy Corp. 4 p.
42409401	Fuldner, H. (1992) Determination of the Density of Terbuthylazine (TK 12669): Lab Project Number: AD 91/11T. DES. Unpublished study prepared by Ciba-Geigy Ltd. 7 p.
42587501	Popendorf, W.; Selim, M.;Kross, B. (1992) Chemical Manufacturers Association Antimicrobial Exposure Study: Second replacement to MRID 41761201: Lab project number Q626. Unpublished study prepared by the University of Iowa.
42567401	Nye, D. (1992) Discussion of the Formation of Impurities in the Manufacture of Terbuthylazine. Unpublished study prepared by FMC Corp. 11 p.
42677401	Morrissey, M. (1993) Stability Determinations of Terbuthylazine: Final Report: Lab Project Number: 6124-111: P92-0004. Unpublished study prepared by Hazleton Wisconsin, Inc. 41 p.
42790001	Wu, D. (1992) Aerobic Aquatic Metabolism of (carbon 14)-Bellacide 320: Lab Project Number: 92041: RPT0094. Unpublished study prepared by Xenobiotic Labs, Inc. 83 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Terbuthylazine. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Terbuthylazine and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Terbuthylazine RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the com-plete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, …250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with pet-itions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for

microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous corres-pondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a tran-smittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ Name
Signature

Company Name _____

Company Contact: _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

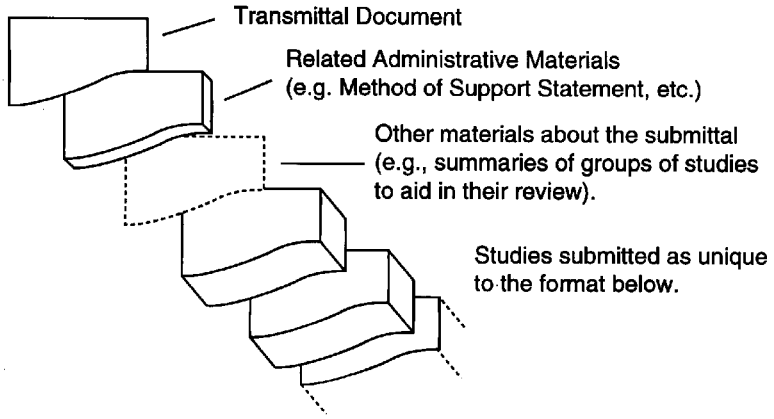
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

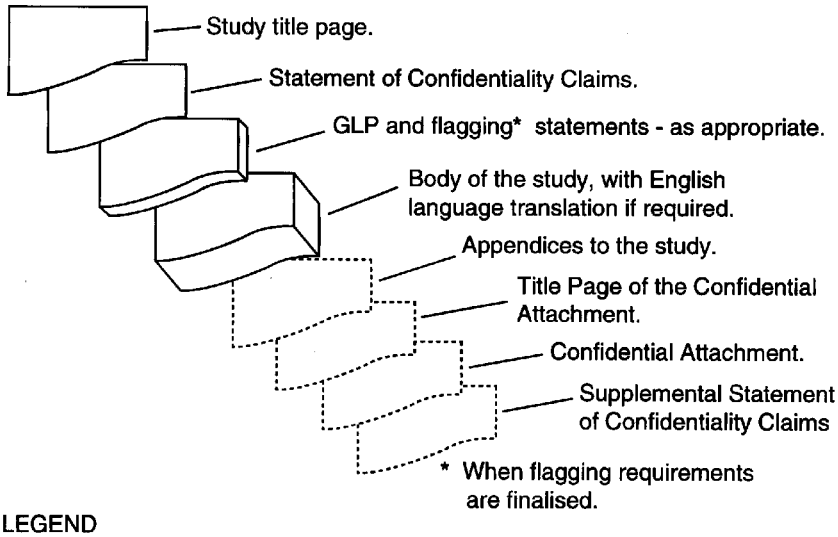
Submitter_____

ATTACHMENT 7.

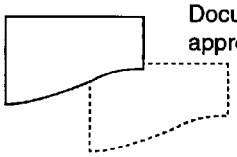
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS,
AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients
Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the

certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,**" all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Product Specific Data Call-In

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

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

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD

protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number

5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

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

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as

well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

TERBUTHYLAZINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Terbuthylazine. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Terbuthylazine Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Terbuthylazine, please contact Virginia Dietrich at (703) 308-8157.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact CP Moran at (703) 308-8590.

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

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

RE: **Terbuthylazine**

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed

"**Certification of Offer to Cost Share in the Development Data**" **form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data

requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

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

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

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

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient terbuthylazine (2-tert-Butylamino-4-chloro-6-ethylamino-s-triazine) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient terbuthylazine.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	279-3139	terbuthylazine … 4.0%	liquid
	9386-34	terbuthylazine … 4.0%	liquid
2	279-3137	terbuthylazine … 44.7%	liquid
	UT93000300	terbuthylazine … 44.7%	liquid

Table 2 lists the product the Agency was unable to batch. This product was considered not to be similar to other products in terms of of acute toxicity. Registrants of this product are responsible for meeting the acute toxicity data requirements for this product.

Table 2.

Registration Number	Percent Active Ingredient	Form
279-3138	terbuthylazine … 96%	wettable powder

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4. *___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-006A June 1995

R.E.D. FACTS

Terbuthylazine

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews appropriate studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2645, terbuthylazine.

Use Profile

Terbuthylazine is an algicide, microbicide and microbiostat used to control slime-forming algae, fungi, and bacteria. It is registered for use in commercial and industrial water cooling systems, and in residential and commercial ornamental ponds, fountains and aquaria. Terbuthylazine is formulated as a soluble concentrate/liquid, and is applied as a continuous feed or intermittent slug treatment, using either open pouring or closed system methods.

Use practice limitations currently require users to preclean systems before applying the pesticide, and prohibit: discharge of effluent containing the pesticide into sewage systems without notifying the sewage treatment plant authority; discharging effluent containing the pesticide into lakes, streams, ponds, estuaries, oceans, or public waters; use where treated water will come into contact with lawns, trees, shrubs, or other desirable plants since injury may result; and using water from treated systems for irrigation or spraying of agricultural crops, lawns, or ornamental plants, or for watering cattle, goats, hogs, horses, poultry or sheep, or for human consumption.

Regulatory History

Initially, in 1975, terbuthylazine was registered as a herbicide in the U.S., and several tolerances for residues in food and feed were established. However, since no end-use products were registered for these uses, the tolerances were revoked in 1992. Meanwhile, in 1986, algicide and microbicide/microbistat end-use products were registered. EPA has issued four Data Call-In notices for terbuthylazine. Five products currently are registered.

Human Health Assessment

Toxicity

Terbuthylazine generally is of relatively low acute toxicity. It has been placed in Toxicity Category III, the second-to-lowest of four categories, for acute oral, dermal, and inhalation effects. Terbuthylazine is mildly to moderately irritating to the eyes, and slightly irritating to the skin, and has also been placed in Toxicity Category III for these effects. It is not a skin sensitizer.

In a subchronic toxicity study using rats, terbuthylazine caused decreased body weight gain as well as decreased thymic, kidney and liver weights. A study using rabbits resulted in decreased body weight gain and food consumption, and mortality in one female. In another rabbit study, all the animals developed difficulty in breathing, piloerection, sedation, curved body posture, dermal irritation, and decreased body weight gain and food consumption.

In chronic toxicity and carcinogenicity studies using mice and rats, decreases in body weight gain and food consumption were observed. Two studies using mice and rats caused no increase in tumors. However, a third study using rats caused an increased incidence of testicular tumors in males and mammary gland carcinomas in females, but only at a dose at which excessive systemic toxicity also was observed. Based on this study, EPA's Carcinogenicity Peer Review Committee has classified terbuthylazine as a Group D carcinogen--one for which there is inadequate evidence to determine carcinogenicity in humans.

Terbuthylazine caused no signs of developmental toxicity in a study using rabbits. However, in a study using rats, maternal toxicity was observed as reduced body weight gain and food intake, and developmental toxicity was observed in the litter as a lack of bone formation in one toe. Reproductive toxicity data is not available, but will be required if food uses are proposed in the future. Available studies indicate that terbuthylazine is not mutagenic.

Dietary Exposure

Dietary exposure to terbuthylazine is not expected since no products with food uses currently are registered.

Occupational and Residential Exposure

Workers may be exposed to terbuthylazine during applications in commercial/industrial settings. In addition, workers may be exposed to this pesticide after application, while cleaning or maintaining water cooling towers, and other people (including children) may be exposed while wading or swimming in treated ornamental ponds or fountains. Because of the use patterns and dilution factors involved, however, EPA believes that post-application exposure to terbuthylazine in both commercial and residential settings is minimal.

Since terbuthylazine is associated with developmental toxicity effects, EPA assessed the risks to workers who apply this pesticide using the open pouring method compared to the metering pump method. The Agency found that the risk to commercial applicators who routinely use the open pouring method is unacceptable. Margins of Exposure (MOEs) for these workers are very low for both typical and high use rates, both short- and intermediate-term. However, MOEs for workers using closed pump systems are well above 100, the margin generally considered acceptable. MOEs for workers using both open pouring and metering pump methods in residential settings also are acceptably high.

EPA therefore is prohibiting commercial applications of terbuthylazine using the open pouring method, and is requiring use of closed systems along with certain personal protective equipment (PPE), to reduce exposure and risk to acceptable levels for all commercial uses.

Human Risk Assessment

Terbuthylazine is of relatively low acute toxicity, and is classified as a Group D carcinogen because there is inadequate evidence to determine its carcinogenicity in humans. However, it is associated with developmental toxicity in a study using rats.

Terbuthylazine has no food-related uses at present so dietary exposure is not of concern. However, workers are exposed while applying this pesticide in commercial/industrial and residential settings, using open pouring and closed system methods. EPA has found that the risk to commercial/industrial workers using open pouring methods is unacceptable. The Agency is prohibiting open pouring methods for commercial/industrial uses of terbuthylazine, and requiring use of closed systems with PPE in commercial/industrial settings.

Environmental Assessment

Environmental Fate

Terbuthylazine is stable to hydrolysis, and to aqueous photolysis. It degrades very slowly under aerobic aquatic conditions, and will persist under most aquatic conditions.

Ecological Effects

Terbuthylazine is practically nontoxic to birds on an acute and subacute dietary basis. However, it is moderately toxic to both cold and warm water fish, slightly toxic to aquatic invertebrates, and highly toxic to estuarine/marine invertebrates from acute exposures. Terbuthylazine is expected to be phytotoxic to aquatic plants because it belongs to the triazine family (which includes many herbicides), is released to waterways, and dissipates slowly in the environment.

Ecological Effects Risk Assessment

No significant risks to birds or mammals are expected from use of terbuthylazine. Although terbuthylazine is moderately toxic to fish and slightly toxic to freshwater invertebrates, these species are not expected to be at risk under typical use and exposure scenarios. In high exposure situations, however, levels of concern for high risk, restricted use, and endangered species are met or exceeded. Because its use patterns are not associated with estuarine or marine environments, significant risk to estuarine/marine invertebrates is not expected. Phytotoxicity to aquatic plants is anticipated, and EPA has required relevant studies as confirmatory data.

Risk Mitigation

EPA is requiring the following risk mitigation measures for terbuthylazine, as discussed earlier:

- To reduce risks to commercial/industrial applicators, EPA will prohibit open pouring methods and require that only closed system methods of application, with specified PPE, be used for commercial application of terbuthylazine.
- To adequately mitigate potential risks to fish, freshwater invertebrates, and aquatic plants from release of effluent to waterways:
  - EPA will coordinate regulatory oversight of terbuthylazine under FIFRA, the federal pesticide law administered by the Agency's Office of Pesticide Programs, and the National Pollutant Discharge Elimination System (NPDES) administered by the Office of Water in conjunction with the states.
  - EPA will require compliance with the Endangered Species Protection Program when it goes into effect.

Additional Data Required

The generic database supporting terbuthylazine is substantially complete. Confirmatory data measuring the toxicity of this pesticide to aquatic plants were recently required of registrants, and must be submitted to EPA by January 1996. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All terbuthylazine end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Effluent Discharge Labeling Statements

All end-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the effluent discharge labeling statements described in PR Notice 93-10.

Other Labeling Requirements

Except where indicated otherwise, the following statements must appear on all end-use products containing terbuthylazine that are intended primarily for industrial use:

Application Restrictions:

For products intended for industrial use:

"Open pouring of this product is prohibited."

"Mixing, loading, and application must be with a closed system (one that prevents the chemical from contacting handlers or other persons) and during handling of the chemical personal protective equipment must be worn. Personal protective equipment includes a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves. A chemical-resistant apron must be immediately available during loading and application and must be worn in case of a leak, spill, or other exposure to the concentrate."

For products intended for homeowner use:

"Persons that mix, load, or apply this product must wear a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment. If no such instructions for washables exist, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

User Safety Recommendations:

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

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

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

Regulatory Conclusion

Currently registered pesticide products containing the active ingredient terbuthylazine, labeled and used as specified in the RED document, will not pose unreasonable risks or adverse effects to humans or the environment.

Therefore, all uses of these products are eligible for reregistration. Terbuthylazine products will be reregistered once the required product specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for terbuthylazine during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV.*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the terbuthylazine RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the terbuthylazine RED, or reregistration of individual products containing terbuthylazine, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.