# REREGISTRATION ELIGIBILITY DECISION

# TEBUTHIURON

# LIST A

# CASE 0054

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

15 JUN 1994

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 tebuthiuron which includes the active ingredient tebuthiuron. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It 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 Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Linda Propst at (703) 308-8165.

Sincerely yours,

Daniel M. Barolo, 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-XXXX)*** * XXXX = the case code for the RED (see front cover of RED)
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

**By express:**

Document Processing Desk **(RED-SRRD-XXXX)***
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.

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## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| a.i. | Active Ingredient |
| CAS | Chemical Abstracts Service |
| CSF | Confidential Statement of Formula |
| EEC | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem. |
| EP | End-Use Product |
| EPA | U.S. Environmental Protection Agency |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| GRAS | Generally Recognized As Safe as designated by FDA |
| 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 |
| LOEL | Lowest Observed Effect Level |
| MP | Manufacturing-Use Product |
| MPI | Maximum Permissible Intake |

## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| MOE | Margin Of Exposure (PAD) |
| 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 |
| OPP | Office of Pesticide Programs |
| PADI | Provisional Acceptable Daily Intake |
| ppm | Parts Per Million |
| $Q^*_1$ | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |
| RED | Reregistration Eligibility Decision |
| RfD | Reference Dose |
| RS | Registration Standard |
| TD | Toxic Dose. The dose at which a substance produces a toxic effect. |
| TC | Toxic Concentration. The dose at which a substance produces a toxic effect. |
| TGAI | Technical Grade Active Ingredient. |
| TMRC | Theoretical Maximum Residue Contribution. |

## EXECUTIVE SUMMARY

### Reregistration Decision

Based on the reviews of the generic data for the active ingredient tebuthiuron, the Agency has sufficient information on the health effects of tebuthiuron and on its potential for causing adverse effects in fish and wildlife and the environment. Based on this information, the Agency concludes that products containing tebuthiuron for all registered uses are eligible for reregistration. The Agency has determined that all uses of tebuthiuron, as currently registered, will not cause unreasonable risk to humans. However, tebuthiuron may pose a significant risk to on- and off-site endangered terrestrial, semi-aquatic, and aquatic plant species and may also have adverse effects on other off-site nontarget plants. In addition, the Agency is concerned about the potential for ground water contamination from registered uses of tebuthiuron.

In order to reduce both the risk to endangered and other nontarget plants and the concern for ground water contamination, the Agency is requiring a ground water label advisory as well as label revisions for tebuthiuron end-use products, including lower application rates and limits on the number and frequency of applications for all registered use sites. In addition, the Agency has initiated discussion with the registrant to identify portions of the tebuthiuron use area that are vulnerable to ground water contamination and is requiring that this information be submitted within 4 months after the issuance of this RED. Based on the information regarding vulnerable use areas, the registrant is also required to submit, within 4 months after the issuance of this RED, proposed label restrictions for tebuthiuron to further reduce ground water contamination concerns.

The scientific data base is adequate to support the reregistration eligibility of all registered uses of tebuthiuron. The Agency is, however, requiring additional product chemistry data on preliminary analysis (Guideline 62-1) and analytical methods to verify certified limits (Guideline 62-3); these data are considered confirmatory for the reregistration of tebuthiuron. In addition, data pertaining to the magnitude of the residue in animal commodities (Guideline 171-4j) and residue analytical methods for milk and animal tissues (Guideline 171-4d) remain outstanding and are due to the Agency by 4/29/94; these data are also considered confirmatory for the reregistration of tebuthiuron.

### Background

Tebuthiuron is a relatively nonselective, soil activated herbicide registered for use to control broadleaf and woody weeds, grasses, and brush on terrestrial feed crop sites (pastures and rangeland) and on terrestrial non-food crop sites [airports/landing fields, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agricultural uncultivated areas/soils, and under newly applied asphalt and concrete]. The registered single active ingredient formulations of tebuthiuron include granular (3 and 5%), pelleted/tableted (20 and 40%), wettable powder (80%), water dispersible granules (dry flowable, 85%), and technical grade/solid (95%). Registered multiple active ingredient formulations include three granular formulations (1% tebuthiuron plus one other active ingredient, 2% tebuthiuron plus one other active ingredient, and 2% tebuthiuron plus

another active ingredient). Currently registered maximum application rates range from 2 to 16.02 lb ai/A. All formulations may be applied as broadcast, banded, and/or spot treatments using ground equipment; the pelleted/tableted formulations may also be applied using aerial equipment.

Tebuthiuron was first registered by Elanco Products Company in 1974. The registration was later transferred to DowElanco in 1989. A Registration Standard was issued in July 1987 (NTIS #PB87-231866) for all pesticide products containing the active ingredient, tebuthiuron. This document identified the additional generic data required to support the continued registration of the use of tebuthiuron as an herbicide. The use patterns registered at that time included terrestrial feed, terrestrial non-food, and aquatic non-food (ditchbanks) sites. In 1992, DowElanco (technical producer), dropped their support of the only aquatic use site (ditchbanks); therefore, the environmental fate and residue chemistry data required in the Registration Standard for aquatic use sites are no longer required for tebuthiuron.

Additionally, in the Registration Standard, the Agency identified concerns about the potential for ground water contamination by tebuthiuron and the hazard to endangered plant species from the use of tebuthiuron on pasture and rangeland. A ground water Data-Call-In was issued for tebuthiuron on May 24, 1988 which required a small scale retrospective ground water monitoring study (Guideline 166-2). An additional Data-Call-In, issued July 31, 1991, required residue chemistry studies on the magnitude of the residues in meat and milk (Guideline 171-4j); although these data, as well as data on residue analytical methods for meat and milk remain outstanding, they are considered confirmatory for the reregistration of tebuthiuron. With the exception of these residue chemistry data, the Agency has now completed its review of the target data base for tebuthiuron, including data submitted in response to the 1987 Registration Standard and subsequent ground water Data-Call-In for tebuthiuron.

Supporting Rationales for Reregistration Decision

Acute toxicity studies indicate that tebuthiuron is moderately toxic by the oral route (toxicity categories = III in mice and dogs, II in rats, and II in cats and rabbits), practically non-toxic by the dermal route (Toxicity Category IV), and only slightly toxic by the inhalation route (Toxicity Category III). Tebuthiuron is not a dermal irritant, causes only a slight irritation to the eyes (Toxicity Category IV), and is not a dermal sensitizer.

Tebuthiuron does not appear to cause any adverse developmental or reproductive effects. Based on an acceptable carcinogenicity in rats and two supplemental carcinogenicity studies in mice in which no compound-related carcinogenic effects were observed, the Health Effects Division (HED) RfD Committee classified tebuthiuron as a Group D carcinogen (not classifiable as to human carcinogenicity). The available data indicate that tebuthiuron does not appear to be mutagenic.

The Reference Dose (RfD) for tebuthiuron is 0.07 mg/kg/day, based on a NOEL of 7.0 mg/kg/day and an uncertainty factor of 100. The NOEL was derived from a two-generation reproduction study in rats which demonstrated depressed body weight gain in F1 females at 14 mg/kg/day. The TMRC for the overall U.S. population from all tolerances is $6.4 \times 10^{-3}$ mg/kg/day,

which represents 9% of the RfD. The subgroup most highly exposed, non-nursing infants (<1 year), has a TMRC from all tolerances of 2.3 x $10^{-2}$ mg/kg/day, or 32% of the RfD. The children (1-6 years) subgroup has a TMRC from all tolerances of 1.5 x $10^{-2}$ mg/kg/day, which represents 21% of the RfD. The chronic dietary risk from exposure to tebuthiuron (including published tolerances on meat and milk) appears to be minimal. The OPP RfD Committee did not recommend an acute dietary analysis. A reassessment of tolerances is also included in this document.

There is a potential for mixer/loader/applicator dermal and inhalation exposure to tebuthiuron. Occupational risks are, however, considered to be minimal due to its low toxicity [acute toxicity category IV by dermal route and III by inhalation route, negative for developmental and reproductive adverse effects, and classification as a Group D carcinogen (not classifiable as to human carcinogenicity)].

Tebuthiuron is resistant to biological and chemical degradation under environmental conditions. Its principal route of dissipation in the environment appears to be mobility; although laboratory data indicate that photodegradation on soil may occur slowly, this is not likely to be a route of dissipation in the environment. Transport to ground water (through leaching) and surface water (following runoff) are likely as a result of tebuthiuron's persistence and low adsorption to soil. According to the Pesticides in Ground Water Database (1992), tebuthiuron has been detected in ground water in Texas (two wells) and California (one well). A small-scale retrospective ground-water study conducted for the Agency in Texas indicates that tebuthiuron is persistent and mobile and can leach to ground water. Moreover, the results of the study indicated that tebuthiuron was persistent and mobile enough to leach at least 15 feet to the water table, then still be present above minimum detection levels more than 4 years after the application.

Tebuthiuron is practically non-toxic to birds, fish, and aquatic invertebrates, and is slightly toxic to mammals. Current registered uses of tebuthiuron should not pose a hazard to terrestrial or aquatic organisms. However, phytotoxicity to on- and off-site endangered terrestrial, semi-aquatic, and aquatic plant species as well as phytotoxicity to off-site non-target plants is a concern. When the Agency completes its Endangered Species program, additional precautionary labeling may be required to mitigate the risk to endangered plant species.

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

# I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for 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 tebuthiuron. The document consists of six sections. Section I is the introduction. Section II describes tebuthiuron, 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 tebuthiuron. Section V discusses the reregistration requirements for tebuthiuron. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## II. CASE OVERVIEW

### A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- **Common Name:** tebuthiuron
- **Chemical Name:** N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'dimethylurea
- **Chemical Family:** substituted urea
- **CAS Registry Number:** 34014-18-1
- **OPP Chemical Code:** 105501
- **Empirical Formula:** $C_9H_{16}N_4OS$
- **Trade and Other Names:** Spike (U.S.); Graslan (Australia); Herbic (Japan); Herbec (Canada); Perflan, Bimate, Combine (Brazil, Latin America)
- **Basic Manufacturer:** DowElanco

### B. Use Profile

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

For tebuthiuron:

**Type of Pesticide:** herbicide; relatively nonselective, soil activated, readily absorbed through plant roots

**Mode of Action:** inhibits photosynthesis

**Use Sites:** Terrestrial Feed Crop: pastures, rangeland

Terrestrial Non-food Crop: airports/landing fields, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agricultural uncultivated areas/soils, under pavement (roads/sidewalks) in areas where no future landscaping is planned

**Target Pests:** broadleaf and woody weeds, grasses, and brush

**Formulation Types Registered:**

Single active ingredient
3.0 and 5.0% Granular
20.0 and 40.0% Pelleted/Tableted
80.0% Wettable Powder
85.0% Water Dispersible Granules (Dry Flowable)
95.0% Technical Grade/Solid

Multiple active ingredient
1.0% Granular (tebuthiuron plus one other active ingredient)
2.0% Granular (tebuthiuron plus one other active ingredient)
2.0% Granular (tebuthiuron plus another active ingredient)

**Method and Rates of Application:**

Granular: Apply the 3% granular at up to 16.02 lb ai/A or the 5% granular at up to 6.0 lb ai/A as a broadcast treatment using a spreader to airports/landing fields, industrial areas (outdoor), nonagricultural uncultivated areas/soils, and under pavement in areas where no future landscaping is planned. May also be applied as a spot treatment. Reapply when needed for vegetation control.

Pelleted/Tableted: Apply up to 4.0 lb ai/A to pasture and rangeland as a broadcast treatment using aerial or ground equipment; reapply when needed for vegetation control. Apply up to 6.0 lb ai/A to industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, and nonagricultural uncultivated areas/soils as a broadcast treatment using aerial or ground equipment; reapply when needed for vegetation control. May also be applied as a spot treatment.

Wettable Powder: Apply up to 6.0 lb ai/A to airports/landing fields, industrial areas (outdoor), nonagriculural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas, and under pavement in areas where no future landscaping is planned as a soil broadcast or banded treatment using ground equipment. May also be applied as a spot treatment using a hand-held sprayer. Reapply when needed either

for vegetation control or to maintain bare ground.

Water dispersible granules (dry flowable): Apply up to 5.95 lb ai/A to airports/landing fields, industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, and under pavement in areas where no future landscaping is planned as a broadcast or banded treatment using ground equipment. May also be applied as a spot treatment using a hand-held sprayer. Reapply when needed for vegetation control.

**Use Practice Limitations:**

All formulations: Do not apply to ditches used to transport irrigation or potable water. Do not apply on or near desirable woody or herbaceous plants or in areas where their roots may extend. Do not apply in areas where the pesticide may be moved from the treated area by flowing water, wind, or mechanical means. Do not apply when soil is frozen or saturated with moisture.

## C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the usage of tebuthiuron on an aggregate and site (crop) basis. These estimates are derived from a variety of published and proprietary sources available to the Agency. The range of data presented accounts for annual fluctuations in use patterns as well as the variability resulting from the use of data from various information sources. The table below summarizes the amounts of tebuthiuron used by site.

## ESTIMATED ANNUAL U.S. USAGE OF TEBUTHIURON

| Site | Site Acreage | Acres Treated | Site Treated | Lbs a.i. Applied |
|---|---|---|---|---|
| | (000) | (000) | (%) | (000) |
| Electric utilities (*) | 9,390 | 10 - 18 | 0.1 - 0.2 | 20 - 35 |
| Pipelines (*) | 2,195 | 4 - 10 | 0.2 - 0.5 | 8 - 20 |
| Railroads (*) | 1,085 | 15 - 25 | 1.0 - 2.0 | 45 - 60 |
| Other indus. facilities (*) | 1,865 | <9 | <0.5 | 45 |
| Roadways (*) | 11,000 | 5 - 8 | <0.1 - 0.1 | 10 - 15 |
| Greenhs./nurseries, CA | 60 | NA | NA | 0.00 -0.05 |
| Landscape maint., CA | NA | NA | NA | 0.7 - 1.1 |
| Rangeland (**) | 806,000 | 95 -165 | 0.0 -<0.1 | 95 - 165 |
| Farm only -- | | | | |
| Pastured cropland | 57,820 - 58,675 | 5 - 40 | 0.0 - 0.1 | 2 - 8 |
| Woodland | 59,335 - 65,215 | 2 - 20 | 0.0 -<0.1 | 1 - 20 |
| Oth. pastures/rngelnd (#) | 343,590 - 377,245 | 9 - 70 | 0.0 -<0.1 | 4 - 25 |
| Lots, roads, etc. | 25,680 - 28,505 | 2 - 7 | 0.0 -<0.1 | 2 - 9 |
| Hay except alfalfa | 33,785 - 36,110 | <1 - 10 | 0.0 -<0.1 | <1 - 30 |
| Alfalfa | 24,150 - 25,060 | 0 - 1 | 0.0 -<0.1 | 0 - <1 |
| TOTAL (##) | 1,032,000 -1,045,000 | 140 -315 | N/A | 230 - 410 |

(*) Site acreage given is that potentially available for herbicide treatment. (**) Site acreage given is that suitable (but not necessarily available) for grazing/browsing but generally not suitable for cultivation. Some rangeland is not available because of other uses (e.g., hunting), environmental restrictions, etc.

(#) Other than pastured cropland and pastured woodland.

(##) Excludes farm other pastures/rangeland to avoid double counting (with most or all of this site included in above rangeland).

SOURCES --

1 - US EPA information, reports and proprietary sources
2 - CA EPA, Pesticide Use Report, Annuals 1990 and 1988
3 - US DOC/Census, 1987 Census of Agriculture, CA and US
4 - CO Pesticide Use Survey, Estimated Use 1989
5 - DowElanco, Tebuthiuron Use Document
6 - DowElanco, Market Use Specifics, 1/31/94

NOTE 1: NA = not available.

NOTE 2: Estimates are for total U.S. unless indicated otherwise. "CA", e.g., indicates that estimates are for California only (and do not represent total U.S. site and usage).

## D. Data Requirements

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

## E. Regulatory History

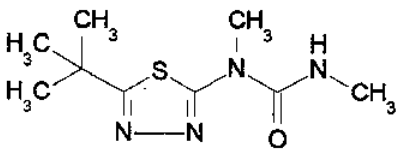
Tebuthiuron was first registered by Elanco Products Company in 1974. The registration was later transferred to DowElanco in 1989. A Registration Standard was issued in July 1987 (NTIS #PB87-231866) for all pesticide products containing the active ingredient, tebuthiuron. This document identified the additional generic data required to support the continued registration of the use of tebuthiuron as a herbicide. The use patterns registered at that time included terrestrial feed, terrestrial non-food, and aquatic non-food (ditchbanks) sites. In 1992, DowElanco (technical producer), dropped their support of the only aquatic use site (ditchbanks); therefore, the environmental fate and residue chemistry data required in the Registration Standard for aquatic use sites are no longer required for tebuthiuron.

Additionally, in the Registration Standard, the Agency identified concerns about the potential for ground water contamination by tebuthiuron and the hazard to endangered plant species from the use of tebuthiuron on pasture and rangeland. A ground water Data-Call-In was issued for tebuthiuron on May 24, 1988 which required a small scale retrospective ground water monitoring study (Guideline 166-2). An additional Data-Call-In, issued July 31, 1991, required residue chemistry studies on the magnitude of the residues in meat and milk (Guideline 171-4j). This Reregistration Eligibility Decision document reflects an assessment or reassessment of all data submitted to date in response to the Registration Standard and subsequent Data-Call-Ins for tebuthiuron.

## III. SCIENCE ASSESSMENT

### A. Physical Chemistry Assessment

The chemical structure and physical/chemical characteristics of tebuthiuron [N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'dimethylurea] are described below:




| | |
|---|---|
| Empirical Formula: | $C_9H_{16}N_4OS$ |
| Molecular Weight: | 228.3 |
| CAS Registry No.: | 34014-18-1 |
| PC Code: | 105501 |

| | |
|---|---|
| **Color** | Colorless to white |
| **Physical State** | Crystalline solid at 25°C |
| **Melting Point** | 159-161° C at 760 mmHg |
| **Solubility at 25° C** | 2.5 mg/mL water, 60 mg/mL acetonitrile<br>70 mg/mL acetone, 170 mg/mL methanol,<br>20 mg/mL ethanol, 250 mg/mL chloroform,<br>60 mg/mL methyl cellosolve,<br>3.7 mg/mL benzene, and 6.1 mg/mL hexane |
| **Vapor Pressure** | $2 \times 10^{-6}$ mmHg at 25°C |
| **Oxidizing/reducing action** | No evidence of gas evolution or temperature rise over 24 hours with ammonium dihydrogen phosphate, potassium permanganate, or powdered zinc |
| **Flammability** | N/A |
| **Explodability** | Negative in tests using 10 impacts with 8-lb hammer from 20 inches |
| **Storage stability** | Four years in polyethylene-lined commercial packaging, at ambient warehouse temperatures |
| **Viscosity** | N/A |
| **Miscibility** | N/A |
| **Corrosion** | Noncorrosive in commercial packaging |

The following Product Chemistry data are required for tebuthiuron technical (the Agency considers these data confirmatory for the reregistration of tebuthiuron):

- (62-1) Preliminary Analysis: Samples must be analyzed for nitrosamine content. Additional data are required for an impurity (CBI) listed on the CSF.

- (62-3) Analytical Method to Verify the Certified Limits: A validation of the method is required.

## B. Human Health Assessment

### 1. Toxicology Assessment

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

#### a. Acute Toxicity

The acute toxicity data on tebuthiuron are summarized below.

| TEST | RESULTS | CATEGORY |
|---|---|---|
| (81-1) Oral $LD_{50}$ - rat | M/F = 477/387 mg/kg | II |
| - mouse | M/F = 528/620 mg/kg | III |
| - rabbit | 286 mg/kg; M,F | II |
| - cat | > 200 mg/kg; M,F | II |
| - dog | > 500 mg/kg; M,F | III |
| (81-2) Dermal $LD_{50}$ - rabbit | > 5000 mg/kg; M,F | IV |
| (81-3) Inhalation $LC_{50}$ - rat | > 3.696 mg/l; M,F | III |
| (81-4) Eye irritation - rabbit* | slight irritation | IV |
| (81-5) Dermal irritation - rabbit* | nonirritating | IV |
| (81-6) Dermal sensitization - guinea pig* | nonsensitizing | - |

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

The oral $LD_{50}$ values for technical tebuthiuron ranged from 387 to 477 mg/kg in rats (toxicity category II) (MRID# 40583901) and 528 to 620 mg/kg in mice (toxicity category III) (MRID# 00226375), suggesting that the compound has moderate toxicity. The oral $LD_{50}$ values were similar in dogs and chickens (>500 mg/kg; toxicity category III) but were lower in rabbits (286 mg/kg; toxicity category II) and perhaps in cats (>200 mg/kg; toxicity category II) (MRID# 00226375). In these species, the adverse clinical signs of toxicity were generally

referable to the central nervous system and included ataxia, anorexia, dyspnea, hypothermia, hyperirritability, loss of righting reflex, vomiting, and tremors. In an acute dermal rabbit study (MRID# 40583902), the $LD_{50}$ for tebuthiuron was greater than 5000 mg/kg (toxicity category IV). In an acute inhalation study in rats (MRID# 00155730), the $LC_{50}$ value was greater than 3.696 mg/l (toxicity category III). Optical application of tebuthiuron to rabbits produced only slight irritation (i.e., slight conjunctival hyperemia at one hour post-treatment) to the eyes (toxicity category IV) (MRID# 40583903). A primary dermal irritation study indicated that tebuthiuron is not a skin irritant in rabbits (toxicity category IV ) (MRID# 40583902). No dermal sensitization occurred with tebuthiuron in guinea pigs (MRID# 40583904).

**b. Subchronic Toxicity**

When tebuthiuron was administered in the diet for 90 days to rats at levels of 0, 20, 50, or 125 mg/kg/day, the NOEL was 50 mg/kg/day and the LOEL was 125 mg/kg/day. The toxic effects observed in both sexes were reduced body weight, increases in relative liver, kidney and gonad weights, and slight vacuolation of pancreatic acinar cells. In addition, males also had increased relative spleen and prostate gland weights (MRID# 00020662).

Administration of tebuthiuron in the diet for 90 days to dogs at levels of 0, 500, 1000, or 2500 ppm resulted in a NOEL of 500 ppm (12.5 mg/kg/day). The LOEL was 1000 ppm (25 mg/kg/day), based upon findings of anorexia, weight loss, increases in blood urea nitrogen and alkaline phosphatase, and increases in spleen and thyroid gland weights (MRID# 00020663).

Dermal application of 1000 mg/kg (only dose tested) of tebuthiuron to rabbits for 6 hours per day for 21 consecutive days resulted in slight erythema which cleared by 7 days, and increased blood glucose values. The NOEL was less than 1000 mg/kg/day (MRID# 00149733).

**c. Chronic toxicity**

The required chronic toxicity study in rodents (GL# 83-1) is satisfied by a chronic/carcinogenicity feeding study in rats (MRID # 00020714; see below under B.1.d).

Dogs were fed tebuthiuron via capsule at doses of 0, 12.5, 25, or 50 mg/kg/day for one year. The NOEL was 25 mg/kg/day. The LOEL was 50 mg/kg/day, based on clinical signs of anorexia, diarrhea, and emesis and increases in thrombocyte count, alanine transferase and alkaline phosphatase levels, and weight of the liver, kidney and thyroid gland (MRID# 00146801).

### d. Carcinogenicity

In two studies of identical design, tebuthiuron was fed to 40 Harlan (Wistar-derived) rats/sex/group of 400, 800 or 1600 ppm (20, 40 or 80 mg/kg/day) for 2 years. There were 60 rats/sex/study for controls. The systemic NOEL was 40 mg/kg/day. The systemic LOEL was 80 mg/kg/day (highest dose tested), based upon a reduction in weight gain and elevated kidney weights. No compound-related carcinogenic effects were observed (MRID# 00020714).

In two studies of identical design, tebuthiuron was fed to 40 Harlan ICR mice/sex/group of 400, 800 or 1600 ppm (57, 114 or 228 mg/kg/day) for 2 years. There were 60 mice/sex/study for controls. The systemic NOEL for mice was 1600 ppm (228 mg/kg/day, the highest dose tested). No compound-related carcinogenic effects were observed (MRID# 00020717). The mouse studies were considered to be supplemental. The dose levels were judged to be inadequate for carcinogenicity testing. However, the Health Effects Division (HED) RfD Committee concluded that another study would not be needed at this time because information available from both the rat and mouse studies provide adequate information for risk assessment purposes. Based on these studies, in which no compound-related carcinogenic effects were observed, the HED RfD Committee classified tebuthiuron as a Group D (not classifiable as to human carcinogenicity) carcinogen.

### e. Developmental Toxicity

Rats were given 0, 15, 30, or 45 mg/kg/day tebuthiuron in the diet on gestation days 6-15. The NOEL for maternal toxicity was 30 mg/kg/day. The LOEL was 45 mg/kg/day, based upon reductions in body weight gain and food consumption. The NOEL for developmental toxicity was 45 mg/kg/day (highest dose tested). No compound-related developmental effects were observed (MRID# 00020803).

Rabbits were administered 0, 10, or 25 mg/kg/day tebuthiuron by gavage on gestation days 6-18. The NOEL for rabbit maternal toxicity was greater than 25 mg/kg/day (highest dose tested). An apparent decrease in fetal weights at the 25 mg/kg/day dose level (24.8 g/fetus at 25 mg/kg/day vs. 30.0 g/fetus in controls) was observed. The decrease is probably the result of an increased number of fetuses per litter (5.7 fetuses/litter in the 25 mg/kg/day group vs. 4.4 fetuses/litter in the control group), which suggests that a NOEL for developmental toxicity is greater than 25 mg/kg/day. Therefore, no compound-related developmental effects were observed (MRID#s 00020644; 40776301).

### f. Reproductive Toxicity

In a two-generation study in rats, the time-weighted average tebuthiuron intake for the dietary levels 100, 200 or 400 ppm fed is 7, 14 or 28 mg/kg/day.

The study indicated a systemic toxicity NOEL of 7 mg/kg/day. There was a reduced rate of body weight gain in $F_1$ females during a 101-day premating period at higher dose levels of 14 and 28 mg/kg/day. The reproductive NOEL was the highest dose tested (28 mg/kg/day) (MRID# 00090108).

In a three-generation study in rats, both of the dietary levels that were examined (28 and 56 mg/kg/day) produced a reduction in mean body weight gain in $F_{1b}$ weanling pups. Thus, a reproductive NOEL could not be established in this three-generation reproduction study (MRID# 00020643).

### g. Mutagenicity

Results of in vitro mutagenicity studies indicate that tebuthiuron does not appear to be mutagenic. The results of these studies are summarized in the table below.

Mutagenicity Studies With Tebuthiuron

| Study Type | GL No. | Results |
|---|---|---|
| Salmonella reverse gene mutation (Ames assay) | 84-2 | Negative, with or without metabolic activation (HDT = 5 mg/plate). (MRID# 00141691) |
| Forward Gene Mutation (mouse lymphoma L5178Y cells) | 84-2 | Negative, without metabolic activation (HDT = 1000 ug/ml). Slightly positive (mutation index = 2) w/ metabolic activation, at ≥ 700 ug/ml. Cytotoxicity observed at ≥ 200 ug/ml. (HDT = 800 ug/ml). (MRID# 00145041) |
| Structural Chromosome Aberration in CHO cells | 84-2 | Positive at the HDT (1550 ug/ml with metabolic activation; 1950 ug/ml w/out activation). Cytotoxicity observed at the HDTs. (MRID# 411341-01) |
| Unscheduled DNA Synthesis | 84-4 | Negative in primary hepatocyte of rats (HDT = 800 ug/ml; cytotoxicity observed at 900 ug/ml).(MRID# 407509-01) |

### h. Metabolism

A metabolic study of tebuthiuron was conducted in four species (rats, rabbits, dogs, and mice), using gavage administration of single doses of radiolabelled compound (10 or 160 mg/kg). Tebuthiuron was readily absorbed, extensively metabolized, and rapidly excreted in all four species. A species difference appeared to occur with mice. The total recovery of radioactivity 96 hours after compound administration was 74% to 107% of the administered dose. At the low dose level, most radioactivity was eliminated over 24 hours. In rats, rabbits and dogs, elimination in the urine accounted for 84% to 95% of the dose (0.4% to 0.7% was excreted as unchanged parent compound), and elimination in the feces

accounted for 1 to 31%. Biliary excretion was demonstrated in rats. Mice eliminated less radioactivity in urine (66%, with 23% as unchanged parent compound) and more in feces (31%) than the other three species. At least seven major metabolites were excreted in the urine of all species. Tissue distribution studies did not demonstrate any unusual tissue localization of metabolites. (MRID# 40849101).

In a study in lactating rats, dietary administration of radiolabelled tebuthiuron (5 or 10 mg/kg/day; immediately postpartum for 48 hours), resulted in the appearance of radioactive tebuthiuron and/or its metabolites in the milk at levels of 2.7 to 6.2 ppm (MRID# 00106081).

### i. Reference Dose (RfD)

The RfD for tebuthiuron was determined to be 0.07 mg/kg/day based on results of the 2-generation rat reproduction study (MRID# 00090108). The NOEL was 7 mg/kg/day for systemic toxicity, based upon a reduction in body weight gain at levels of 14 and 28 mg/kg/day in $F_1$ females during a 101-day premating period. An uncertainty factor of 100 was used; this reflects a factor of 10 for interspecies extrapolation and a factor of 10 for intraspecies variance. A toxicological evaluation has not been performed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to establish an Acceptable Dietary Intake (ADI).

## 2. Exposure Assessment

### a. Dietary Exposure

#### Plant Metabolism

The qualitative nature of the residue in grasses is adequately understood. The residues of concern are tebuthiuron and its metabolites 103(OH) [N-5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'-dimethylurea], 104 [N-5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea], and 109 [N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea]. The molecular structures of the metabolites of concern are presented in Table A.

#### Animal Metabolism

The qualitative nature of the residue in milk and ruminant tissues is adequately understood. The residues of concern in fat, meat, kidney, and liver are tebuthiuron and its metabolites 104, 106 [N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea], 108 [2-dimethylethyl-5-amino-1,3,4-thiadiazole] and 109. The terminal residues of concern in milk are tebuthiuron and its metabolites 104, 104(OH) [N-(5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methylurea], 106, 109, and 109(OH) [N-5-(2-hydroxy-1,1-

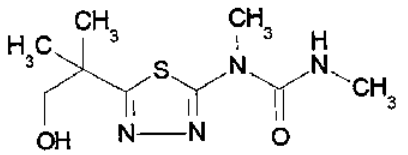
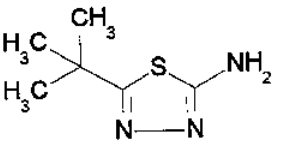
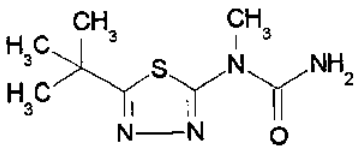
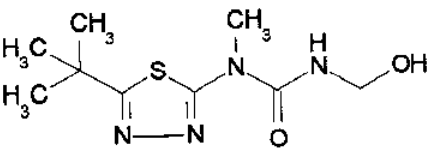
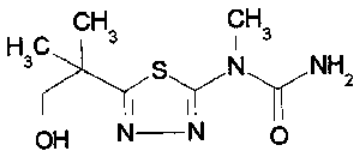
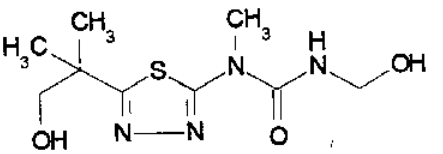
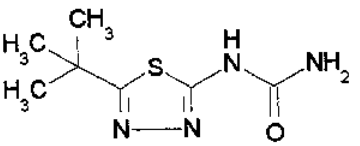
dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea]. A poultry metabolism study is not required since grasses are not considered to be poultry feed items. The molecular structures of the metabolites of concern are presented in Table A.

**Residue Analytical Method**

An adequate method is available for the enforcement of plant commodity tolerances. A GLC method with flame photometric detection is designated as Method II in PAM Vol. II. Tebuthiuron and metabolites 104 and 109 are thermally degraded on the GLC column and are determined as 5-(1,1-dimethylethyl)-N-methyl-1,3,4-thiadiazol-2-amine; metabolite 103(OH) is determined as 5-(2-hydroxy-1,1-dimethylethyl)-N-methyl-1,3,4-thiadiazol-2-amine. The stated detection limits are 0.1 ppm for tebuthiuron and metabolites 104 and 109, and 0.2 ppm for metabolite 103(OH).

A revised enforcement method for milk, to include hydrolysis steps and the determination of metabolites 104(OH) and 109(OH), and a revised enforcement method for animal tissues, to include hydrolysis steps and the determination of metabolite 108, are under development by DowElanco. A validation of these methods is required. Data are outstanding and due to the Agency by 4/29/94. These data are considered confirmatory because an adequate method (GC/flame photometric detector) exists to determine tebuthiuron and some metabolites (104, 106, and 109) in milk and ruminant tissue until a more inclusive method is submitted and validated. The existing method is listed as Method I in PAM, Vol. II. The new enforcement method is needed primarily to determine additional metabolites of toxicological concern.

Table A. The chemical structures of the metabolites of concern of tebuthiuron.

| Structure<br>**Metabolite:** Chemical name | Structure<br>**Metabolite:** Chemical name |
|---|---|
|  <br>**103 (OH):** N-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'-dimethylurea |  <br>**108:** 2-dimethylethyl-5-amino-1,3,4-thiadiazole |
|  <br>**104:** N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea |  <br>**109:** N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea |
|  <br>**104 (OH):** N-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea |  <br>**A [109 (OH)]:** N-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea |
|  <br>**106:** N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea | |

**Storage Stability**

Storage stability data indicate that residues of tebuthiuron and its metabolites containing the thiadiazole moiety [103(OH), 104, and 109] are stable in/on grass forage and hay for up to 29 months at -20° C. Storage stability data for animal commodities remain outstanding. These data are considered confirmatory.

**Magnitude of the Residue in Plants**

All data requirements for the magnitude of the residue in plants have been evaluated and deemed acceptable.

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

Data requirements pertaining to magnitude of the residue in animal commodities remain outstanding; a feeding study with ruminants is currently being conducted and is due to the Agency by 4/29/94. A feeding study with poultry is not required since grasses are not considered to be a feed item of poultry. An existing ruminant feeding study is considered inadequate because the feeding level was only about 30% of the anticipated dietary burden and because not all metabolites of concern were determined. However, based on an extrapolation of the findings of that study and on the total radiolabeled residue levels found in the nature of the residue study, it can be concluded that total tebuthiuron residues in ruminant meat and milk are not likely to exceed the current tolerances by a significant amount. The outstanding data on residues in meat and milk are therefore considered confirmatory.

**Confined/Field Rotational Crops**

Data pertaining to confined/field rotational crops are not required.

**b. Occupational and Residential Exposure**

**Mixer/Loader/Applicator Exposure (Pesticide Handlers)**

There is a potential for handler exposure to mists and aerosols generated during spray applications of the wettable powder and dry flowable formulations and to dusts generated during the granular and pelleted formulation applications. Exposure is via the dermal and inhalation route. There is also the potential for exposure as a result of the normal mixing/loading operations. Thus, tebuthiuron meets EPA's exposure criteria for requiring mixer/loader/applicator data.

However, according to the current toxicity database, this chemical does not meet any of EPA's acute or chronic toxicity criteria for the requirement

of mixer/loader/applicator exposure monitoring data. Therefore, mixer/loader/applicator data are not required to support the reregistration of tebuthiuron.

**Postapplication/Reentry Exposure (Workers)**

The potential for postapplication exposure to tebuthiuron residue is low because it is applied to sites where postapplication/reentry is unlikely. In addition, since this chemical may cause adverse effects to non-target plants, label directions contain warnings not to apply tebuthiuron to areas such as residential lawns, landscaped areas, patios, driveways, tennis courts, and swimming pools. Tebuthiuron does not meet EPA's exposure or toxicity criteria for the requirement of postapplication/reentry data. Therefore, postapplication/reentry data are not required to support the reregistration of tebuthiuron.

## 3. Risk Assessment

The data available on the toxicological effects of tebuthiuron in animals are sufficient for assessing human risks.

In acute toxicity studies, tebuthiuron is moderately toxic by the oral route (toxicity categories = III in mice and dogs, II in rats, and II in cats and rabbits), practically non-toxic by the dermal route (Toxicity Category IV), and only slightly toxic by the inhalation route (Toxicity Category III). Tebuthiuron is not a dermal irritant, causes only a slight irritation to the eyes (Toxicity Category IV), and is not a dermal sensitizer.

Tebuthiuron does not appear to cause any adverse developmental or reproductive effects. It is classified as a Group D carcinogen (not classifiable as to human carcinogenicity). The available data indicate that tebuthiuron does not appear to be mutagenic.

### a. Dietary

**Toxicological Endpoints**

The Dietary Risk Evaluation System (DRES) chronic analysis used a Reference Dose (RfD) of 0.07 mg/kg/day, based on a NOEL of 7.0 mg/kg/day and an uncertainty factor of 100. The NOEL was derived from a two-generation reproduction study in rats which demonstrated depressed body weight gain in F1 females at 14 mg/kg/day. The OPP RfD Committee did not recommend an acute dietary analysis.

**Residue Data**

The DRES chronic analysis used tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 DRES subgroups. All published tolerances are listed in the Tolerance Index System (TIS) and 40 CFR §180.390. Tolerances exist for tebuthiuron use on grass hay and forage as well as secondary residues in meat of cattle, goats, horses, and sheep and in milk. A tolerance reduction from 20 ppm to 10 ppm was recommended for grass hay and forage based on data showing that combined residues of tebuthiuron and its regulated metabolites did not exceed 10 ppm on any grass forage or hay sample in field trials conducted under label conditions. No recommendation was made for the reassessment of the meat and milk tolerances. At this time there are no pending tolerances for tebuthiuron.

**Results**

The TMRC for the overall U.S. population from all tolerances is $6.4 \times 10^{-3}$ mg/kg/day, which represents 9% of the RfD. The recommended tolerance reduction on grass hay and forage does not affect the TMRC since no change was made to any meat or milk tolerances. The subgroup most highly exposed, non-nursing infants (<1 year), has a TMRC from all tolerances of $2.3 \times 10^{-2}$ mg/kg/day, or 32% of the RfD. The children (1-6 years) subgroup has a TMRC from all tolerances of $1.5 \times 10^{-2}$ mg/kg/day, which represents 21% of the RfD.

**Conclusions/Recommendations**

The dietary analysis for tebuthiuron presents a worst-case estimate of the chronic dietary risk by using tolerance level residues and 100 percent crop treated assumptions for all commodities. The dietary risk from exposure to tebuthiuron (including published tolerances on meat and milk) appears to be minimal.

**b. Occupational and Residential**

**Conclusions**

As discussed above (Section B.2.b), there is a potential for mixer/loader/applicator dermal and inhalation exposure to tebuthiuron. Occupational risks are, however, considered to be minimal due to its low toxicity [acute toxicity category IV by dermal route and III by inhalation route, negative for developmental and reproductive adverse effects, and classification as a Group D carcinogen (not classifiable as to human carcinogenicity)].

## C. Environmental Assessment

### 4. Environmental Fate

All laboratory environmental fate data requirements necessary to support the reregistration of tebuthiuron for the uses set forth in this RED have been satisfied. Required terrestrial field dissipation studies (164-1 and 164-5), have not yet been submitted; these studies are due to the Agency by 7/31/94. It is unlikely, though, that additional information supplied by these studies would change the overall assessment of the degradation, mobility, or accumulation of tebuthiuron in the environment. The Agency, therefore, has sufficient information at this time to provide an overall qualitative assessment for tebuthiuron.

#### a. Environmental Chemistry, Fate and Transport

Additional studies reviewed since the 1987 Registration Standard are as follows:

**Photodegradation in water**

Tebuthiuron did not photodegrade in sterile aqueous buffered (pH 5) solutions that were continuously irradiated for 33 days with a xenon light source at approximately 25°C. Tebuthiuron was the only compound identified in the irradiated and dark control solutions at all sampling intervals. At 33 days posttreatment, tebuthiuron comprised 96.3-97.0% and 99.7-100.1% of the recovered radioactivity in the irradiated and dark control solutions, respectively. (MRID 41328001)

The Agency concludes that tebuthiuron is stable to photodegradation in water.

**Aerobic soil metabolism**

In a 9-month study, thiadiazole-labeled $^{14}C$ tebuthiuron, at a concentration of 6 ppm in sandy loam soil incubated in darkness at 24°C and 75% of field moisture capacity, degraded with a half-life (calculated by the registrant) of 35.4 months. The degradates identified by two-dimensional TLC were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), 5-(1,1-dimethylethyl)-2 methylamino-1,3,4-thiadiazol (compound 107), and 5-(1,1-dimethylethyl)-2 amino-1,3,4-thiadiazol (compound 108). The concentration of compound 104, which accounted for 6.9% of the applied radioactivity after 9 months of incubation, appeared to be increasing at the end of the experiment. (MRID 41328001)

The Agency concludes that tebuthiuron is stable to aerobic soil metabolism and will persist in an aerobic soil environment.

**Anaerobic soil metabolism**

Following 30 days of aerobic incubation at 24 ± 1°C and 75% of 0.33 bar moisture capacity and 60 days under flooded conditions in a sandy loam soil, thiadiazol-labeled $^{14}C$ tebuthiuron (nominal concentration 6 ppm) exhibited very little metabolism. After 60 days of anaerobic incubation, the concentration of parent tebuthiuron had decreased 4.7% from the concentration at initiation of flooding. Degradates identified were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), and N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methyl-N'-hydroxymethyl-urea (compound 109). (MRID 41328002)

The Agency concludes that tebuthiuron is stable to anaerobic soil metabolism and is likely to persist in an anaerobic soil environment.

**Anaerobic aquatic metabolism**

Tebuthiuron degraded with a half-life (calculated by the registrant) of >1 year in an anaerobic system containing pond water and sediment incubated for 365 days in darkness at 25.5 ± 0.8°C. During the study there was very little degradation of tebuthiuron, with 93.7% of the applied radiocarbon remaining as parent material at day 365. Degradates were reported to comprise approximately 1.4% of the applied radioactivity at the termination of the study. (MRID 41913101)

The Agency concludes that tebuthiuron is stable to anaerobic aquatic metabolism and is likely to persist in an anaerobic aquatic environment.

**Aerobic aquatic metabolism**

Tebuthiuron did not degrade appreciably in pond water and sediment that was incubated in darkness at 24 ± 1°C for 4 weeks under aerobic conditions. After 4 weeks of incubation, 95.2% of the applied radioactivity was present in parent tebuthiuron. Degradates identified by two-dimensional TLC were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), 5-(1,1-dimethylethyl)-2 methylamino-1,3,4-thiadiazole (compound 107), 5-(1,1-dimethylethyl)-2 amino-1,3,4-thiadiazole (compound 108), and N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methyl-N'-hydroxymethyl-urea (compound 109). (MRID 41372501)

The Agency concludes that tebuthiuron is stable to aerobic aquatic metabolism and is likely to persist in water and sediment in an aerobic aquatic environment.

**Bioaccumulation in fish**

In a 28-day flow-through study in which bluegill sunfish were exposed to a nominal tebuthiuron concentration of 5.0 ppm, bioconcentration factors of 1.98, 3.40, and 2.63 were reported for edible tissue, nonedible tissue, and whole fish, respectively. Residues in the tissues consisted primarily of tebuthiuron and two metabolites (N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methyl-N'-hydroxymethyl-urea [compound 109]) and compound 103(OH), an hydroxylated form of parent tebuthiuron). Accumulated residues depurated rapidly from fish tissue with depuration half-lives of 0.33 and 0.51 days reported for edible and nonedible tissue, respectively. (MRID 40819501)

Based on the study submitted and the reported octanol/water coefficient (log $K_{ow}$ = 1.79), the Agency concludes that there is slight potential for tebuthiuron residues to accumulate in fish.

**Small Scale Retrospective Ground Water Monitoring Study**

A small-scale retrospective ground water monitoring study was performed on a ranch near Sarita, Texas, that had last been treated with tebuthiuron on March 24, 1986. The results of the study indicated that tebuthiuron was persistent and mobile enough to leach at least 15 feet to the water table, then still be present above minimum detection levels more than 4 years after the application.

The extensive site characterization gives a high level of confidence that this study was performed with a reasonable "high exposure" scenario. The site is comprised of eolian sands over fluvial deposits. Monitoring wells were installed to avoid discontinuous, restrictive clay layers that are found at some portions of the site.

Sampling was discontinued after data showed that, in areas where restricting soil layers did not impede downward flow of ground water, tebuthiuron had leached and was still present in ground water at concentrations of up to 23 parts per billion (ppb). Twenty-three parts per billion is high compared to other herbicides that are also ground water contaminants and applied at the same rate. Pesticide Root Zone Modeling (PRZM) of the study site predicted that tebuthiuron would quickly leach to the water table through sandy soils with little organic matter. However, PRZM did not accurately predict the persistence in the soil's unsaturated zone for tebuthiuron over time.

Soil sampling at and near the study site showed convincingly that tebuthiuron can persist at relatively high concentrations in soil and soil water if restrictive layers block leaching to the ground water. (MRID 42390901)

The Agency concludes that tebuthiuron is persistent and mobile and can leach to ground water.

**b. Environmental Fate Assessment**

Based on acceptable environmental fate laboratory data reviewed in the 1987 Registration Standard and data submitted and reviewed subsequent to the Registration Standard, tebuthiuron is persistent and mobile. The principal route of dissipation appears to be transport to ground and surface water. Tebuthiuron is stable to hydrolysis and photodegradation in water (t½ = much greater than 30 days). It has a soil photolysis half-life of 39.7 days. Tebuthiuron is metabolized very slowly in soil under aerobic (t½ ≈ 35.4 months) and anaerobic conditions (t½ = much greater than 60 days). In aerobic and anaerobic aquatic metabolism studies, tebuthiuron's respective half-lives were much greater than 1 month and >1 year. Tebuthiuron is very mobile to mobile ($K_{ads}$ for sand, sandy loam, loam, and clay loam soils were 0.11, 0.62, 0.82, and 1.82, respectively). The compound's $K_{oc}$ was reported as 4. In addition, aged leaching data indicate that one metabolite, N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 104) has similar mobility to parent tebuthiuron. Terrestrial and aquatic field dissipation studies have not been submitted, however, an interim terrestrial field dissipation report supports the results of the laboratory studies. In California, Nebraska, and Florida field half-lives were estimated at 1-2 years. In CA and NE, tebuthiuron moved into the 6-12" soil depth, with small quantities detected at 12-18" and 18-24". In a FL soil (92% sand), tebuthiuron leached to a depth of >72". Tebuthiuron has slight potential to accumulate in fish with bioconcentration factors of 1.98, 3.40, and 2.63 reported for edible tissue, nonedible tissue, and whole fish, respectively. Accumulated residues depurated rapidly.

Degradation products identified in laboratory studies were N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea (compound 104), N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-methylurea (compound 105), 5-(1,1-dimethylethyl)-2 methylamino-1,3,4-thiadiazol (compound 107), 5-(1,1-dimethylethyl)-2 amino-1,3,4-thiadiazol (compound 108), and N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-(hydroxymethyl)-N-methylurea (compound 109). After 9 months of aerobic soil incubation, compound 104 accounted for 6.9% of the applied radioactivity. This was the highest concentration of any degradation product identified in the laboratory studies.

In summary, tebuthiuron is resistant to biological and chemical degradation under environmental conditions. Its principal route of dissipation in the environment appears to be mobility; transport to ground water (through leaching) and surface water (solubilize in runoff) are likely to occur after the application of tebuthiuron. Laboratory data indicate that photodegradation on soil may occur slowly but is not likely to be a route of dissipation in the environment. Transport to ground water (through leaching) and surface water (following runoff) are likely as a result of tebuthiuron's persistence and low adsorption to soil. According to the Pesticides in Ground Water Database (1992), tebuthiuron has been detected in ground water in Texas (two wells) and California (one well). A small-scale retrospective ground-water study indicates that tebuthiuron is persistent and mobile and

can leach to ground water. Moreover, the results of the study indicated that tebuthiuron was persistent and mobile enough to leach at least 15 feet to the water table, then still be present above minimum detection levels more than 4 years after the application.

## 5. Ecological Effects

All ecological effect data requirements necessary to support the reregistration of tebuthiuron for the uses set forth in this RED have been satisfied. The Agency, therefore, has sufficient information at this time to provide an overall qualitative assessment for tebuthiuron. [Required terrestrial and aquatic field studies (124-1 and 124-2) have been waived; however, the Agency reserves the right to require these studies, at a later date, if it is determined that a regulatory decision cannot be made in the absence of these studies.]

### a. Ecological Effects Data

The ecotoxicological data base is adequate to characterize the toxicity of tebuthiuron to nontarget terrestrial and aquatic organisms when used on terrestrial feed and terrestrial nonfood sites.

#### (1) Terrestrial Data

In order to establish the toxicity of tebuthiuron to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD50) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC50) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant).

**Avian Acute Toxicity**

| Species | % Test Material (TGAI) | LD50 | Conclusions |
|---|---|---|---|
| Mallard duck | 98 | >2000 mg/kg | practically non toxic |

Based on acute toxicity data, tebuthiuron is practically non-toxic to birds. An avian acute oral study performed on the mallard duck resulted in a LD50 value of greater than 2000 mg/kg. (MRID 00041692)

**Avian Subacute Toxicity**

| Species | % Test Material | LC50 | Conclusions |
|---|---|---|---|
| Bobwhite Quail | 99.1 | >5113 ppm | practically non toxic |
| Mallard Duck | 99.1 | >5093 ppm | practically non toxic |

On a subacute dietary basis, tebuthiuron is practically non toxic to birds. Two studies, one on the mallard duck and one on the bobwhite quail produced LC50s >5000 ppm. (MRIDs 40601002, 40601001).

**Avian Reproduction**

Avian reproduction studies are required when birds may be exposed repeatly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Tebuthiuron is a persistent herbicide; in areas of low precipitation, it has been estimated that the time required for tebuthiuron to reach a non-detectable level in soils from decomposition is between 3 and 7 years.

| Species | % A.I. | NOEL |
|---|---|---|
| Bobwhite quail | 96.4 | no repro. effect at up to 100 ppm |
| Mallard duck | 96.4 | no repro. effect at up to 100 ppm |

Two avian reproductive studies, one on the bobwhite quail and one on the mallard duck show no effect on reproduction at dietary levels up to 100 ppm. (MRIDs 00104243, 00093690).

**Toxicity to Nontarget Mammals**

The available mammalian data indicate that tebuthiuron is slightly to moderately toxic to small mammals on an acute basis.

| SPECIES | $LD_{50}$(mg/kg) |
|---|---|
| Mouse (female) | >528 < 620 |
| Rat (female) | 387.5 |
| Rabbit | 286 |

Regarding chronic toxicity, a two-generation reproduction study with

rats produced a NOEL of 100 mg/kg/day and a LOEL of 200 mg/kg/day.

**(2) Aquatic Data**

**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 are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout) and the other should use a warmwater species (preferably the bluegill sunfish).

| Species | % Test Material (TGAI) | LC50 | Conclusions |
|---|---|---|---|
| Rainbow trout | 98 | 143 ppm | practically non toxic |
| Bluegill sunfish | 98 | 106 ppm | practically non toxic |

Two 96-hour acute toxicity studies show that tebuthiuron is practically non-toxic to fish, with LC50 values of 143 mg/l for rainbow trout and 106 mg/l for bluegill sunfish. (MRID 00020661)

**Freshwater Fish Toxicity - Acute Studies with Formulated End-Use Products**

Formulated product testing on fish may be required when a pesticide is applied directly to water. Since tebuthiuron is not applied directly to water, these data are not currently required. Two fish toxicity studies using formulated products have been submitted, however, and are discussed below for informational purposes only.

A 96-hour $LC_{50}$ study performed on the fathead minnow shows that an 80% WP formulation is practically non-toxic to fish with an $LC_{50}$ value of greater than 180 ppm. (MRID 00041685)

A 96-hour $LC_{50}$ study performed on the fathead minnow shows that a 20% P/T formulation is practically non-toxic to fish with an $LC_{50}$ value of greater than 180 ppm. (MRID 00041685)

**Fish Early Life Stage**

A fish early life stage test is required when a product is applied directly to water or is expected to be transported to aquatic sites <u>and</u> 1) exposure of

aquatic organisms will be continual or recurrent; or 2) the lowest LC50 is 1 mg/l or less; or 3) the EEC in water is equal to or greater than 0.01 of any LC50; or 4) if the EEC is less than any LC50 and the product has reproductive effects on, or cumulative effects in aquatic organisms or has a half-life in water greater than 4 days.

Tebuthiuron is highly soluble in water (2500 ppm) suggesting a high potential for transport from the application site. Tebuthiuron is also stable to photolysis and hydrolysis (t1/2 much greater than 30 days at pH 3, 6, and 9). Pasture and rangeland are use sites which potentially allow for pesticide transport to water.

| Species | % A.I. | Results |
|---|---|---|
| Fathead minnow (embryo-larvae) | 98 | MATC (growth) >9.3 <18 mg/l; survival unaffected at ≤76 mg/l |
| Rainbow trout (embryo-larvae) | 98 | MATC (growth & survival) >26 <52mg/l |

An early life-stage study performed with the rainbow trout shows that survival and growth are impaired at environmental concentrations of ≤52 mg/l. The MATC (Maximum Allowable Toxic Concentration) is > 26 < 52 mg/l. The fathead minnow early life-stage study shows survival to be unaffected at concentrations as high as 76 mg/l, whereas growth is impaired at ≤ 18 mg/l. The MATC for the fathead minnow is >9.3 <18 mg/l. (MRIDs 00090084, 00090083).

**Freshwater Invertebrate Toxicity**

The minimum testing required to assess the hazard of a pesticide is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

| Species | % Test Material (TGAI) | LC50 | Conclusions |
|---|---|---|---|
| Daphnia magna | 99.2 | 297 ppm | practically non-toxic |

There is sufficient information to characterize tebuthiuron as practically non-toxic to aquatic invertebrates. (MRID 00041694).

**Aquatic Invertebrate Life Cycle**

A freshwater invertebrate life-cycle test is required when a product is applied directly to water or is expected to be transported to aquatic sites and 1) exposure of aquatic organisms will be continual or recurrent; or 2) the lowest $LC_{50}$ is 1 mg/l or less; or 3) the EEC in water is equal to or greater than 0.01 of any $LC_{50}$; or 4) if the EEC is less than any $LC_{50}$ and the product has reproductive effects on, or cumulative effects in, aquatic organisms or has a half-life in water greater than 4 days.

As discussed previously under fish early life stage testing requirements, there is a high potential for transport of tebuthiuron from the application site.

| Species | % A.I. | Results |
|---|---|---|
| Daphnia magna | 97.4 | MATC (growth and fecundity) >21.8 < 44.2 ppm |

An aquatic invertebrate life-cycle test performed with *Daphnia magna* shows a significant reduction in growth and fecundity at >44.2 mg/l. The MATC (Maximum Allowable Toxic Concentration) is >21.8 <44.2 ppm. (MRID 00138700)

**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. The large-scale use of tebuthiuron on rangeland may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour $LC_{50}$ for an estuarine fish, a 96-hour $LC_{50}$ for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

| Species | % Test Material (TGAI) | LC50 | Conclusions |
|---|---|---|---|
| Eastern oyster | 98 | >180<320 ppm | Practically non-toxic |
| Pink Shrimp | 98 | 62 ppm | Slightly toxic |

There is sufficient information to characterize tebuthiuron as practically

non-toxic to oyster embryos and slightly toxic to pink shrimp. The guideline requirement for testing with a marine or estuarine fish species is waived due to the demonstrated low toxicity of tebuthiuron to freshwater fish as well as marine and freshwater invertebrates. (MRID 0004168)

**Field Monitoring Studies**

Field monitoring studies may be required on a case-by-case basis depending on the intended use pattern of the chemical, the toxicity to non-target organisms, and pertinent environmental fate characteristics. Tebuthiuron is extremely persistent in the soil, especially in areas of low precipitation. Tebuthiuron is also highly soluble in water, suggesting a high potential for transport from the application site. When applied over extensive areas, as in the case of rangeland brush control, tebuthiuron would seem to have a high potential for contamination of aquatic systems within the watershed. For these reasons, monitoring studies measuring residues in runoff waters, hydrosoil, and catchment ponds were required.

Instead of a single monitoring study, several studies were submitted by the registrant. The acceptable field monitoring studies are summarized in the following table:

| Location | Application Rate | Maximum Residues | Calculated % Lost from Watershed |
|---|---|---|---|
| Boise, Idaho | 1.0 lb ai/A | Catchment pond = 12 ppb. Weir (runoff from entire watershed) = 14 ppb. Spring = 7 ppb. | 1.9% |
| Arizona | 3.0 lb ai/A | Weir pond = 33 ppb. Weir (runoff from entire watershed) = 54 ppb. | 0.05% |
| Hondo, Texas | 2.0 lb ai/A | Catchment pond = 70 ppb. Hydrosoil = 70 ppb. | 0.08% |
| Marietta, Oklahoma | 2.0 lb ai/A | Catchment pond = 180 ppb (following a 7" rainfall event). Hydrosoil = 140 ppb. | 4.53% |

The initial monitoring studies show that tebuthiuron moves from the application site through runoff. It is detectable in the runoff water and in ponds receiving runoff from the treated watershed. Maximum residue levels in catchment ponds ranged from 12 ppb to 70 ppb under conditions of normal rainfall. After a single rainfall event of 7 inches, tebuthiuron levels of 180 ppb were detected in one pond. Maximum levels in hydrosoil ranged from 70 ppb - 140 ppb. (MRIDs 00090097, 00090103, 00090105, 00090106, 00090107, 00090109)

In 1982, the registrant was requested to continue monitoring water and hydrosoil at the various study sites, especially in the catchment pond at the Marietta, Oklahoma site. This information was considered essential in order to better determine the long-term availability of tebuthiuron for runoff into

aquatic systems and the likelihood of long-term buildup of tebuthiuron in the hydrosoil.

In 1988, the registrant submitted supplemental information for the four field monitoring studies which documented changes in residue levels until 1984. The Agency reviewed the supplemental information and indicated that tebuthiuron is "a persistent herbicide with a propensity for solubilizing in runoff water three years or longer after application," and that "tebuthiuron is lost over time (3 years) such that the concentrations decrease to a very low level (0.0003 ppm to undetectable)". However, residues may remain in soil surrounding the catchments, particularly the lower soil layers. Some pellets may not be carried to a catchment area by runoff. The studies reported aquatic residues ranging from < 1 ppb (measured at the conclusion of the Texas study) up to 180 ppb (measured on 5/5/81 in the Oklahoma study) and hydrosoil residues from < 50 ppb up to 140 ppb. (MRIDs 40640002, 40640004, 40640001, 40640003)

This series of studies, when taken together, provide adequate environmental monitoring information and can be used to satisfy the field monitoring data requirement (70-1). However, these studies can only be considered valid for use patterns with a single application; they are invalid for uses which require more than one application per year or multiple year applications.

**(3) Non-Target Insects Data**

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD50 study with the technical material.

| Species | % Test Material | LD50 | Conclusion |
|---|---|---|---|
| Apis Mellifera | 99.1 | > 100 ug/bee | Practically non-toxic |

There is sufficient information to characterize tebuthiuron as practically non-toxic to bees. (MRID 40840401).

**(4) Non-Target Plants Data**

Terrestrial plant testing (seed germination, seedling emergence and vegetative vigor) is required for herbicides which have terrestrial nonfood/feed or aquatic nonfood (except residential) use patterns and which have endangered or threatened plant species associated with the site of application. The above conditions apply to tebuthiuron (refer to Section IV.B.4, Endangered Species)

Aquatic plant testing is required for any herbicide applied to terrestrial nonfood (rights-of-way) or aquatic nonfood (except residential) as in the case of tebuthiuron. The following species should be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier 1 toxicity data on the technical material are listed below:

| Species | % A.I. | EC50 |
|---|---|---|
| Seed Germination (10 species) | 99.6 | NOEL > 6 lbs a.i./Acre |

Seed germination testing at the Tier II level is not required as none of the terrestrial species tested at the maximum label rate exhibited a 25% or greater detrimental effect as compared to the control.

The acceptable Tier II toxicity data on the technical material are listed below:

| Species | % AI | $EC_{50}$ |
|---|---|---|
| *Anabaena flos-aquae* | 99.08 | 4.06 ppm (Day 5) |
| *Skeletonema costatum* | 99.08 | 0.05 ppm (Day 5) |
| *Navicula pelliculosa* | 99.08 | 0.081 ppm (Day 5) |
| *Lemna gibba* | 99.08 | 0.135 ppm (Day 14) |
| *Selenastrum capricornutum* | 98 | 0.05 ppm (Day 5) |
| Seedling emergence & Vegetative Vigor (10 species) | 99.6 | $EC_{25}$ for radish, cabbage, cucumber and wheat = 0.05, 0.03, 0.06, 0.07 lb ai/A |

## b. Ecological Effects Risk Assessment

### 1. Risk to Terrestrial Organisms

Avian and mammalian species will be exposed to tebuthiuron through the consumption of insect and plant food material containing tebuthiuron residues or by directly consuming tebuthiuron granules.

a. Acute Effects

The maximum application rate for tebuthiuron, 6 lbs ai/A, is found on labels for terrestrial nonfood crop use. As tebuthiuron is applied as a pelleted or granular formulation for this use pattern, the $LD_{50}$ value was

chosen for the toxicity analysis because birds and mammals encounter granules as discrete doses. The number of $LD_{50}$'s/sq. ft. was calculated for a broadcast application (6 lbs ai/A) with no soil incorporation.

$$\text{mg/sq ft} = \frac{\text{appl. rate (ai lbs/A) x 453,590 mg/lb}}{\text{43,560 sq ft/acre}}$$

$$\text{Single dose} = \frac{\text{mg/sq ft}}{\text{LD}_{50}\text{ mg/kg x weight of bird (kg)}}$$
$LD_{50}$/sq ft

$$\text{mg/sq ft} = \frac{\text{6 lbs ai/A x 453,590 mg/lb}}{\text{43,560 sq ft/acre}} = \text{62.5 mg/sq ft}$$

$$\text{Single dose} = \frac{\text{62.5 mg/sq ft}}{\text{2,000 mg/kg x 1.082 kg (mallard)}} = 0.03$$
$LD_{50}$/sq ft

The number of $LD_{50}$s/sq ft was 0.03 for the mallard. As this number falls below both the Restricted Use Classification (0.2 $LD_{50}$s/sq ft) and the endangered species level of concern (0.1 $LD_{50}$s/sq ft), acute hazard to nontarget avian species is not expected from a granular/pelleted application at $\leq$ 6 lbs a.i./A.

The maximum use rate for tebuthiuron in a wettable powder form is 6 lbs a.i./A. After a direct application to vegetation at this use rate, the expected residue levels on various avian food items would range from 42 to 1440 ppm. Since tebuthiuron is considered practically nontoxic to birds on a dietary basis ($LC_{50}$ >5000 ppm), acute hazard to avian species is not expected from a wettable powder application at $\leq$ 6 lbs a.i./A.

While tebuthiuron is practically nontoxic to avian species on an acute basis, the existing data indicate that it is slightly to moderately toxic to mammals. A rabbit, for instance, could conceivably consume enough granules to reach a lethal acute dose. The highest percent ai granular formulation for non-cropland use is a 6% formulation. If each granule contains approximately 0.006 mg ai tebuthiuron, a 1.0 kg rabbit (Eastern cottontail) would have to consume 47,666 granules to receive a lethal dose of 286 mg/kg. Therefore, use of a 6 % granular formulation on noncropland should result in minimal hazard to small mammal species such as the Eastern cottontail.

b. Chronic Effects

Avian reproduction studies showed no adverse effects at dietary levels up to 100 ppm. When tebuthiuron is applied directly to vegetation at the maximum use rate for wettable powders (6 lbs ai/A), the expected residue levels on various avian

food items (42 - 1440 ppm) would exceed 100 ppm. Little is known about the persistence of tebuthiuron on plant surfaces. However, significant chronic exposure to birds is not expected due to the following information.

About two-thirds of the total tebuthiuron use is on rangeland and pastureland. The maximum application rate for this use pattern is 4 lbs ai/A/year. Actual plant residue data for forage grasses exist for a rangeland use pattern. Residue monitoring at test sites covering a wide range of climatic, edaphic, and geographical conditions all showed residues in grasses to be below 20 ppm.

For rangeland and pastureland use, tebuthiuron is always applied to the ground as a pelleted/tableted formulation and is never applied directly to vegetation. Therefore, the residue monitoring values represent tebuthiuron that is taken up from the soil and transported to the plant tissues. These values are probably realistic indicators of long-term exposure to avian species. As these residue values (20 ppm) do not exceed the NOEL of 100 ppm in the avian reproduction studies, chronic hazard to birds is not expected.

**2. Risk to Aquatic Organisms**

Since tebuthiuron is practically nontoxic on an acute basis to fish and aquatic invertebrates, none of the registered uses would result in acute effects or direct mortality to these organisms.

Of concern, however, is the potential for chronic hazard to aquatic organisms. Two fish early life-stage studies showed that the survival and/or growth of fish embryo-larvae are affected at levels well below 100 ppm. A fresh water invertebrate life-cycle test shows growth and reproductive effects also at levels well below 100 ppm.

The maximum application rate for tebuthiuron is 6 lb ai/A. This application rate is for a non-cropland use and represents a worst case situation. In order to calculate an aquatic EEC, the standard scenario of a 10 acre field running off into a one acre waterbody was employed. Since tebuthiuron is highly soluble in water (2300 ppm), 5 percent runoff from the treated area was assumed. With 5 percent runoff, a total of three pounds tebuthiuron is available to enter the waterbody (6 lbs X 10 X 0.05 = 3 lbs). The resulting expected concentrations of tebuthiuron in a one acre body of water of various depths are as follows:

| Depth of Water | Concentration, ppm |
|---|---|
| 6 inches | 2.2 |
| 1 foot | 1.1 |
| 3 feet | 0.4 |
| 6 feet | 0.2 |

These estimated aquatic concentrations are well below the MATC's for fathead minnow (> 9.3 < 18 mg/l), rainbow trout (> 26 < 52 mg/l), and Daphnia magna (> 21.8 < 44.2 mg/l). Therefore, chronic hazard to aquatic organisms is not expected.

Field monitoring studies (3 years in duration following a single application) reported aquatic residues ranging from < 1 ppb (measured at the conclusion of the Texas study) up to 180 ppb (measured on 5/5/81 in the Oklahoma study) and hydrosoil residues from < 50 ppb up to 140 ppb. The studies were performed utilizing various application rates (1-3 lbs a.i./A) but these rates do not reflect the worst case. The maximum label rate for tebuthiuron is 6 lb a.i./A. Corrected for the maximum label rate, the minimum and maximum aquatic residues found in the studies would be < 6 ppb and 1080 ppb, respectively. Using the same reasoning for the hydrosoil values, the tebuthiuron residues ranged from < 300 to 840 ppb. These values indicate that at the maximum application rate of 6 lbs. a.i./A tebuthiuron is not expected to pose a hazard to aquatic organisms (lowest MATC value of >9.3 < 18 ppm for the fathead minnow) assuming a maximum of one application per 3 years.

### 3. Risk to Nontarget Plants

Exposure of nontarget terrestrial and aquatic plants to tebuthiuron is based on expected runoff from an unincorporated ground application.

### Terrestrial and Semi-Aquatic Plants

Terrestrial plant EEC's are calculated by estimating the runoff from one acre treated at the maximum application rate to an adjacent one acre site. Semi-aquatic plant EEC's are calculated by estimating the runoff from a 10 acre site treated at the maximum application rate to an adjacent one acre wetland area. For example, at a maximum ground application rate of 6.0 lbs a.i./A (noncropland, pastureland) and anticipated 5% runoff of applied pesticide, runoff into areas adjacent to treated sites is expected to be 0.30 lbs. a.i./A (see table below). Runoff into a wetland area (i.e. moist, saturated or flooded soils) away from treated sites is expected to be approximately 3.0 lbs a.i./A.

| USE SITE | MAX. APPL. RATE (LBS AI/A) | LEVEL OF CONCERN[1] | TERR. PLANTS ADJACENT TO USE SITE | | SEMI-AQUATIC PLANTS IN WET AREAS AWAY | | AQUATIC PLANTS | |
|---|---|---|---|---|---|---|---|---|
| | | | EEC[2] (lbs ai/A) | Risk Quot. | EEC[2] (lbs ai/A) | Risk Quot. | EEC[2,3] (ppm) | Risk Quot. |
| Noncrop (rights-of-way, industrial,fences) | 6.0 | $EC_{25}$ = 0.03<br>$EC_{50}$ = 0.05 | 0.30 | 10.0 | 3.0 | 100 | 0.54 | 10.8 |
| Rangeland (receiving >20 inches of rain/year) | 4.0 | $EC_{25}$ = 0.03<br>$EC_{50}$ = 0.05 | 0.20 | 6.7 | 2.0 | 67 | 0.36 | 7.2 |
| Rangeland (receiving < 20 inches of rain/year) | 2.0 | $EC_{25}$ = 0.03<br>$EC_{25}$ = 0.05 | 0.10 | 3.3 | 1.0 | 33 | 0.18 | 3.6 |

1. Levels of Concern: a) terrestrial plants - lowest $EC_{25}$ value (cabbage - percent emergence and weight) = 0.03 lbs a.i./A for seedling germination and emergence tests; this value is compared to runoff; b) aquatic plants - lowest $EC_{50}$ value from aquatic plant studies (*Selenastrum capricornutum* $EC_{50}$ = 0.05 ppm).

2. EEC values are based on runoff from ground applications.

3. EEC values for aquatic plants were extrapolated from the results of environmental monitoring conducted in rangelands in the southwestern United States. The highest observed residue from the Oklahoma site (0.18 ppm in a catchment pond after 2.0 lbs a.i./A application to watershed) was extrapolated for 4 and 6 lbs a.i./A applications.

A high level of concern exists for both endangered and nonendangered terrestrial and semi-aquatic plants if the EEC exceeds the $EC_{25}$ value for the most sensitive plant species tested or, in another words, the risk quotient is greater than one. In the above table, the shaded areas indicate that the high level of concern for endangered and nonendangered terrestrial and semi-aquatic plants has been exceeded for all use patterns.

## Aquatic Plants

Environmental monitoring data were considered in order to better estimate the aquatic plant hazard from tebuthiuron. The following table summarizes the maximum residue values found at four study sites and the extrapolated values for the maximum application rate (6 lbs a.i./A):

**Highest Observed Tebuthiuron Concentrations in Ponds and Extrapolated Values**

| Study Location | Acreage | Application Rate | Max. Residue Values | Extrapolated Values for 6 lb ai/A |
|---|---|---|---|---|
| Texas | 28.9 | 2 lbs ai/A | 0.07 ppm | 0.21 ppm |
| Idaho | 98 | 1 lb ai/A | 0.002 ppm | 0.012 ppm |
| Oklahoma | 11 | 2 lbs ai/A | 0.18 ppm | 0.540 ppm |
| Arizona | 168 | 3 lbs ai/A | 0.05 ppm | 0.100 ppm |

Data from the Oklahoma site were used as a high exposure situation. As the extrapolated value for this site (0.54 ppm) exceeds the $EC_{50}$ values of four of the five aquatic plant species tested, the high level of concern for aquatic plants has been exceeded.

To further assess the potential hazard to aquatic plants, an estimated environmental concentration (EEC) was calculated for tebuthiuron on both rangeland and pastureland using the models PRZM 2.0 and EXAMS 2.94. For the rangeland scenario, a site in Oklahoma was chosen as representative of an area receiving less than 20 inches of annual rainfall. Tebuthiuron was applied in a pelleted form at 2 lbs ai/A (the maximum application rate for rangeland receiving < 20 inches of rainfall per year). For the pastureland scenario, a site in New York was chosen as representative of an area receiving > 20 inches of rainfall per year. Tebuthiuron was applied in a pelleted form at 6 lbs ai/A (the maximum application rate for a pasture receiving > 20 inches of rainfall per year). The standard one hectare waterbody, two meters deep was used in both scenarios.

In the Oklahoma rangeland scenario, the one in ten year maximum 4-day EEC for tebuthiuron was 0.36 ppm (range of 0.096 to 0.37 ppm). This value is greater than both the unrefined aquatic EEC (0.183 ppm) and the results from residue monitoring at the Oklahoma site (0.180 ppm). The New York pastureland scenario produced a one in ten year 4-day maximum EEC of 0.92 ppm tebuthiuron (range of 0.24 to 0.96 ppm).

In both scenarios, the one in ten year maximum EEC exceeds the $EC_{50}$s for four out of the five aquatic plant species tested. As tebuthiuron has an extremely long half-life in aerobic soils ($t_{1/2}$ = 36 mo.), 80% of the amount applied remains one year after application and 63% of this amount remains two years after application. Thus, even when tebuthiuron is applied every other year, its dissolved concentration in pond water steadily increases over the 36 year simulation.

In conclusion, a high level of concern exists for both endangered and nonendangered aquatic plants if the EEC exceeds the $EC_{50}$ value for the most

sensitive plant species tested or, in another words, the risk quotient is greater than one. In the above table, the shaded areas indicate that the high level of concern for endangered and nonendangered aquatic plants has been exceeded for all use patterns of tebuthiuron. Successive applications of tebuthiuron will compound this hazard due to the extremely long half-life of this chemical. Results from environmental monitoring studies indicate that tebuthiuron is lost over time (3 years) such that concentrations decrease to a very low level (0.0003 ppm to undetectable). Therefore, restriction of tebuthiuron applications to once every three years may reduce the risk to nontarget plants. However, as residues may remain in the soil surrounding catchments, there is a potential for tebuthiuron to solubilize in runoff water three years or longer after application.

### 4. Risk to Endangered Species

Based on the conclusions in the preceding sections of this document, all registered uses of tebuthiuron pose a significant risk to off-site endangered terrestrial, semi-aquatic, and aquatic plant species. Furthermore, all endangered plant species inhabiting certain use areas (i.e. rights-of-way and rangelands) are likely to be jeopardized as they may receive a direct application of tebuthiuron.

## 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 tebuthiuron as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing tebuthiuron. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of tebuthiuron, 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 tebuthiuron and to determine that tebuthiuron can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing tebuthiuron 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 tebuthiuron 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 tebuthiuron, 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 reviews of the generic data for the active ingredient tebuthiuron, the Agency has sufficient information on the health effects of tebuthiuron and on its potential for causing adverse effects in fish and wildlife and the environment. Based on this information, the Agency concludes that products containing tebuthiuron for all registered uses are eligible for reregistration.

The Agency has determined that tebuthiuron products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

### 2. Eligible and Ineligible Uses

The Agency has determined that all registered uses of tebuthiuron are eligible for reregistration.

## B. Regulatory Position

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

### 1. Tolerance Reassessment

The available data for grass forage and hay support a reduction in the established tolerances from 20 ppm to 10 ppm.

The adequacy of the established tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep cannot be fully assessed until the required feeding study is submitted and reviewed. Extrapolation of residue data from a 0.3X cattle feeding study indicates that the established meat, fat, and meat byproduct tolerances will not be exceeded. No feeding study data are available for milk, but results of the nature of the residue study in ruminants show that established tolerance for milk will not be exceeded. The Agency used existing tolerances to estimate risk, and considers the feeding study confirmatory data.

Existing tolerances for the herbicide tebuthiuron and its metabolites containing the dimethylethyl thiadiazole moiety are currently established in 40 CFR §180.390. The reassessment of the established tolerances is summarized in Table A. below.

Table A. Tolerance Reassessment Summary

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Correct Commodity Definition |
|---|---|---|---|
| Cattle, fat | 2 | | |
| Cattle, mbyp | 2 | | |
| Cattle, meat | 2 | | |
| Goats, fat | 2 | | |
| Goats, mbyp | 2 | | |
| Goats, meat | 2 | | |
| Grass, hay | 20.0 | 10 | |
| Grass, rangeland, forage | 20 | 10 | Grass, forage |
| Horses, fat | 2 | | |
| Horses, mbyp | 2 | | |
| Horses, meat | 2 | | |
| Milk | 0.3 | | |
| Sheep, fat | 2 | | |
| Sheep, mbyp | 2 | | |
| Sheep, meat | 2 | | |

The 40 CFR tolerance expression under §180.390 should be modified as follows:

**§ 180.390 Tebuthiuron; tolerances for residues.**

(a) Tolerances are established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*,*N'*-dimethylurea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, and *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following agricultural commodities:

| Commodity | Parts per million |
|---|---|
| Grass, hay | 10 |
| Grass, forage | 10 |

(b) Tolerances are established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea, 2-dimethylethyl-5-amino-1,3,4-thiadiazole, and *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following raw agricultural commodities:

| Commodity | Parts per million |
|---|---|
| Cattle, fat | 2 |
| Cattle, mbyp | 2 |
| Cattle, meat | 2 |
| Goats, fat | 2 |
| Goats, mbyp | 2 |
| Goats, meat | 2 |
| Horses, fat | 2 |
| Horses, mbyp | 2 |
| Horses, meat | 2 |
| Sheep, fat | 2 |
| Sheep, mbyp | 2 |
| Sheep, meat | 2 |

(c) A tolerance is established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-dimethylurea, and *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following raw agricultural commodity:

| Commodity | Parts per million |
|---|---|
| Milk | 0.3 |

**Codex Harmonization**

No Codex MRLs have been established or proposed for residues of tebuthiuron. Therefore, issues of compatibility with respect to U.S. tolerances and Codex MRLs do not exist.

**2. Endangered Species Statement**

The Agency has concerns about the exposure of endanged plant species to tebuthiuron as discussed above in the science assessment chapter. On July 15, 1982, the US Fish and Wildlife Service developed a biological opinion on the proposed registration of tebuthiuron for use in the control of woody plant species on rangeland in seven southwestern states. It was determined that this chemical was likely to jeopardize 19 listed plant species (EPA-81-4). On September 23, 1982, the EPA requested the reinitiation of a formal Section 7 consultation on the conditional registration for the expanded use of tebuthiuron on pasture and rangeland in 17 additional states. USFWS determined that 10

additional listed plant species were likely to be jeopardized by the expanded use of this herbicide.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use 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 in the Federal Register in 1994 a description of the program and by 1995 have available enforceable county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under The Endangered Species Protection Program.

### 3. Labeling Rationale/Risk Mitigation Measures

#### a. Worker Protection Standard

The current registered uses of tebuthiuron do not include uses associated with the production of an agricultural plant on/in any farm, forest, nursery, or greenhouse. Thus, tebuthiuron, as currently registered, does not fall within the scope of the Worker Protection Standard and the requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," concerning the Agency's labeling regulations for worker protection statements (40 CFR 156, subpart K) are not applicable to tebuthiuron end-use products at this time.

#### b. Personal Protective Equipment (PPE) Requirements

The following PPE is the minimum PPE required for all persons handling products containing tebuthiuron: long sleeved shirt, long pants, shoes and socks. In addition, if the tebuthiuron end-use products are in Toxicity Category I, II, or III for acute dermal toxicity or skin irritation potential, chemical-resistant or waterproof gloves (whichever is appropriate) are required.

#### c. Ground Water Labeling Requirements

**Based on the environmental fate assessment for tebuthiuron, the Agency is requiring the following:**

**Ground Water Advisory:** "This chemical is known to leach through soil into ground water under certain conditions as a result of registered (rangeland and

non-crop) uses. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination".

"A shallow water table is defined as depth to water table of 30 feet or less. Permeable soils include, but are not limited to sandy soils."

Additional restrictions on the use of tebuthiuron will be required for vulnerable use areas, given its mobility and persistence in the environment. The Agency has initiated discussion with the registrant to identify such portions of the tebuthiuron use area and is requiring that this information be submitted within 4 months after the issuance of this RED. The registrant should consult with EPA and State Pesticide Agencies for additional guidance on the development of specific soil series label information. In addition, based on the information regarding vulnerable use areas, the registrant is required to submit, within 4 months after the issuance of this RED, proposed label statements for tebuthiuron to further reduce ground water contamination concerns. At that time, the Agency will consider modifying the above label advisory.

**Label Revisions:** In order to reduce the concern for ground water contamination at this time, the Agency is requiring revised labeling for tebuthiuron end-use products, including lower application rates and limits on the number and frequency of applications for all registered use sites. The Agency notes that current labeling requirements for certain vulnerable use areas are more restrictive than the requirements listed below; the current requirements for these areas must remain on labels. Labels must be revised as follows:

**Use Directions:**

Granular, Pelleted/Tableted, and Water Dispersable Granules (Dry Flowable) Formulations

For vegetation control by broadcast (aerial and ground equipment) and banded applications: The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

Spot Treatments (hand-held equipment): May be applied at rates up to the equivalency of 6 lb ai/A when needed.

Wettable Powder Formulation

For vegetation control by broadcast and banded applications (ground equipment): The maximum label rate and frequency of application is 1-2 lbs ai/a

once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

For total vegetation control and maintainence of bare ground by broadcast and banded applications (ground equipment): may be applied one time per year at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in any 3 year period.

Spot treatments (hand-held equipment): may be applied at rates up to the equivalency of 6 lb ai/A when needed.

**d. Ecological Effects Labeling Requirements**

Based on the results of aquatic/terrestrial plant testing and previous biological opinions, there is a presumption of risk for all endangered plant species which may be exposed to tebuthiuron. At the present time, EPA is consulting with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species from the use of pesticides. When this program goes into effect, endangered species precautionary labeling will be required.

**Based on the ecological effects assessment for tebuthiuron, the following labeling is required at this time:**

**Environmental Hazard Statement:**

Granular and Pelleted/Tableted Formulations

"In case of spills, collect, cover or incorporate granules/pellets spilled on the soil surfaces to prevent contamination to water. Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

Wettable Powder and Water Dispersable Granular (Dry Flowable) Formulation

"Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

In addition, the Agency notes that the requirements for revised labeling specified above under Ground Water Labeling, including lower application rates

and limits on the number and frequency of applications, are measures that will reduce (but not eliminate) the risks to non-target plants and the potential for ground water contamination.

## 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 tebuthiuron for the above eligible uses has been reviewed and determined to be substantially complete.

#### 2. Labeling Requirements for Manufacturing-Use Products

The Agency has determined that current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

### 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

##### a. Compliance with the Worker Protection Standard

The current registered uses of tebuthiuron do not include uses associated with the production of an agricultural plant on/in any farm, forest, nursery, or greenhouse. Thus, tebuthiuron, as currently registered, does not fall within the scope of the Worker Protection Standard and the requirements of PR Notice 93-7, "Labeling Revisions

Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," concerning the Agency's labeling regulations for worker protection statements (40 CFR 156, subpart K) are not applicable to tebuthiuron end-use products at this time.

**b. Personal Protective Equipment (PPE) Requirements; Labeling**

Registrants of end-use products that contain tebuthiuron must compare the personal protective equipment requirements set forth in this section to the personal protective equipment requirements, if any, on their current labeling and retain the more protective. For guidance in choosing which requirement is more protective, see Supplement Three of PR Notice 93-7.

The personal protective equipment requirements, as established in this RED for end-use products that contain tebuthiuron, are as follows:

"Applicators and other handlers must wear:
--Long sleeved shirt and long pants
--Shoes plus socks"

In addition, gloves are required if the tebuthiuron end-use products are in Toxicity Category I, II, or III for acute dermal toxicity or skin irritation potential. The glove statement shall be one of the following:

--"Waterproof gloves" for dry formulations or for formulations where water is the only solvent
--"Chemical-resistant gloves" for all other formulations

See PR Notice 93-7 for additional guidance regarding glove selection.

**c. Revised Labeling Regarding Application Rates and Number and Frequency of Applications**

The following maximum application rates and number and frequency of applications must be included on labels in the Directions for Use Section for the specified uses of tebuthiuron in order to decrease the concern for ground water contamination and the risk to non-target plants:

<u>Granular, Pelleted/Tableted, and Water Dispersable Granules (Dry Flowable) Formulations</u>

For vegetation control by broadcast (aerial and ground equipment) and banded applications: The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at

rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

Spot Treatments (hand-held equipment): May be applied at rates up the equivalency of 6 lb ai/A when needed.

Wettable Powder Formulation

For vegetation control by broadcast and banded applications (ground equipment): The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

For total vegetation control and maintainence of bare ground by broadcast and banded applications (ground equipment): may be applied one time per year at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in any 3 year period.

Spot treatments (hand-held equipment): may be applied at rates up to the equivalency of 6 lb ai/A when needed.

**d. Other Labeling Requirements**

**Environmental Hazard Statement:**

Granular and Pelleted/Tableted Formulations

"In case of spills, collect, cover or incorporate granules/pellets spilled on the soil surfaces to prevent contamination to water. Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

Wettable Powder and Water Dispersable Granular (Dry Flowable) Formulation

"Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

**Ground Water Advisory:** "This chemical is known to leach through soil into ground water under certain conditions as a result of registered (rangeland and non-crop) uses. Use of this chemical in areas where soils are permeable, particu-

larly where the water table is shallow, may result in ground-water contamination".

"A shallow water table is defined as depth to water table of 30 feet or less. Permeable soils include, but are not limited to sandy soils."

## 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 tebuthiuron 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.

# VI. APPENDICES

# APPENDIX A. Table of Use Patterns Subject to Reregistration

USES ELIGIBLE FOR REREGISTRATION

| SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| FOOD/FEED USES | | | | | | | | | | | |
| PASTURES | | | | Use Group: TERRESTRIAL FEED CROP | | | | | | | |
| Soil broadcast treatment., When needed., Aircraft. | P/T | NA | 4 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Ground. | P/T | NA | 4 lb A | * | 1/Y | | NS | NS | NS | | |
| Spot soil treatment., When needed., By hand. | P/T | NA | .09375 lb 1K sq.ft | * | 1/Y | | NS | NS | NS | | |
| RANGELAND | | | | Use Group: TERRESTRIAL FEED CROP | | | | | | | |
| Soil broadcast treatment., When needed., Aircraft. | P/T | NA | 4 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Ground. | P/T | NA | 4 lb A | * | 1/Y | | NS | NS | NS | | |
| Spot soil treatment., When needed., By hand. | P/T | NA | .09375 lb 1K sq.ft | * | 1/Y | | NS | NS | NS | | |
| NON-FOOD/NON-FEED | | | | | | | | | | | |
| AIRPORTS/LANDING FIELDS | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | |
| Soil band treatment., When needed., Backpack sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |

| SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| AIRPORTS/LANDING FIELDS (con't) | | | | Use Group: TERRESTRIAL NON-FOOD CROP (con't) | | | | | | | |
| Soil broadcast treatment., When needed., Sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Spreader. | G | NA | 16.02 lb A | * | NS | | NS | NS | NS | | |
| | G | NA | 4 lb A | * | NS | | NS | NS | NS | | G03, GA4 |
| Soil broadcast treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Backpack sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., By hand. | G | NA | .0932 lb 1K sq.ft | * | NS | | NS | NS | NS | | G03, GA4 |
| Spot soil treatment., When needed., Hand held sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Not on label. | G | NA | UC<br>.36 lb 1K sq.ft | *<br>* | NS | | NS | NS | NS | | |
| INDUSTRIAL AREAS (OUTDOOR) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | |
| Soil band treatment., When needed., Backpack sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |

| SITE Application Type, Application Timing, Application Equipment — Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| INDUSTRIAL AREAS (OUTDOOR) (con't) | | | | Use Group: TERRESTRIAL NON-FOOD CROP (con't) | | | | | | | |
| Soil broadcast treatment., When needed., Aircraft. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Ground. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Spreader. | G | NA | 16.02 lb A | * | NS | | NS | NS | NS | | |
| | G | NA | 4 lb A | * | NS | | NS | NS | NS | | G03, GA4 |
| Soil broadcast treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Backpack sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., By hand. | G | NA | .0932 lb 1K sq.ft | * | NS | | NS | NS | NS | | G03, GA4 |
| | P/T | NA | .1406 lb 1K sq.ft | * | 1/Y | | NS | NS | NS | | |
| Spot soil treatment., When needed., Hand held sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Not on label. | G | NA | UC<br>.36 lb 1K sq.ft | *<br>* | NS | | NS | NS | NS | | |

| SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS — Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | | |
| Soil band treatment., When needed., Backpack sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil band treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil band treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil broadcast treatment., When needed., Aircraft. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | | | |
| Soil broadcast treatment., When needed., Ground. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | | | |
| Soil broadcast treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil broadcast treatment., When needed., Sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil broadcast treatment., When needed., Spreader. | G | NA | 16.02 lb A | * | NS | | NS | NS | | | |
| | G | NA | 4 lb A | * | NS | | NS | NS | | | G03, GA4 |
| Soil broadcast treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Spot soil treatment., When needed., Backpack sprayer. | DF | NA | UC | * | NS | | NS | NS | | | |
| | WP | NA | UC | * | NS | | NS | NS | | | C46 |

| SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't) | | | | | | | | | | | |
| Spot soil treatment., When needed., By hand. | G | NA | .0932 lb 1K sq.ft | * | NS | | NS | NS | NS | | G03, GA4 |
| | P/T | NA | .1406 lb 1K sq.ft | * | 1/Y | | NS | NS | NS | | |
| Spot soil treatment., When needed., Hand held sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Not on label. | G | NA | UC<br>.36 lb 1K sq.ft | *<br>* | NS | | NS | NS | NS | | |
| NONAGRICULTURAL UNCULTIVATED AREAS/SOILS Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | | |
| Soil band treatment., When needed., Backpack sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil band treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Aircraft. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Ground. | P/T | NA | 6 lb A | * | 1/Y | | NS | NS | NS | | |
| Soil broadcast treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |

| SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't) — Use Group: TERRESTRIAL NON-FOOD CROP (con't) | | | | | | | | | | | |
| Soil broadcast treatment., When needed., Spreader. | G | NA | 16.02 lb A | * | NS | | NS | NS | | | |
| | G | NA | 4 lb A | * | NS | | NS | NS | | | G03, GA4 |
| Soil broadcast treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Spot soil treatment., When needed., Backpack sprayer. | DF | NA | UC | * | NS | | NS | NS | | | |
| | WP | NA | UC | * | NS | | NS | NS | | | C46 |
| Spot soil treatment., When needed., By hand. | G | NA | .0932 lb 1K sq.ft | * | NS | | NS | NS | | | G03, GA4 |
| | P/T | NA | .1406 lb 1K sq.ft | * | 1/Y | | NS | NS | | | |
| Spot soil treatment., When needed., Hand held sprayer. | DF | NA | UC | * | NS | | NS | NS | | | |
| | WP | NA | UC | * | NS | | NS | NS | | | C46 |
| Spot soil treatment., When needed., Not on label. | G | NA | UC<br>.36 lb 1K sq.ft | *<br>* | NS | | NS | NS | | | |
| ORNAMENTAL HERBACEOUS PLANTS — Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | | |
| Soil treatment., Not on label., Not on label. | G | NA | UC | * | NS | | NS | NS | | | GA4, G03 |
| UNDER PAVEMENT (ROADS/SIDEWALKS) — Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | | |
| Soil band treatment., When needed., Backpack sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil band treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |
| Soil band treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | | | C46 |

| SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only) | Form | Minimum Application Rate | Maximum Application Rates | Soil Text (Max Dse) | Max. Apps @ Max Rate | Maximum Dose /crop cycle, or /year | Min. Interv (days) | Restr. Entry Interv (days) | Geographic Allowed | Geographic Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NON-FOOD/NON-FEED (con't) | | | | | | | | | | | |
| UNDER PAVEMENT (ROADS/SIDEWALKS) (con't) | | | | Use Group: TERRESTRIAL NON-FOOD CROP (con't) | | | | | | | |
| Soil broadcast treatment., When needed., Hand held sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Soil broadcast treatment., When needed., Spreader. | G | NA | 16.02 lb A | * | NS | | NS | NS | NS | | |
| | G | NA | 4 lb A | * | NS | | NS | NS | NS | | G03, GA4 |
| Soil broadcast treatment., When needed., Tank-type sprayer. | DF | NA | 5.95 lb A | * | NS | | NS | NS | NS | | |
| | WP | NA | 6 lb A | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Backpack sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., By hand. | G | NA | .0932 lb 1K sq.ft | * | NS | | NS | NS | NS | | G03, GA4 |
| Spot soil treatment., When needed., Hand held sprayer. | DF | NA | UC | * | NS | | NS | NS | NS | | |
| | WP | NA | UC | * | NS | | NS | NS | NS | | C46 |
| Spot soil treatment., When needed., Not on label. | G | NA | UC<br>.36 lb 1K sq.ft | *<br>* | NS | | NS | NS | NS | | |

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
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
DF : WATER DISPERSABLE GRANULES (DRY FLOWABLE)
G : GRANULAR
P/T : PELLETED/TABLETED
WP : WETTABLE POWDER

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label)

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
C46 : Do not apply through any type of irrigation system.
G03 : Do not graze livestock in treated areas.
GA4 : Do not feed treated forage to livestock.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

# 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 Tebuthiuron covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Tebuthiuron 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 Tebuthiuron

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| **PRODUCT CHEMISTRY** | | | |
| 61-1 | Chemical Identity | all | 40493801, CSF dated 3/26/93 |
| 61-2A | Start. Mat. & Mnfg. Process | all | 40493801, 42720001 |
| 61-2B | Formation of Impurities | all | 40493801, 41031801, 42720001 |
| 62-1 | Preliminary Analysis | all | 41005701 |
| 62-2 | Certification of limits | all | 40493801, CSF dated 3/26/93 |
| 62-3 | Analytical Method | all | 40768302, 40768303, 40768305, 41005701 |
| 63-2 | Color | all | 40493802 |
| 63-3 | Physical State | all | 40493802 |
| 63-4 | Odor | all | 40493802 |
| 63-5 | Melting Point | all | 40493802 |
| 63-7 | Density | all | 40493802, 40493803 |
| 63-8 | Solubility | all | 40493802 |
| 63-9 | Vapor Pressure | all | 00020773 |
| 63-10 | Dissociation Constant | all | 40493802 |
| 63-11 | Octanol/Water Partition | all | 00020781 |
| 63-12 | pH | all | 40493802 |
| 63-13 | Stability | all | 40493802, 42726201 |
| 63-14 | Oxidizing/Reducing Action | all | 40493804 |
| 63-16 | Explodability | all | 40493804 |

## Data Supporting Guideline Requirements for the Reregistration of Tebuthiuron

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| 63-17 | Storage stability | all | 40493804 |
| 63-20 | Corrosion characteristics | all | 40493804 |
| **ECOLOGICAL EFFECTS** | | | |
| 71-1A | Acute Avian Oral - Quail/Duck | B,C | 00041692 |
| 71-2A | Avian Dietary - Quail | B,C | 40601001 |
| 71-2B | Avian Dietary - Duck | B,C | 40601002 |
| 71-4A | Avian Reproduction - Quail | B,C | 00093690 |
| 71-4B | Avian Reproduction - Duck | B,C | 00104243 |
| 72-1A | Fish Toxicity Bluegill | B,C | 00020661 |
| 72-1C | Fish Toxicity Rainbow Trout | B,C | 00020661 |
| 72-2A | Invertebrate Toxicity | B,C | 00041694 |
| 72-3B | Estuarine/Marine Toxicity - Mollusk | B,C | 00041684 |
| 72-3C | Estuarine/Marine Toxicity - Shrimp | B,C | 00041584 |
| 72-4A | Early Life Stage Fish | B,C | 00090083, 00090084 |
| 72-4B | Life Cycle Invertebrate | B,C | 00138700 |
| 72-6 | Aquatic Organism Accumulation | B,C | 40819501 |
| 72-7B | Actual Field - Aquatic Organisms | B,C | 00090097, 00090103, 00090106, 00090107, 00090109 |
| 122-1A | Seed Germination/Seedling Emergence | B,C | 41066902 |

## Data Supporting Guideline Requirements for the Reregistration of Tebuthiuron

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| 123-1A | Seed Germination/Seedling Emergence | B,C | 41066901 |
| 123-1B | Vegetative Vigor | B,C | 41066901 |
| 123-2 | Aquatic Plant Growth | B,C | 41080401, 41080402, 41080403, 41080404 |
| 141-1 | Honey Bee Acute Contact | B,C | 40840401 |
| **TOXICOLOGY** | | | |
| 81-1 | Acute Oral Toxicity - Rat - Mouse/Rabbit/Cat/Dog | B,C | 40583901<br>00226375 |
| 81-2 | Acute Dermal Toxicity - Rabbit | B,C | 40583902 |
| 81-3 | Acute Inhalation Toxicity - Rat | B,C | 00155730 |
| 81-4 | Primary Eye Irritation - Rabbit | | 40583903 |
| 81-5 | Primary Dermal Irritation - Rabbit | | 40583902 |
| 81-6 | Dermal Sensitization - Guinea Pig | | 40583904 |
| 82-1A | 90-Day Feeding - Rodent | B,C | 00020662 |
| 82-1B | 90-Day Feeding - Non-rodent | B,C | 00020663 |
| 82-2 | 21-Day Dermal - Rabbit | B,C | 00149733 |
| 83-1A | Chronic Feeding Toxicity - Rodent | B,C | 00020714 |
| 83-1B | Chronic Feeding Toxicity - Non-Rodent | B,C | 00146801 |
| 83-2A | Oncogenicity - Rat | B,C | 00020714 |
| 83-2B | Oncogenicity - Mouse | B,C | 00020717 |
| 83-3A | Developmental Toxicity - Rat | B,C | 00020803 |

## Data Supporting Guideline Requirements for the Reregistration of Tebuthiuron

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| 83-3B | Developmental Toxicity - Rabbit | B,C | 00020644, 40776301 |
| 83-4 | 2-Generation Reproduction - Rat | B,C | 00090108 |
| 84-2A | Gene Mutation (Ames Test) | B,C | 00141691 |
| 84-2B | Structural Chromosomal Aberration | B,C | 41134101 |
| 84-4 | Other Genotoxic Effects | B,C | 00145041, 40750901 |
| 85-1 | General Metabolism | B,C | 40849101, 00106081 |
| **ENVIRONMENTAL FATE** | | | |
| 161-1 | Hydrolysis | B,C | 00020779 |
| 161-2 | Photodegradation - Water | B,C | 41305101 |
| 161-3 | Photodegradation - Soil | B,C | 41050201 |
| 162-1 | Aerobic Soil Metabolism | B,C | 41328001 |
| 162-2 | Anaerobic Soil Metabolism | B,C | 41328002 |
| 162-3 | Anaerobic Aquatic Metabolism | B,C | 41913101 |
| 162-4 | Aerobic Aquatic Metabolism | B,C | 41372501 |
| 163-1 | Leaching/Adsorption/Desorption | B,C | 40768401 |
| 165-4 | Bioaccumulation in Fish | B,C | 40819501 |
| 166-2 | Ground Water - Small Retrospective | B,C | 42390901 |
| **RESIDUE CHEMISTRY** | | | |
| 171-4A | Nature of Residue - Plants | B | 00020645, 00020756,00020766 |

## Data Supporting Guideline Requirements for the Reregistration of Tebuthiuron

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| 171-4B | Nature of Residue - Livestock | B | 00020648, 00020650, 00020651, 00020652, 00020721, 00020767, 00027805, 00027810, 00041675, 00106080, 40985001, 40985002 |
| 171-4C | Residue Analytical Method - Plants | B | 00020656, 00020740, 00041673, 00094745, 00106080, 41196901 |
| 171-4D | Residue Analytical Method - Animal | B | confirmatory data to be submitted 4/29/94 |
| 171-4E | Storage Stability | B | 42630501 (plants); confirmatory data for animal commodities to be submitted 4/29/94 |
| 171-4J | Magnitude of Residues - Meat/Milk/Poultry/Egg | B | 0041673, 00106080; additional confirmatory data to be submitted 4/29/94 |
| 171-4K | Crop Field Trials - grass forage | B | 00020757, 00020764, 0041671, 00094745, 42630502 |
| | grass hay | | 00020705, 00094745, 42630502 |

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

## GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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| 41066901 | Waldrep, T. (1988) Influence of Tebuthiuron on Seedling Emergence and Vegetative Vigor of Ten Crop Plants: Proj. ID 61988008. Unpublished study prepared by Lilly Research Laboratories. 24 p. |
| 41066902 | Waldrep, T. (1988) Influence of Tebuthiuron on the Germination of Seeds of Ten Crop Plants: Proj. ID 61988007. Unpublished study prepared by Lilly Research Laboratories. 11 p. |
| 41080401 | Negilski, D.; Grothe, D.; Cocke, P. (1989) Toxicity of Tebuthiuron to the Blue-Green Alga (Anabaena flos-aquae) in a Static Test System: Laboratory Project ID J004489. Unpublished study prepared by Lilly Research Laboratories. 44 p. |
| 41080402 | Negilski, D.; Cocke, P. (1989) Toxicity of Tebuthiuron to a Marine Diatom (Skeletonema costatum) in a Static Test System: Laboratory Project ID J00389. Unpublished study prepard by Lilly Research Laboratories. 43 p. |
| 41080403 | Negilski, D.; Cocke, P. (1989) Toxicity of Tebuthiuron to a Freshwater |

## BIBLIOGRAPHY

| MRID | CITATION |
|---|---|
| | Diatom (Navicula pelliculosa) in a Static Test System: Laboratory Project ID J00888. Unpublished study prepared by Lilly Research Laboratories. 47 p. |
| 41080404 | Negilski, D.; Cocke, P. (1989) Toxicity of Tebuthiuron to Duckweed (Lemna gibba) in a Static Renewal Test System: Laboratory Project ID J00588. Unpublished study prepared by Lilly Research Laboratories. 62 p. |
| 41134101 | Negilski, D.; Garriott, M.; Kindig, D. (1989) The Effect of Tebuthiuron (EL-103, Compound 075503) on the in vitro Induction of Chromosomal Aberrartions in Chinese Hamster Ovary Cells: Project No. 890111CTX655; 890125CTX655; 890201CAB655. Unpublished study prepared by Lilly Research Laboratories. 49 p. |
| 41196901 | Lear, P. (1989) Multiresidue Methodology Testing of Tebuthiuron and 6 of its Metabolites: Project ID: 132-002. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 56 p. |
| 41305101 | Saxena, A. (1989) Artificial Sunlight Photodegradation of ⊢Carbon 14σ-Tebuthiuron in a Buffered Aqueous Solution: Final Report: Lab Project Number: HLA/6237/105. Unpublished study prepared by Hazleton Laboratories America, Inc. 66 p. |
| 41328001 | Rainey, D. (1989) Aerobic Soil Metabolism of [carbon 14] Tebuthiuron: Lab Project Number: ABC/0425. Unpublished study prepared by DowElanco 21 p. |
| 41328002 | Rainey, D. (1989) Anaerobic Soil Metabolism of [carbon 14] Tebuthiuron: Lab Project Number: ABC/0426. Unpublished study prepared by DowElanco 19 p. |
| 41372501 | Rainey, D. (1989) Aerobic Aquatic Metabolism of [Carbon 14] Tebuthiuron: Lab Project ID ABC-0446. Unpublished study prepared by DowElanco. 21 p. |
| 41913101 | Kesterson, A.; Wick, M. (1991) Anaerobic Aquatic Metabolism of [14C]Tebuthiuron: Lab Project Number: 1332: 407. Unpublished study prepared by PTRL East, Inc. 71 p. |
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## BIBLIOGRAPHY

| MRID | CITATION |
|---|---|
| | Kenedy Ranch, Sarita, Texas: Lab Project Number: 1-1208-3. Unpublished study prepared by The Johnson Co., Inc. 678 p. |
| 42630501 | West, S.; Morgan, R.; Turner, L. (1993) Long-term Frozen Storage Stability of Tebuthiuron and Its Major Metabolites in Grass Forage and Hay: Lab Project Number: AAC8907. Unpublished study prepared by DowElanco. 25 p. |
| 42630502 | West, S.; Ervick, D.; Turner, L. (1993) Determination of Residues of Tebuthiuron and Its Metabolites in Forage and Hay following Application of Spike Herbicide to Rangeland and Pasture Grasses: Lab Project Number: ACC8907.01. Unpublished study prepared by DowElanco. 223 p. |
| 42720001 | Murphy, G. (1993) Tebuthiuron Product Chemistry Review: Response to Letter from EPA's Lois A. Rossi (Rec. 3/19/92): Lab Project Number: GLM32993: GLM32993CA. Unpublished study prepared by DowElanco. 29 p. |
| 42726201 | Murphy, G. (1993) Determination of Stability of Tebuthiuron Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR93025. Unpublished study prepared by DowElanco Formulation Science and Technology Lab. 9 p. |

# APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Tebuthiuron. 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 Tebuthiuron 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. Tebuthiuron 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.

- INDEX-


| | | Text Page | Example Page |
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| | D. 2 Statement of Data Confidentiality Claims (based on FIFRA §10(d)(1)) | 8 | 13 |
| | D. 3 Confidential Attachment | 8 | 15 |
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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 complete 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 multiple volumes is permissible so long as the entire study is paginated 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 petitions 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 in 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.)

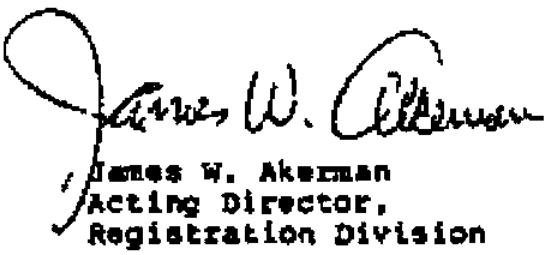
G. Special Requirements for Submitting Data to the Docket

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.



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<br>1234 West Smith Street<br>Cincinnati, OH 98765 | -and- | Jones Chemical Company<br>5678 Wilson Blvd<br>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 correspondence 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 transmittal 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

Page 1 of X
(X is the total number of pages in the study)

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).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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 _____

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 words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

| PAGE | LINE | REASON FOR THE DELETION | FIFRA REFERENCE |
|---|---|---|---|
| 6 | 14 | Identity of Inert Ingredient | §10(d)(1)(C) |
| 12 | 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 noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

| PAGE | LINES | REASON FOR THE DELETION | FIFRA REFERENCE |
|---|---|---|---|
| 20. | 2-17 | Description of the 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 _____

Study Director _____

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 _____

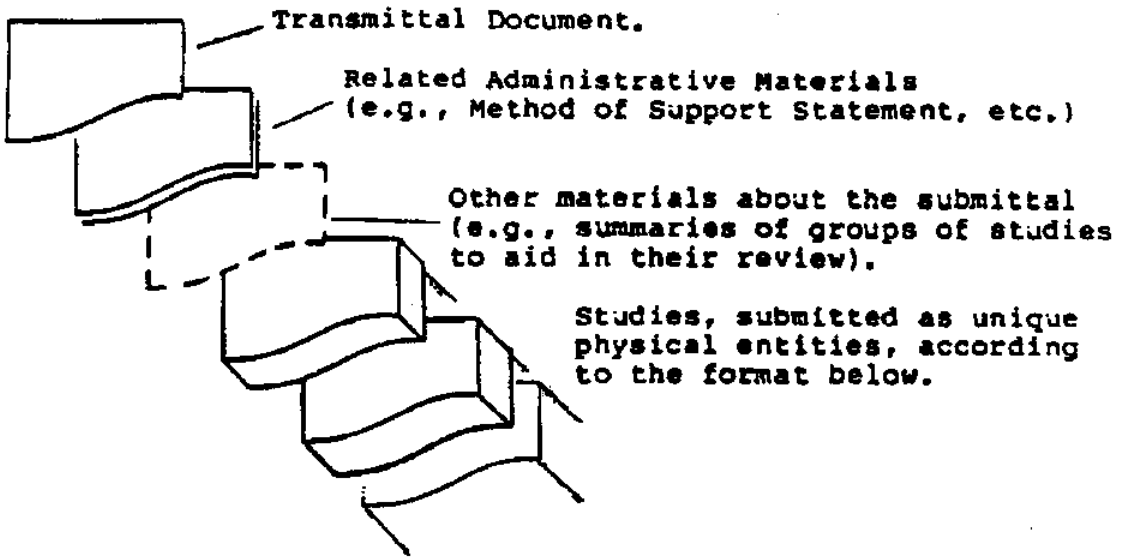
Example 3.

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.

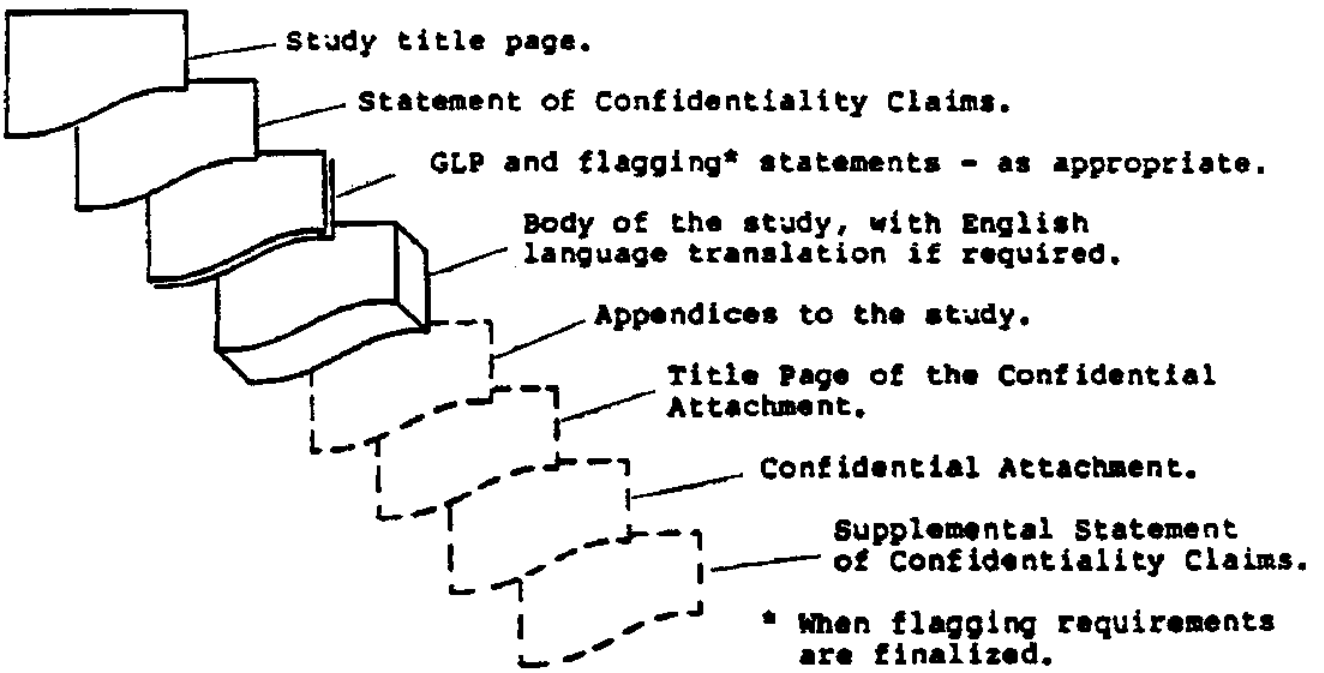
Submitter _____

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 10(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.

Anne E. Lindsay

**Anne E. Lindsay, Director**
**Registration Division (H-7505**

# APPENDIX F. Combined Generic and Product Specific Data Call-In

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 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 and 2070-0057 (expiration date 3-31-96).

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
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

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

## III-B. OPTIONS FOR RESPONDING TO THE AGENCY

### 1. Generic Data Requirements

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

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

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

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

#### a. Voluntary Cancellation -

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

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks

provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

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

c. Generic Data Exemption -

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

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

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

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

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for

each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)

(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

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

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

address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your

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

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

Option 4. Submitting an Existing Study

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

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

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

a. You must certify at the time that the existing study is submitted that the raw

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

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

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

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

If you are citing a study of which you are not the original data submitter, you must

submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

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

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)

(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)

(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

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

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

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

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

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

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

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

## III-D REQUESTS FOR DATA WAIVERS

### 1. Generic Data

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

#### a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If

the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

## SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to

FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

requirement.

## IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the

information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

## SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA 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 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

# Attachment 1. Chemical Status Sheets

Tebuthiuron DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Tebuthiuron are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Tebuthiuron are needed. These data are needed to fully complete the reregistration of all eligible Tebuthiuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Peg Perreault at (703) 308-8055.

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

Peg Perreault, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Tebuthiuron

TEBUTHIURON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Tebuthiuron. 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 Tebuthiuron 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 Tebuthiuron are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Tebuthiuron 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 Tebuthiuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Tebuthiuron, please contact Peg Perreault at (703) 308-8055.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) 308-8069.

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

Sue Rathman
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: **Tebuthiuron**

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

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

## INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form. BOTH** "Data Call-In Response" forms must be completed.

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

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

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

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

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

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

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

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

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

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

## DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

| 1. Company name and Address | 2. Case # and Name<br>0054 Tebuthiuron<br>Chemical # and Name 105501<br>Tebuthiuron | 3. Date and Type of DCI<br>GENERIC |
|---|---|---|

| 4. EPA Product Registration | 5. I wish to cancel this product registration voluntarily | 6. Generic Data | | 7. Product Specific Data | |
|---|---|---|---|---|---|
| | | 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below. | 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." | 7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response." | 7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response." |
| | | | | | |

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

**DATA CALL-IN RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

| 1. Company name and Address | 2. Case # and Name | 3. Date and Type of DCI |
|---|---|---|
| SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 | 0054 Tebuthiuron | PRODUCT SPECIFIC |

| 4. EPA Product Registration | 5. I wish to cancel this product registration voluntarily. | 6. Generic Data | | 7. Product Specific Data | |
|---|---|---|---|---|---|
| | | 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below. | 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." | 7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response." | 7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response." |
| NNNNNN-NNNNN | | N.A. | N.A. | | |

8. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

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

## INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

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

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

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

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

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

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

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

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

| | |
|---|---|
| EUP | End-Use Product |
| MP | Manufacturing-Use Product |
| MP/TGAI | Manufacturing-Use Product and Technical Grade Active Ingredient |
| PAI | Pure Active Ingredient |
| PAI/M | Pure Active Ingredient and Metabolites |
| PAI/PAIRA | Pure Active Indredient or Pute Active Ingredient Radiolabelled |
| PAIRA | Pure Active Ingredient Radiolabelled |
| PAIRA/M | Pure Active Ingredient Radiolabelled and Metabolites |
| PAIRA/PM | Pure Active Ingredient Radiolabelled and Plant Metabolites |
| TEP | Typical End-Use Product |
| TEP ___% | Typical End-Use Product, Percent Active Ingredient Specified |
| TEP/MET | Typical End-Use Product and Metabolites |

TEP/PAI/M Typical End-Use Product or Pure Active Ingredient and Metabolites

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

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

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

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

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

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

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

this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating



that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

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

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

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

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been

submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of



existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

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

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

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

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

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

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

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

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

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

the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

| | | |
|---|---|---|
| Item 10. | **ON BOTH FORMS:** | This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form. |
| Item 11. | **ON BOTH FORMS:** | Enter the date of signature. |
| Item 12. | **ON BOTH FORMS:** | Enter the name of the person EPA should contact with questions regarding your response. |
| Item 13. | **ON BOTH FORMS:** | Enter the phone number of your company contact. |

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

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

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address

2. Case # and Name
0054 Tebuthiuron
Chemical # and Name 105501
Tebuthiuron

3. Date and Type of DCI
GENERIC

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 62-1 | Preliminary Analysis | | | | | all | TGAI | 6 mos. | |
| 62-3 | Analytical Method | | | | | all | TGAI | 6 mos. | |

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

## REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0054 Tebuthiuron

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| | **Prod Chem - Regular Chemical** | | | | | | | | |
| 61-1 | Product identity & composition (1) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 61-2(a) | Descriptn starting materials, (1,2) productn & formulatn process | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 61-2(b) | Discussion of formation of (1,3) impurities | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 62-1 | Preliminary analysis (1,4) | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 62-2 | Certification of limits (1,5) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 62-3 | Analytical method (1) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-2 | Color | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 63-3 | Physical state | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 63-4 | Odor | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 63-5 | Melting point (6) | | | | | ABCDEFGHIJKLMNO | TGAI | 8 mos. | |
| 63-6 | Boiling point (7) | | | | | ABCDEFGHIJKLMNO | TGAI | 8 mos. | |
| 63-7 | Density | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0054 Tebuthiuron
EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 63-8 | Solubility | | | | | ABCDEFGHIJKLMNO | TGAI/PAI | 8 mos. | |
| 63-9 | Vapor pressure | | | | | ABCDEFGHIJKLMNO | TGAI/PAI | 8 mos. | |
| 63-10 | Dissociation constant | | | | | ABCDEFGHIJKLMNO | TGAI/PAI | 8 mos. | |
| 63-11 | Octanol/water partition coefficient (8) | | | | | ABCDEFGHIJKLMNO | PAI | 8 mos. | |
| 63-12 | pH (9) | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 63-13 | Stability | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-14 | Oxidizing or reducing action (10) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-15 | Flammability (11) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-16 | Explodability (12) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-17 | Storage stability | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-18 | Viscosity (13) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-19 | Miscibility (14) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-20 | Corrosion characteristics | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 63-21 | Dielectric breakdown voltage (15) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| | Acute Toxic - Regular Chemical | | | | | | | | |
| 81-1 | Acute oral toxicity-rat (1,36,37) | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 81-2 | Acute dermal toxicity-rabbit/rat (1,2,37) | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |
| 81-3 | Acute inhalation toxicity-rat (3) | | | | | ABCDEFGHIJKLMNO | MP/EP and TGAI | 8 mos. | |

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

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

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0054 Tebuthiuron

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 81-4 | Primary eye irritation-rabbit (2) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 81-5 | Primary dermal irritation (1,2) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 81-6 | Dermal sensitization (4) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

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

# FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

## Case # and Name: 0054 Tebuthiuron

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

**Use Categories Key:**

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

**Footnotes:** [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

**Prod Chem - Regular Chemical**

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
6 Required if technical chemical is solid at room temperature.
7 Required if technical chemical is liquid at room temperature.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

**Acute Toxic - Regular Chemical**

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

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

**FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS**

**Case # and Name: 0054 Tebuthiuron**

**Footnotes (cont.):**

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

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

Batching has been accomplished using the readily available information described above. Frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use 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 formul- ation 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 cited, the registrant must clearly identify the material tested by its EPA registration number. If more than one Confidential Statement Of Formula (CSF) exists for a product registration, 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.

The following information (Table I) lists two batches (2 products each) containing tebuthiuron.

Table I: Batched Products.

| Batch No. | EPA Reg. No. | % Tebuthiuron & Other Active Ingredient | Formulation Type |
|---|---|---|---|
| 1 | 34913-9 | 3.0 | Granular |
| | 34913-10 | 5.0 | Granular |
| 2 | 34913-15 | (3.0) 3-(3,4 Dichloro-phenyl)-1-1-dimethylurea. (1.0) Tebuthiuron. | Granular |
| | 34913-16 | (6.0) 3-(3,4-Dichloro-phenyl)-1,1-dimethylurea. (2.0) Tebuthiuron. | Granular |

Seven products (Table II) were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making, and not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table II: Products Not Batched

| EPA Reg. Number | % Tebuthiuron & Other Active Ingredient | Formulation Type |
|---|---|---|
| 62719-107 | 80.0 | Wettable Powder |
| 62719-109 | 95.0 | Technical |
| 62719-111 | 5.0 | Granular |
| 62719-121 | 20.0 | Pelleted/Tableted |
| 62719-122 | 40.0 | Pelleted/Tableted |
| 62719-128 | (4.0) Trifluralin.<br>(2.0) Tebuthiuron. | Granular |
| 62719-135 | 85.0 | Water Dispersable Granules |

# 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).

## 62 Analysis and Certification of Product Ingredients

### 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 $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ 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 $\geq$ 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 <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> 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 $\mu$m 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 ($\pm$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 $\leq 2$ or $\geq 11.5$.
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 $\leq 2$ or $\geq 11.5$.
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 $\leq 2$ or $\geq 11.5$.
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 | b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
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| | | | | | | | | |

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

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

## 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<br>Washington, DC 20460<br>CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA | Form Approved<br>OMB No. 2070-0106<br>2070-0057<br>Approval Expires 3-31-96 |

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

| Company Name | Company Number |
|---|---|
| Product Name | EPA Reg. No. |

I Certify that:

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

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

| EPA | United States Environmental Protection Agency<br>Washington, DC 20460<br>CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS | Form Approved<br>OMB No. 2070-0107<br>2070-0057<br>Approval Expires 3-31-96 |
|---|---|---|

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

| Company Name | Company Number |
|---|---|
| Product Name | EPA Reg. No. |

I Certify that:

1. For each study cited in support of registration or reregistration 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)(D) 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)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

| Signature | Date |
|---|---|
| Name and Title (Please Type or Print) | |

EPA Form 8570-31 (4-90)

# APPENDIX G. FACT SHEET

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-F-94-006
April 1994

# EPA R.E.D. FACTS

# Tebuthiuron

## 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 a complete set of 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 for tebuthiuron.

## Use Profile

Tebuthiuron is a relatively nonselective, soil activated herbicide that acts by inhibiting photosynthesis. It is used to control broadleaf and woody weeds, grasses and brush on feed crop sites (pasture and rangeland) and a variety of non-food crop sites including airports/landing fields, outdoor industrial areas, non-agricultural rights-of-way, fencerows, hedgerows, uncultivated areas/soils, and under paved roads and sidewalks in areas where no future landscaping is planned. Primary uses include rangeland and near railroads and other industrial facilities.

Single active ingredient formulations include granular, pelleted/tableted, wettable powder, water dispersible granules, and technical grade/solid products. Three multiple active ingredient formulations (granulars) also are registered. All formulations may be applied as broadcast, banded or spot treatments using ground equipment. The pelleted/tableted formulations also may be applied using aerial equipment.

## Regulatory History

Tebuthiuron was first registered as a pesticide in the U.S. in 1974. EPA issued a Registration Standard for tebuthiuron in July 1987 (NTIS #PB87-231866), which identified the potential for groundwater contamination as well as hazards to endangered plant species from use of tebuthiuron on pasture and rangeland, and which required additional generic data.

In 1988, EPA issued a Ground Water Data Call-In which required a small scale retrospective ground water monitoring study. A 1991 Data Call-In required residue chemistry studies on residues in meat and milk. In 1992, the technical producer stopped supporting the only aquatic use site (ditchbanks).

Currently, 12 pesticide products are registered which contain the active ingredient tebuthiuron.

## Human Health Assessment

### Toxicity

In acute toxicity studies, tebuthiuron is moderately toxic by the oral route. It has been placed in Toxicity Category II for this effect in rats, rabbits and cats, and in Category III for mice and dogs. (Category I indicates the greatest degree of acute toxicity and IV the least.) Tebuthiuron is practically non-toxic by the dermal route (Toxicity Category IV), and only slightly toxic by the inhalation route (Toxicity Category III). The pesticide is not a dermal irritant, causes only slight irritation to the eyes (Toxicity Category IV), and is not a dermal sensitizer.

Tebuthiuron does not appear to cause any adverse developmental or reproductive effects. Based on an acceptable carcinogenicity study in rats and two supplemental carcinogenicity studies in mice, in which no compound-related carcinogenic effects were observed, tebuthiuron is classified as a Group D carcinogen (not classifiable as to human carcinogenicity). The available data indicate that tebuthiuron does not appear to be mutagenic.

### Dietary Exposure

Tolerances or maximum residue limits are established for residues of tebuthiuron on grass hay and forage; in the meat of cattle, goats, horses and sheep; and in milk (see 40 CFR 180.390). A reduction in the grass hay and forage tolerance from 20 ppm to 10 ppm is recommended since residues do not typically exceed the lower value.

EPA's worst-case exposure estimates indicate that the overall U.S. population is exposed to 9% of the Reference Dose (RfD) or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Non-nursing infants (up to 1 year old) are exposed to 32% of the RfD, and children age 1-6 are exposed to 21% of the RfD. The effect of

concern is depressed body weight gain, as observed in a rat reproduction study.

This worst-case estimate of tebuthiuron's chronic dietary risk assumes that residues are at tolerance level and that 100% of all commodities are treated. Actual exposure is less, and dietary risks are considered minimal.

### Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to tebuthiuron during normal mixing and loading operations, to mists during spray applications, and to dusts during application of solid formulations. This exposure is by inhalation and to the skin. However, tebuthiuron is of sufficiently low toxicity that exposure monitoring data are not required. The potential for post-application exposure is low due to the nature of the registered use sites. Again, since the pesticide is of relatively low toxicity, post-application/reentry data are not required.

### Human Risk Assessment

Although tebuthiuron is moderately toxic by the oral route, it is only slightly toxic by inhalation and is practically non-toxic through the skin. It is not a skin irritant or sensitizer, and causes only slight irritation to the eyes. Tebuthiuron does not appear to cause developmental or reproductive effects, to be mutagenic or to cause cancer.

People may be exposed to residues of tebuthiuron in meat or milk. The dietary risk from this exposure, however, appears to be minimal. Occupational pesticide users (mixers, loaders and applicators) also may be exposed to tebuthiuron by inhalation and through the skin. The risks of this exposure again are considered minimal due to the pesticide's low toxicity.

## Environmental Assessment

### Environmental Fate

Tebuthiuron is persistent and mobile and can leach to ground water, as indicated by a small-scale retrospective ground water study. It is resistant to biological and chemical degradation, and its principle route of dissipation in the environment appears to be mobility. Transport to ground water through leaching and to surface water through run-off are likely as a result of tebuthiuron's persistence and low adsorption to soil. Tebuthiuron has been detected in ground water in Texas and California. The Agency is concerned about the potential for ground water contamination from registered uses of tebuthiuron.

### Ecological Effects

Tebuthiuron is practically nontoxic on an acute basis to birds, fish and aquatic invertebrates, but is slightly toxic to mammals. Current registered uses of tebuthiuron should not pose a hazard to terrestrial or aquatic organisms. However, tebuthiuron may pose a significant risk to on- and off-site endangered terrestrial, semi-aquatic, and aquatic plant

species and may also have adverse effects on other off-site non-target plants.

**Ecological Effects Risk Assessment**

Application of tebuthiuron to rangeland (the most typical use pattern) exceeds the Agency's high level of concern for nontarget terrestrial and aquatic plants. Each application of tebuthiuron compounds this hazard due to the pesticide's extremely long half-life. By reducing the maximum application rates and limiting the frequency of applications to once every three years, EPA expects to reduce the risk to non-target plants.

All registered uses of tebuthiuron pose a significant risk to off-site endangered terrestrial, semi-aquatic and aquatic plant species. Further, all endangered species in certain use areas, such as rangelands and rights-of-way, are likely to be jeopardized as they may receive direct applications of tebuthiuron. EPA may require additional labeling and use modifications when implementing the Endangered Species Protection Program.

## Additional Data Required

EPA is requiring additional generic confirmatory data for tebuthiuron including two product chemistry studies (Preliminary Analysis and Analytical Methods to Verify Certified Limits). The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula, and revised labeling for reregistration.

## Product Labeling Changes Required

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

**Worker Protection Standard (WPS)** - The current registered uses of tebuthiuron do not include uses associated with the production of an agricultural plant on/in any farm, forest, nursery, or greenhouse. Thus, tebuthiuron, as currently registered, does not fall within the scope of the Worker Protection Standard for Agricultural Pesticides and the requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," concerning the Agency's labeling regulations for worker protection statements (40 CFR 156, subpart K) are not applicable to tebuthiuron end-use products at this time.

**Personal Protective Equipment (PPE) Requirements**

Registrants must compare the following PPE requirements with those (if any) on their current labeling and retain the more protective. Labeling must bear the following minimum PPE requirement:

"Applicators and other handlers must wear:

--Long sleeved shirt and long pants

--Shoes plus socks"

In addition, gloves are required if the product is in Toxicity Category I, II, or III for acute dermal toxicity or skin irritation potential. The glove statement must be one of the following:

--"Waterproof gloves" for dry formulations or for formulations where water is the only solvent;

--"Chemical-resistant gloves" for all other formulations.

See PR Notice 93-7 for additional guidance on glove selection.

**Ground Water Label Advisory** - Due to its persistence and mobility in the environment, tebuthiuron end-use products must bear the following Label Advisory:

"This chemical is known to leach through soil into ground water under certain conditions as a result of registered (rangeland and non-crop) uses. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination".

"A shallow water table is defined as depth to water table of 30 feet or less. Permeable soils include, but are not limited to sandy soils."

Additional use restrictions will be required for areas vulnerable to ground water contamination, once these areas are identified (within 4 months after issuance of this RED).

**Use Rates and Number of Applications** - The following maximum application rates and number and frequency of applications must be included in the Directions for Use section of the label, to reduce the potential for ground water contamination and the risks to non-target plants:

- Granular, Pelleted/Tableted, and Water Dispersable Granules (Dry Flowable) Formulations

  For vegetation control by broadcast (aerial and ground equipment) and banded applications: The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

  Spot Treatments (hand-held equipment): May be applied at rates up to the equivalency of 6 lb ai/A when needed.

- Wettable Powder Formulation

  For vegetation control by broadcast and banded applications (ground equipment): The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however,

no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

For total vegetation control and maintainence of bare ground by broadcast and banded applications (ground equipment): may be applied one time per year at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in any 3 year period.

Spot treatments (hand-held equipment): may be applied at rates up to the equivalency of 6 lb ai/A when needed.

**Other Labeling Requirements (Environmental Hazard Statement)**

Granular and Pelleted/Tableted Formulations

"In case of spills, collect, cover or incorporate granules/pellets spilled on the soil surfaces to prevent contamination to water. Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

Wettable Powder and Water Dispersable Granular (Dry Flowable) Formulation

"Do not apply to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate".

## Regulatory Conclusion

Based on reviews of the generic data for the active ingredient tebuthiuron, EPA has determined that tebuthiuron 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, products containing tebuthiuron for all registered uses are eligible for reregistration.

Products that contain tebuthiuron as the sole active ingredient will be reregistered once the required confirmatory generic data, product specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products which also contain other active ingredients will be reregistered after the other active ingredients are determined to be eligible for reregistration.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for tebuthiuron 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.

Following the comment period, the tebuthiuron RED document 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 tebuthiuron RED, or reregistration of individual products containing tebuthiuron, 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, from 8:00 am to 6:00 pm Central Time, Monday through Friday.