



Reregistration Eligibility Decision (RED)

Butralin



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Richard J. Otten, Agent
CFPI
5116 Wood Valley Dr.
Raleigh, N.C. 27613

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 butralin which includes the active ingredient butralin. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 29, 1997 contains the Agency's evaluation of the data base of these chemicals, 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 ingredients to confirm the risk assessments.

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

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA to consider aggregate risk. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative C.P. Moran (703) 308-8590. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Luminello at (703) 308-8075.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

1. DATA CALL-IN (DCI) OR "90-DAY RESPONSE"--If generic data are required for reregistration, a DCI letter will be enclosed describing such data. If product specific data are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

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

3. APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**
 - a. Application for Reregistration (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

BUTRALIN

LIST B

CASE 2075

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

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BUTRALIN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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Neil Anderson	Biological Analysis Branch
Ed Brandt	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Renee Costello	Environmental Risk Branch II
Karen McCormack	Environmental Risk Branch II
James Hetrick	Environmental Risk Branch II
David Wells	Environmental Risk Branch II

Health Effects Risk Assessment

Paula Deschamp	Reregistration Characterization and Assessment Branch
Stan Gross	Toxicology Branch II
Thomas Campbell	Occupational and Residential Exposure Branch

Registration Support Risk Assessment

Daniel Kenney	Fungicide-Herbicide Branch
Al Smith	Registration Support Branch

Risk Management

Tom Luminello	Reregistration Branch III
Margaret Rice	Reregistration Branch III

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
μg/g	Micrograms Per Gram
μg/L	Micrograms per Liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

GLOSSARY OF TERMS AND ABBREVIATIONS

N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U. S. Environmental Protection Agency (referred to as "the Agency") has completed its reregistration eligibility decision of the pesticide active ingredient 4-(1,1-dimethylethyl)-N-(1-methylpropyl)-2,6-dinitrobenzeneamine, also known as butralin. This decision includes a comprehensive reassessment of the required data and the use patterns of currently registered products. On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. FQPA requires the Agency to consider the special sensitivity of infants and children to a pesticide, aggregate exposure to a pesticide from dietary, drinking water and non-occupational exposures and cumulative effects from other compounds with a common mode of toxicity when establishing or reassessing tolerances. Butralin has no food uses. It's only use is a plant growth regulator on tobacco to control the growth of suckers on the stalk. The Agency does not consider tobacco a "food" use and does not establish tolerances on tobacco. However, notwithstanding the lack of a need for a tolerance, the Agency has evaluated potential butralin exposures from drinking water and non-occupational sources and determined that there would be no exposure of consequence. Therefore, the only potential exposures of concern are for handlers and post-application workers. The Agency believes inhalation risks to handlers and post-application workers from butralin are very low, that dermal risks to handlers can be mitigated with chemical-resistant gloves, and that dermal risks to post-application workers can be mitigated with a restricted-entry interval and early-entry personal protective equipment. Based upon available data, the Agency has also concluded that risk to freshwater and terrestrial nontarget organisms and water resources will be minimal. Therefore, the tobacco use of butralin has been determined to be eligible for reregistration. Certain confirmatory data are being required of the registrant.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of butralin and whether it is appropriate to consider exposure from butralin with other compounds in order to address potential cumulative effects. However, based on the lack of food uses, the unlikelihood of residues in drinking water, and the absence of non-occupational exposure, the Agency believes that the contribution of butralin exposure to the exposure of other chemicals with a common mode/mechanism of toxicity is likely to be minimal.

There are currently tolerances for food uses of butralin listed in 40 CFR § 180.358 which have been removed from all butralin labels and will be proposed for revocation. These food uses were cancelled several years ago. The ornamental grass and turf use was cancelled in March 1997. There are no existing stocks of any butralin products other than the currently registered product, Tamex 3 EC, which is for tobacco use only.

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

I. INTRODUCTION

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

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

The Food Quality Protection Act of 1996 amends both the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. Although butralin has no food uses and specific determinations outlined in FQPA are not required for reregistration, EPA believes that consideration of available data relating to special sensitivity of infants and children, as well as the potential for aggregate exposures and cumulative effects is prudent for butralin and all non-food use chemicals.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of butralin. The document consists of six sections. Section I is the introduction. Section II describes butralin, 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 butralin. Section V discusses the reregistration requirements for butralin. 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

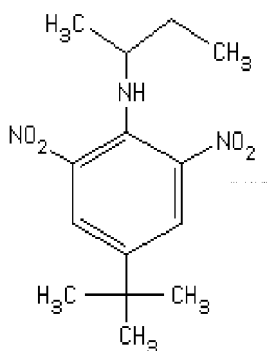
The active ingredient butralin is covered by this Reregistration Eligibility Decision. The product, CFPI Technical Butralin, is the technical grade active ingredient (TGAI) and contains the active ingredient chemical butralin. There is one end use product containing butralin.

Butralin is used as a plant grow regulator on tobacco after the tobacco is topped. All tobacco is topped to stimulate desirable chemical and physical characteristics but also stimulates the growth of suckers. Butralin is a contact-local systemic type of plant growth regulator that inhibits sucker growth.

- **Common Name:** Butralin
- **Chemical Name:** 4-(1,1-dimethylethyl)-N-(1-methylpropyl)-2,6-dinitrobenzeneamine
(CAS Name)

N-sec-butyl-4-tert-butyl-2,6-dinitroaniline
(IUPAC Name)

- **Chemical Structure:**



Butralin

- **Chemical Family:** Dinitroaniline
- **CAS Registry Number:** 33629-47-9
- **OPP Chemical Code:** 106501
- **Empirical Formula:** C₁₄H₂₁N₃O₄

- **Molecular Weight:** 295.34
- **Trade and Other Names:** Technical Butralin
Tamex 3EC
- **Basic Manufacturer:** CFPI (Compagnie Francaise de Produits Industriels)
Agro SA

B. Use Profile

The following is information on the currently registered tobacco use with an overview of use sites and application methods. A more detailed table of the use parameters of butralin on tobacco is found in Appendix A.

For Butralin:

Type of Pesticide for Single Active Ingredient:

Herbicide; Plant Regulator

Use Sites: Terrestrial Non-Food Crop
Tobacco

Types/Formulations Registered:

Manufacturing Product
Waxy Solid 98.8%

End Use Product
Emulsifiable Concentrate 36.5%

Method and Rates of Application:

Equipment - Sprayers

Method and Rate

- Knapsack (pump) sprayer - 1.08 lb/acre
- Jug Application - 1.08 lb/acre
- Handheld dripline - 3.00 lb/acre
- Motorized sprayers - 3.00 lb/acre

Timing - Bloom. After spraying with contact herbicides such as fatty alcohols for sucker control, butralin is used with a systemic herbicide such as maleic hydrazide for continuous sucker suppression.

Use Practice Limitations: One application per growing season. There is a twelve hour re-entry restriction following treatment. There is a preharvest interval

of 7 days for flue-cured tobacco and 30 days for air-cured (burley or Maryland) tobacco.

Butralin is a plant growth regulator that provides extended control of initiation and growth of unwanted vegetative buds in the axils of tobacco plants after topping. If not controlled, these buds will rapidly develop into "suckers" which compete with the leaves for sunlight and nutrients and interfere with curing of air-cured tobacco. The large suckers are expensive to remove by hand prior to harvest and if not removed will result in incomplete and inconsistent curing of marketable leaves causing reduced quality and marketability after curing.

Butralin is applied through commercial equipment by using motorized field sprayers directing a coarse spray that runs down the stalk. It may also be applied to individual plants by using a hand-held dropline, knapsack sprayer, or jug application.

Butralin can be used in a crop management regime that first applies "fatty alcohols" followed by maleic hydrazide. The fatty alcohols kill buds present on the day of the treatment but have no effect on new buds which develop within days after treatment. Maleic hydrazide is a systemic compound which provides longer hormonal effects than fatty alcohols but often does not provide the season long control of buds and suckers which tobacco growers need. By using butralin in sequence with fatty alcohols and/or in combination with maleic hydrazide growers will be able to obtain season long control of sucker growth without resorting to repeated treatments of maleic hydrazide which might result in excessive residues of maleic hydrazide in cured tobacco leaves. Tobacco is usually moved from field to field every year and is grown in rotation with grasses that are tilled back under prior to planting other crops.

C. Data Requirements

There was a December 19, 1984 Data Call-In for Chronic Toxicology studies. When the accelerated reregistration program started under the revisions of FIFRA in 1988, the Phase 2 Data Call-In was issued in 1990. In response, the registrant requested low volume minor use waivers and noted that the turf and ornamental grass use did not trigger most data requirements.

Data required in the Phase 3 Data Call-In of 1991 included new or additional product chemistry, a reduced set of ecological effects, environmental fate, toxicology and spray drift data. During the reregistration process the tobacco use was registered in various states and a conditional Section 3 registration was approved in November 1996. Appendix B includes all data requirements identified by the Agency to support reregistration.

D. Regulatory History

Butralin was first registered in April 1973 for use on turf by Amchem Products, Inc. Amchem Products had been issued an experimental use permit for tobacco field testing in 1971-1973. In 1975 through 1976, preemergent uses of butralin were registered on lima beans, cottonseed, southern peas, soybeans, and watermelon. Amchem Products was acquired by Union Carbide Agricultural Products Company, Inc. in 1977 as a wholly owned subsidiary. In 1985, Union Carbide sold their butralin registrations to CFPI. They remain the sole registrant for products containing butralin. An experimental use permit was issued October 1986 to CFPI who intended to register butralin for use in the United States. At the time butralin had been in use in tobacco production overseas. In January 1991, Amex Preemergence Herbicide (33688-3), the registration for the use of butralin on lima beans, cottonseed, southern peas, soybeans, and watermelons was cancelled. Weedone No Crab (33688-1), registered for use on turf and ornamental grasses was voluntarily cancelled in March 1997. In November 1994, butralin was registered for use on burley tobacco in the States of North Carolina, Tennessee, and Virginia. Use on burley tobacco in the State of Kentucky was registered in June 1996. The use on tobacco was amended in November 1996 to add use on flue-cured tobacco and to allow use in any tobacco growing state. At this time, Tamex 3-EC, is the only registered end use butralin product.

Currently, there are two active products containing butralin which are registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act. They consist of one technical (manufacturing use) product containing 98.8% active ingredient and one emulsifiable concentrate end-use product containing 36.5% active ingredient.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Butralin, the active ingredient in reregistration Case 2075, is assigned CAS #33629-47-9 and the isolated technical has the following physical and chemical properties: melting point 59-61°C; vapor pressure 5.79×10^{-6} mm Hg at 30 C. The octanol/water partition coefficient is Log P = 4.93. The dissociation constant and pH are not known due to very low water solubility at 0.3 ppm. Other solubility values are:

<u>Solvent</u>	<u>Solubility (grams/100g)</u>
Methanol	9.8
Ethanol	7.3
Isopropanol	8.4
Benzene	270.0
Ethylene dichloride	146.0
Acetone	448.0
Water	0.3 ppm

The product identity and composition data requirements for the reregistration of the isolated technical ingredient for guideline series 61 were satisfied by MRIDs 40979802 and 41225203. The analysis and certification of product ingredients data requirements for guideline series 62 were satisfied by MRIDs 40979801 and 41225202. The physical and chemical characteristics data requirements for guideline series 63-2 through 63-13 were satisfied by MRIDs 40979801, 41225201, 41225202, 41784101 and 42616401. The additional data requirements 63-14, 63-15, 63-16, 63-17, 63-18, 63-19, 63-20 and 63-21 will be satisfied by the submission of acceptable product specific data being called in as part of this RED.

B. Human Health Assessment

1. Toxicology Assessment

The toxicology studies reviewed in this human health risk assessment satisfy established guideline requirements for a non-food use pesticide. The butralin toxicology database requirements are satisfied.

a. Acute Toxicity

Table 1: Acute Toxicity of Butralin TGAI

Study	Results	Classification
GLN 81-1 MRID 42112701	Gavage LD50 for male rats 1169.5 mg/kg (914.4 - 1495.9); for females 1049.0 (818.4 - 1345.1). Signs included ruffled coats, lethargy, tremors and diarrhea. Necropsy included dark lungs, oily fluid in the stomach and yellowish stains in the intestine and fat, and ocular and nasal secretions.	III
GLN 81-2 MRID 42660701	Dermal LD50 greater than 2000 mg/kg. Erythema was seen on day 2. Necropsy was unremarkable.	IV
GLN 81-3 MRID 42488201	Acute inhalation: butralin (technical) dissolved in Solvarex 90/180 (naphtha solvent) at 5.24 mg/L for 4 hours produced no deaths.	IV
GLN 81-4 MRID 42488201	Eye irritation using 0.1 gram in eye produced mild to severe irritation up to day 2.	III
GLN 81-5 MRID 42020702	Dermal irritation to 0.5 gram of undiluted technical butralin produced no dermal irritation.	Non-irritant
GLN 81-6 MRID 42660601	Dermal sensitization (Buehler method) using 75% butralin in corn oil for induction and challenge produced no sensitization.	Non-sensitizer

b. Subchronic Toxicity

GLN 82-1. A subchronic toxicity 4 week dose-range-finding study (MRID 43626401), submitted as part of a 90-day rat feeding study (MRID 43652701) was reviewed. This study was determined acceptable for establishing the dosing levels used in the 13 week study. In the range-finding study butralin technical (99% a.i.) was administered in the diet of

Sprague-Dawley rats (5/sex/dose) at dose levels of 0, 2, 10, 50, 250 mg/kg/day for 4 weeks.

No deaths occurred in any of the experimental groups studied. Butralin stained the urine and tissues in the 50 and 250 mg/kg/day dose group animals. Body weights of the high dose animals were reduced by 22-26%, a difference which is not statistically significant from control animal data. Clinical chemistries, hematology or urinalyses were not carried out. At necropsy, the yellow staining by butralin was seen in the subcutaneous and fatty tissue of the 50 and 250 mg/kg/day dosage group animals. Centrilobular hypertrophy was seen in the high dose group males (3/5) and females (4/5). Based on these results in the range-finding study, a dosing level of 200 mg/kg/day was chosen for the top dose in the 13 week feeding study.

GLN 82-1a: In a 90-day subchronic feeding study (MRID 43652701), butralin technical (99% a.i.) was administered to Sprague-Dawley rats (10/sex/dose) in the diet at dose levels of 0 (G1), 10 (G2), 50 (G3) and 200 (G4) mg/kg/day for 13 weeks. Ten additional animals/sex/dose group from the control and high dose groups were carried for 4 weeks beyond the 13 week exposure period as recovery test groups.

Estimated actual dosages to 10.3 mg/kg/day for low-dose animals; 51 mg/kg/day for mid-dose animals; and 202 mg/kg/day for the high-dose animals. There were no mortalities or toxic signs in any of the test animals. Animals in all of the butralin treated groups displayed yellow coloring in the urine and in fat and various tissues at necropsy. The yellow coloring was due to the color of butralin and decreased in the recovery period, persisting only in the high-dose group by the end of the recovery period. Body weight reductions were observed in high-dose males (-17%) and females (-23%) and -14% in mid-dose males. Food consumption was also reduced: -11% for high-dose males, -7% for high-dose females and -9% for mid-dose males. During the recovery period, the high-dose animals gained weight faster than the control animals while consuming about the same amount of food during this 4 week period. There was no effect on water intake which was estimated visually.

There were statistically significant alterations in several clinical chemistry values seen primarily in high-dose males and females as statistically significant changes and often as similar changes in mid-dose animals without achieving statistical significance. The following clinical chemistry changes were statistically significant (with p ranging from < 0.05 to 0.001): Gamma glutamyl transferase (GGT) was elevated by +100% in mid-dose females and +200% in high-dose females. The GGT

elevations reverted to normal by the end of the 4 week recovery period. Total protein and albumin was elevated in high-dose females (+12%) and males (+8%) and also low-dose males (+3%) and males (+6%). Urea was decreased in mid-dose males (-10%) and high-dose males (-13%). Aspartate amino transaminase was decreased in the high dose males (-28%) and mid-dose females (-24%) and males (-24%). Alanine amino transaminase was decreased in females of the low-dose group (-20%), in mid-dose group females (-27%) and in females of the high-dose group (-40%). Total bilirubin was increased in the high-dose females (+66%) and was also elevated after the recovery period. Calcium was increased in the high-dose females (+6%). Glucose was decreased in the high-dose females (-14%).

Liver weights were elevated in the mid-dose males (+40%), in the mid-dose females (+11%) and in the high-dose females (+39%). The liver weight elevation persisted only in the high-dose females (+14%) at the end of the 4 week recovery period. Centrilobular hypertrophy of the liver increased from 1/10 in the control males to 3/10, 6/10 and 9/10 in the low-, mid- to high-dose males, respectively, achieving statistical significance only in the high-dose group. Eight of 10 males and 9/10 females in the high-dose group had normal thyroids by the end of the recovery period. Control animals 2/10 males and 2/10 females exhibited minimal hyperplasia (grade +\-) of the thyroid as did 1/10 high dose females by the end of the recovery period (week 17). Other organ weight changes were statistically significant in the adrenals, heart, kidney, and spleen but occurred as isolated findings without corresponding morphological changes.

Many of the toxic signs seen in the high dose animals at the end of the 13 week treatment period were reversed or tended toward reversal by the end of the 4 week recovery period. These included changes in body weight, hematology, clinical chemistry, organ weight changes and histopathology.

The NOEL for this study was 10 mg/kg/day. The LOEL was the 50 mg/kg/day based on body weight and food consumption reductions; reduced RBCs, Ht and Hb; and alterations in liver and thyroid organ weights.

GLN 82-2. In a 21-day rabbit dermal toxicity study (MRID 40419601), butralin technical (95% a.i.) was administered topically to the clipped dorsal trunk and flanks (intact skin) of New Zealand White rabbits (5/sex/dose) as granular material applied wet (distilled water) to the skin

at daily dose levels of 0 and 1000 mg/kg/day for 5 days/week for a 3-week period.

The only clinical sign observed was yellow/orange staining of the treatment site. There were no signs of toxicity or effects on body weights or food consumption. Hematology, urine analysis, macroscopic pathology and histology, and organ weights were considered to be unremarkable. Adrenal glands of treated males and females were somewhat enlarged, however there were no morphological changes noted.

The NOEL was considered to be greater than 1000 mg/kg/day, the limit dose. This 21-day dermal toxicity study is classified acceptable and does satisfy the guideline requirement for a 21-day dermal toxicity study in the rabbit.

GLN 82-4. A subchronic 13 Week inhalation toxicity study was conducted (MRID 42633601,-03) using butralin in Solvarex 90/180, a proprietary solvent. The study data were submitted to fulfill the 90 day subchronic inhalation toxicity data requirement. The use of "Solvarex" in the administered butralin dose, when considered along with the strong presence of histopathological changes in both the test and vehicle control test animals, resulted in the study being initially classified as "inadequate". The registrant submitted additional test data for the 90-day subchronic inhalation toxicity study which resolved concerns related to the use of Solvarex to "aerosolize" butralin in the administered dose. The study was upgraded to "acceptable".

In the submitted study (MRID 42633601), butralin was administered by the nose-only inhalation route to male and female Fischer F-344 rats (10 animals/sex/group) at concentrations of 0.3, 1.0 and 3.0 mg/L for 6 hours/day, 5 days/week for 13 weeks. Air and vehicle control groups were included.

The animals were restrained in cylindrical tubes with their heads protruding through head ports into a 360 ml flat polycarbonate cylinder exposure chamber. A collision nebulizer was used to generate the test atmospheres which were directed into the exposure chamber. Technical butralin (99.6% a.i.) was dissolved in the Solvarex 90/180 at a concentration of 363 grams butralin/liter of solvent. Analytical exposure concentrations in the chamber were derived from gravimetric filter samples which were analyzed for butralin. The exposure particle sizes ranged from 2.81 to 3.41 micrometers, slightly exceeding the acceptable range of 1-3 micrometers for subchronic studies.

There were no deaths resulting from the administration of the test agent. All animals treated with butralin developed yellow fur. Body weight differences from air control groups were seen only in the high dose animals (male and female) and in the vehicle control animals (male and female). Significant differences from air control animals were seen in all for animals in the vehicle controls and all of the butralin treated animals. These changes included: hematology parameters (primarily related to RBCs (red blood cell counts)); several blood chemistry parameters (calcium (Ca), phosphorous (P), alkaline phosphatase (ALP) and glucose (GLU)); organ weights changes (liver, kidney, adrenal and testes); and a variety of histopathologic findings. The lesions which appeared dose related included respiratory epithelium hyperplasia, nasal pharyngeal duct goblet cell hyperplasia, nasal submucosal edema; liver hepatocyte hypertrophy and cytoplasmic alteration; renal tubular epithelium cytoplasmic droplets; and tracheal hyperplasia. Much of the histopathological changes were seen strongly represented in the vehicle controls and dose related in the butralin treated groups. The NOEL = 0.3 mg/L and the LOEL = 1.0 mg/L based on histopathological effects in the nasal passages, on hematological, clinical chemistry, and histopathology (much of which was based on the respiratory system, the liver and kidney).

c. Chronic Toxicity

Based on the current use pattern of butralin, chronic toxicity data are not required. If in the future additional butralin uses are requested, the Agency may require additional studies.

d. Carcinogenicity

The Agency determined that data were insufficient to evaluate the carcinogenic potential of butralin. Because butralin is a non-food use chemical, chronic data to determine its carcinogenic potential are not required.

e. Developmental Toxicity

GLN 83-3a. In a rat developmental toxicity study (MRIDs 40419603, 42156101, -02 and -03) butralin (96% a.i.) was administered by gavage at 0, 500, 1250 or 2000 mg/kg/day. Maternal toxicity was demonstrated by a statistically significant decrease in body weight and body weight gain at the mid-dose tested (MDT) and high dose tested (HDT). Food consumption and relative efficiency of food utilization was depressed at these same dose levels. Mortality occurred in 2 dams at the HDT. Maternal toxicity was also demonstrated by the 2 and 4 dams aborting at

the MDT and HDT, respectively. In addition, vaginal bleeding occurred in 4 and 6 dams at the MDT and the HDT respectively. Maternal toxicity was less clear at the low dose tested (LDT) were statistically significant decreases occurred in food consumption and nominally, in relative efficiency of food utilization. The maternal toxicity LOEL = 500 mg/kg/day (LDT); a maternal toxicity NOEL was not established.

Malformations were slightly elevated at the MDT and HDT, such as incomplete ossification of the palate and presphenoidal bone, absent sacral vertebrae, and dilated brain ventricles. Statistical analyses of these defects may have indicated a significant increased trend, but no statistical analyses were conducted on these defects, thus the compound relatedness can not be determined. Fetal toxicity was demonstrated at all dose levels. At the LDT and higher, sternbrae 2, 4 and 6 demonstrated delayed ossification and ossification was absent in sternbrae 5 and 6 in the thoracic vertebral centrum 1 and in the caudal vertebral arches. Additional delays and/or absent ossification occurred at higher dose levels. The developmental toxicity LOEL = 500 mg/kg/day (LTD); a developmental toxicity NOEL was not established.

A repeat study (MRIDs 40419602 and -03 and 41742003) was carried out at 0 and 50 mg/kg/day in order to establish a NOEL for the above study. The developmental and maternal NOEL was 50 mg/kg/day; the LOELs for these parameters were greater than 50 mg/kg/day, the only treatment level used. Data from the two studies combined satisfy the guideline requirement for a rat developmental toxicity study.

GLN 83-3b. In a rabbit developmental study (MRIDs 40419601, 41742002 and 42156104) rabbits were administered butralin (97% a.i.) at 0, 8.2, 27.4, or 128 mg/kg/day. The study demonstrated maternal toxicity in the form of decreased body weight and decreased body weight gain, decreased food consumption and decreased efficiency of food utilization. The maternal toxicity NOEL = 8.2 mg/kg/day; the maternal toxicity LOEL = 27.4 mg/kg/day. Fetal toxicity was demonstrated at the MDT and HDT in the form of slight but probable dose related increases in 5 major defects: enlarged fontanelles, one heart defect, a malrotated hind limb, arthrogryposis (major and minor) and scoliosis. The major heart defect was seen in one pup in one litter at the highest dose group. In addition, a probable dose related and compound-related increase was observed in 1) atrium/atria increased size, 2) incomplete closure of abdominal muscular layer, 3) parietals incompletely ossified, 4) spatulate ribs, 5) kinked ribs, 6) fused sternbrae, 7) other anomalies in the ossification of sternbrae, and 8) incompletely/not ossified metacarpals, forelimb phalanges and hindlimbs phalanges. The incidence of these eight

(8) anomalies in fetuses of this study were each higher than historical control data submitted with the study. When these major defects and minor anomalies are considered together, a pattern of increased effects and toxicity appear at the MDT and HDT. The developmental NOEL = 8.2 mg/kg/day; the developmental LOEL = 27.4 mg/kg/day. The study is acceptable.

In the prenatal developmental toxicity study in rats, developmental toxicity (delays or absence in ossification of sternebrae, absence of ossification in thoracic vertebral centra and caudal vertebral arches) was observed in the presence of significant maternal toxicity (increased mortality, abortions, and vaginal bleeding; decreases in body weight gain and food consumption). In contrast, in the rabbit prenatal developmental toxicity study, developmental toxicity (enlarged heart, malrotated hindlimb, and scoliosis) occurred in the mid- and high-dose groups (27.4 and 128 mg/kg/day) in the absence of significant maternal toxicity (decreased body weight and decreased body weight gain).

Based on the results of these studies, the possibility of increased prenatal sensitivity to butralin cannot be ruled out. However, we have no concerns regarding infants' or children's risk to butralin for the following reasons: (1) the registration for turf use was canceled March 1997 so there should be no exposure of infants or children to butralin; (2) MOEs for all butralin use scenarios for which data are available are extremely high indicating that exposures for children would not be of concern; (3) there is no toxicity endpoint for short-term (1-7 day) exposure; further, there would be no intermediate term (one week to several months) exposure scenario for children; since there is no infant's or children's exposure scenario for which a toxicity endpoint has been identified, significant risk to infants and children is unlikely; (4) there was no evidence of increased prenatal or postnatal sensitivity in either the developmental toxicity or the three-generation reproductive toxicity study in rats; and, (5) exposures, should they occur, would be of a dermal nature, whereas in the developmental toxicity study of concern, butralin was administered to the maternal rabbits by gavage.

f. Reproductive Toxicity

Reproductive toxicity data have not been required to support the reregistration of the non-food uses of butralin. In a preliminary Agency review of a three-generation reproduction study in rats (MRIDs 92014039 and 00154259), toxicity in the offspring (decreased pup survival during the lactation period, in association with decreased mean pup weights) was observed in the presence of parental toxicity (decreased body weight) in all three generations at the HDT (1000 ppm; 50 mg/kg/day). The NOELs for the parental rats and their offspring appear to be equivalent (6 mg/kg/day).

g. Mutagenicity

GLN 84-2. The mutagenicity data evaluation concluded that butralin exhibits mutagenic activity in the in vitro studies conducted. Butralin is structurally related to trifluralin, a known carcinogen (see NTP Technical Report No. 34, 1977 ; EPA Peer Review, 1986, Doc. No. 005578/007362). Trifluralin exhibits a mutagenic profile in the Ames test (pre-incubation modification) that is similar to butralin (i.e., positive in S. typhimurium strain TA 100 only in the presence of S9 activation and only at high precipitating doses). With the exception of the positive results for butralin in the mouse lymphoma assay, the overall genetic toxicology profile for the two compounds is similar.

The following studies satisfy guideline requirements (GLN 84-2) for gene mutations:

Gene Mutations

Salmonella typhimurium reverse gene mutation assay (MRID 40121101): Eight concentrations of butralin (1.0 to 10,000 $\mu\text{g}/\text{plate}$) were evaluated in two independent Salmonella typhimurium microsome mutagenicity assays. Results indicated that at high precipitating concentrations (5000 and 10,000 $\mu\text{g}/\text{plate}$), the test material induced reproducible and dose-related increases (1.8 to 2.0- and 2.2 to 2.4-fold, respectively), in revertant colonies of S. typhimurium TA100 in the presence of S9 activation. It was therefore concluded that butralin was mutagenic in this test system. The study is acceptable.

Mouse lymphoma L5178Y TK^{+/−} forward gene mutation assay (MRID 40121102): Butralin was assayed over a concentration range of 7.5 to 50 $\mu\text{g}/\text{mL}$ without S9 activation and at doses ranging from 7.5 to 60 $\mu\text{g}/\text{mL}$ with S9 activation in independent mouse lymphoma forward mutation assays. Without S9 activation, increased mutant colonies and mutation frequencies (MFs) were seen at 40, 45 and 50 $\mu\text{g}/\text{mL}$; cell survival at these levels was 23.2, 7.7, and 6.5%, respectively. In the presence of S9 activation, mutagenic activity was confined to the highest dose; however, less than 10% of the cells survived treatment. Based on the reproducibility of the results, the increased MFs, which were accompanied by increased mutant colony counts, and the evidence of a dose-related effect under non-activated conditions, it was concluded that butralin is mutagenic in this test system; metabolic activation was not required. The study is acceptable.

Chinese hamster ovary (CHO) cell HGPRT gene mutation assay (MRID 40551909): Butralin was negative in the Chinese Hamster ovary (CHO)

cell HGPLT gene mutation assay with and without S9 activation at up to cytotoxic concentrations. The compound was insoluble at concentrations to or greater than 100 µg/mL without S9, and equal or greater near 70 µg/mL with S9. The study is acceptable.

Chromosome Aberrations

In vitro CHO cell chromosome aberration assay (MRID 40551910): Under the conditions of this assay, four doses of butralin ranging from 25 to 1000 µg/mL with or without S9 activation did not induce a clastogenic response in the chromosomes of Chinese hamster ovary (CHO) cells harvested 20 hours after nonactivated dosing or 10 hours after treatment in the presence of metabolic activation. The test material was assayed up to an acceptable cytotoxic dose (100 µg/mL), which approached the limit of solubility (100 µg/mL/-S9; 75 µg/mL/+ S9), with no clastogenic effect. The study is acceptable and satisfies guideline requirements (GLN 84-2) for chromosome aberrations.

GLN 84-4. Other Mutagenic Mechanisms

In vitro unscheduled DNA synthesis in primary rat hepatocytes (MRID 40350901): Primary rat hepatocytes from Fischer 344 males were exposed for 18 hours to butralin in DMSO (94.5% a.i.) at 10 concentrations ranging from 0.5 to 150 µg/mL. The HDT proved to be lethal; precipitation was evident at 25 µg/mL and above. There was no evidence of induced DNA repair (as determined by net nuclear silver grain counts, which measures unscheduled DNA synthesis) at any dosage up to 75.1 µg/mL, a severely toxic (6.6% relative survival) dose. The positive control (2-AAF) responded appropriately. The study is acceptable.

In vitro CHO cell sister chromatid exchange assay (SCE) (MRID 40121103): Under conditions of two independent sister chromatid exchange (SCE) assays, butralin over a concentration range of 2.5 to 30 µg/mL without S9 activation and 5 to 80 µg/mL with S9 activation did not induce a reproducible increase in the SCE frequency of Chinese hamster ovary (CHO) cells. The test material did, however, induce severe mitotic suppression, and prolonged cell harvests were required for high test doses. Although significant ($p < 0.05$) increases in the SCE frequency were seen in the initial assay (highest nonactivated and S9-activated doses), the response occurred at severely cytotoxic doses, was not reproducible, and did not show a dose-response relationship. It was therefore concluded that butralin was assayed to levels inducing cytotoxicity with no genotoxic effects.

These studies satisfy the guideline requirements (GLN 84-4) for other genotoxic effects.

Other Studies: An unclassified mouse dominant lethal assay (MRID 00078460) is listed in the one-liners as negative up to 1000 mg/kg/day (HDT); no further information was available.

h. Metabolism

GLN 85-1. In a metabolism study (MRID 42743201), rats were dosed by gavage with butralin (ring labeled) in corn oil at 8 mg/kg/day (low dose levels) for single and multiple dosing and biliary excretion studies and at 800 mg/kg/day (high dose single dosing) and the distribution and excretion of butralin followed over a 7 day period. Low dose results indicate that about 100 percent of the dosed material was excreted in about 2 days, with 55 to 60% excreted in the feces and 35-45% in urine. The feces contained about 10% unmetabolized butralin. The excretory half life was about 12 hours. Tissues retained only about 1% of the labeled butralin. A similar excretion pattern was seen in the repeat low dose group.

High dose administration of butralin took 5-7 days to achieve 100% excretion of butralin in the urine and feces. The excretory half life was between 2 and 4 days. Of the various tissues, fat and liver tended to retain more butralin residues. Females excreted the butralin residues more slowly than males and retained more metabolite in the tissue (especially the liver and fat).

In a bile excretion study using low dose levels (8 mg butralin/kg), enterohepatic circulation was determined to be a primary pathway for butralin excretion and metabolism. Twelve butralin metabolites were identified in pooled urine, feces and/or bile samples. Metabolites identified at concentrations of 5% to 10% of the administered dose were: 2-methyl-5(6)[1-(1-carboxy-1-methyl)ethyl]-7(4)-nitrobenzimidazole, 2-methyl-5(6)[2-(1-hydroxy-2-methyl)propyl]-7(4)-nitrobenzimidazole, 2-methyl-2(4-amino-3,5-dinitrophenyl)propionic acid and 2-methyl-2(4-amino-3,5-dinitrophenyl)propanol-glucuronide. Butralin, the parent chemical, was present at 10% of the administered dose. There were no metabolites at concentrations greater than 10% of the administered dose identified in the study. The Agency determined the study satisfies the guideline requirement for a metabolism study in rats.

i. Other Toxic Endpoints

Neurotoxicity

Neurotoxicity studies were not required or evaluated in this risk assessment.

Incident Data

No information is available on incidents related to the use of butralin from any of the available databases reviewed.

Potential Risks to Infants and Children

Butralin is not registered for food uses nor is it available for use in the residential setting.

j. Dose Response Assessment

Reference Dose

A Reference Dose (RfD) for butralin is not warranted for the current non-food use pattern of this pesticide. However, if the use pattern and/or registrations change exposure to butralin an RfD determination may be required (RfD Peer Review Committee, September 1996).

Carcinogenicity Classification

A carcinogenicity classification was not determined due to insufficient data to evaluate the carcinogenic potential of butralin (RfD Peer Review Committee, September 1996).

k. Toxicological Endpoints for Risk Assessment

In July 1996 the Toxicological Endpoint Selection Committee met and established endpoints for use in acute dietary and worker risk assessments. The conclusions of the committee are summarized in Table 2 below.

Table 2: Toxicological Endpoints for Butralin

Type and Duration of Exposure	Toxicological Endpoint and Effect	Route of Exposure
Acute Dietary	None. An acute dietary risk assessment is not required since butralin is a non-food-use chemical.	Oral
Short Term Occupational Exposure (1 to 7 days)	A short-term risk assessment is not required; no systemic toxicity was observed at 1000 mg/kg/day in a 21-day dermal rat study.	Dermal
Intermediate Term Occupational Exposure (1 week to several months)	10 mg/kg/day NOEL based on decreased body weight and food consumption, alterations in hematology and clinical chemistry seen at 50 mg/kg/day LOEL in a 13-week rat feeding study. A dermal absorption value of 5% should be used for route-to-route extrapolation.	Dermal
Any Exposure Duration	0.3 mg/L NOEL (80.2 mg/kg/day) based on histopathological effects in nasal passages seen at 1.0 mg/L LOEL in a 90-day rat inhalation study.	Inhalation

Dermal Absorption

A dermal absorption study was not available. A dermal absorption value of 5% was calculated based on the route-to-route extrapolation using the maternal NOEL of 45 mg/kg/day from the developmental toxicity study in rabbits and the systemic NOEL of 1000 mg/kg/day from the 21-day dermal toxicity study in rabbits. The calculated value of 5% for butralin is comparable to the 1% dermal absorption value estimated for trifluralin, a compound structurally similar to butralin. This dermal absorption value will be used for intermediate-term risk assessment since oral studies were selected for this exposure scenario.

A short term (1-7 days) occupational dermal exposure endpoint of toxicological concern was not established. The intermediate term (1 week to several months) occupational dermal exposure endpoint is a NOEL of 10 mg/kg/day observed in a 90-day subchronic rat feeding study. A risk assessment of intermediate term dermal exposure is required.

Inhalation

Based on the physical/chemical properties of butralin (e.g. low volatility) and the formulation/application methods (e.g. no exceptionally high applicator exposure such as from air blast applications), the Agency would not anticipate any mixer/loader/applicator concerns. However, the Agency's database does contain a 90-day rat inhalation study which was evaluated as part of the reregistration process. These data show, as one would expect, that margins of exposure are very high. Inhalation MOEs are in the tens of thousands for all mixer/loader/applicator scenarios.

Based on the tobacco use pattern chronic worker exposure (several months-lifetime) is not expected to occur. The Agency has determined that a risk assessment for chronic occupational exposure is not required at this time.

2. Exposure Assessment

a. Food Source

The currently registered tobacco use of butralin does not result in dietary exposure. Tobacco is never fed to cattle, goats, pigs or any known ruminants since the tobacco is unpalatable and the nicotine in tobacco makes the animals sick.

b. Drinking Water Source

Ground Water: Butralin is persistent but relatively immobile in terrestrial environments. Based upon qualitative leaching index and mobility studies, butralin is not expected to leach into ground water.

Surface Water: Butralin detections were not reported in STORET. Based on the Tier I GENECC EEC, the peak EEC for butralin is 16.89 $\mu\text{g/L}$. A more reliable surface water characterization will be determined when additional batch equilibrium data are received and evaluated. Neither a maximum contamination level (MCL) nor Lifetime Health Advisory Level (HAL) has been established for butralin. The Agency believes foliar interception and subsequent foliar dissipation processes will affect the magnitude of butralin residues available for surface water runoff. Butralin residues that are oversprayed or washed off from the treated plants are likely to be the only butralin residues available for runoff into surface waters.

Considering the limited potential for butralin residues in ground and surface water, butralin drinking water contamination is not expected to be a dietary risk concern.

c. Occupational Exposure Assessment/Characterization Assessment

Handler Exposures & Assumptions

The Agency has determined there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with butralin. Based on the current registered use patterns five (5) major exposure scenarios were identified for butralin:

- (1) mixing/loading liquids for groundboom application.
- (2) applying sprays with groundboom equipment.
- (3) mixing/loading/applying liquids with a backpack sprayer.
- (4) mixing/loading/applying liquids with a low-pressure handwand.
- (5) jug application of liquids.

Post Application Exposure & Assumptions

Occupational: The Agency has determined that there is an exposure potential for persons entering treated sites after application is complete. Workers may be entering treated tobacco areas to perform hand-suckering (hand-labor task) as a supplement to the chemical-suckering treatment. There are no chemical-specific data available upon which to assess the risks from post-application exposures.

3. Mixer/Loader/Applicator Exposure Assessment

Potential daily exposure is calculated using the following formula:

$$\text{Daily Exposure} \left(\frac{\text{mg ai}}{\text{Day}} \right) = \text{Unit Exposure} \left(\frac{\text{mg ai}}{\text{lb}} \right) \times \text{Max. Appl. Rate} \left(\frac{\text{lb ai}}{\text{Acre}} \right) \times \text{Max. Area Treated} \left(\frac{\text{Acres}}{\text{Day}} \right)$$

The calculations of daily exposure to butralin by handlers are used to calculate the daily dose to those handlers. Intermediate-term dermal and short- and intermediate-term inhalation exposure assessments using PHED Version 1.1 surrogate data are presented in Table 3. No chemical-specific data were submitted.

Table 3: Intermediate-Term Dermal and Inhalation Exposure Estimates for Butralin

Exposure Scenario (#)	Baseline Dermal Unit Exposure (mg/lb a.i.) ^a	Baseline Inhalation Unit Exposure (μg/lb a.i.) ^b	Application Rate (lb a.i./acre) ^c	Daily Acres Treated ^d	Daily Dermal Exposure (mg/day) ^e	Daily Inhalation Exposure (mg/day) ^f
Mixer/Loader Exposure Estimates						
Mixing/Loading Liquids for Groundboom Application (1)	2.9	1.2	3.0	80	696	0.29
Applicator Exposure Estimates						
Groundboom Application (2)	0.015	0.7	3.0	80	3.6	0.17
Mixer/Loader/Applicator Exposure Estimates						
Backpack Sprayer(3)	No data (see additional PPE)	30.2	3.0	1	No data (see additional PPE)	0.09
Low Pressure Handwand (4)	103.8	31.2	3.0	1	311	0.09

Scenario (4) also represents jug application method.

No data means no data are available for hand exposure.

^a Baseline dermal unit exposure represents long pants, long sleeve shirt, no gloves, open mixing/loading, open cockpit, open cab tractor.

^b Baseline inhalation exposure represents no respirator.

^c Application rates are maximum values found on butralin label [EPA Reg. No. 33688-4].

^d Daily acres treated values are from EPA OREB estimates of acreage that could be treated in a single day for each exposure scenario of concern.

^e Daily dermal exposure (mg/day) = Exposure (mg/lb a.i.) * Appl. rate (lb a.i./A) * Acres Treated.

^f Daily inhalation exposure (mg/day) = Exposure (μg/lb a.i.) * (1mg/1000 μg)conversion * Appl. Rate (lb a.i./A)

* Acres Treated

a. Occupational Risk Assessment/Characterization

Risk from Dermal and Inhalation Exposures

Dermal: The daily dermal dose is calculated using a 70 kg body weight in the following formula:

$$\text{Daily Dermal Dose} \left(\frac{\text{mg ai/kg}}{\text{Day}} \right) = \text{Daily Dermal Exposure} \left(\frac{\text{mg ai}}{\text{Day}} \right) \times \left(\frac{1}{\text{Body Weight (kg)}} \right) \times 5\% \text{ dermal absorption}$$

These calculations of daily dermal dose of butralin received by handlers are used to assess the dermal risk to those handlers. The intermediate-term dermal MOEs were calculated using a NOEL of 10 mg/kg/day in the following formula:

$$\text{MOE} = \frac{\text{NOEL} \left(\frac{\text{mg/kg}}{\text{day}} \right)}{\text{Daily Dermal Dose} \left(\frac{\text{mg/kg}}{\text{day}} \right)}$$

Inhalation: The daily inhalation dose is calculated using a 70 kg body weight in the following formula:

$$\text{Daily Inhalation Dose} \left(\frac{\text{mg ai/kg}}{\text{Day}} \right) = \text{Daily Inhalation Exposure} \left(\frac{\text{mg ai}}{\text{Day}} \right) \times \left(\frac{1}{\text{Body Weight (kg)}} \right)$$

These calculations of daily inhalation dose of butralin received by handlers are used to assess the inhalation risk to those handlers. The inhalation MOEs were calculated using a NOEL of 80.2 mg/kg/day in the following formula:

$$\text{MOE} = \frac{\text{NOEL} \left(\frac{\text{mg/kg}}{\text{day}} \right)}{\text{Daily Inhalation Dose} \left(\frac{\text{mg/kg}}{\text{day}} \right)}$$

Table 4 presents the risk assessment for intermediate-term dermal and short- and intermediate-term inhalation exposures. The caveats and parameters specific to each exposure scenario and corresponding risk assessment are summarized in Table 5.

Table 4: Intermediate-Term Dermal and Short-Term Inhalation Risk Estimates for Butralin for Baseline and Using Risk Mitigation Measures

Exposure Scenario (Scenario #)	Baseline Absorbed Dermal Dose (mg/kg/day) ^a	Baseline Absorbed Dermal MOE ^b	Baseline Inhalation Dose (mg/kg/day) ^c	Baseline Inhalation MOE ^d	Risk Mitigation Measures (Additional PPE)		
					PPE Dermal Unit Exposure (mg/lb ai) ^e	PPE Absorbed Dermal Dose (mg/kg/day) ^f	PPE Dermal MOE ^g
Mixer/Loader Risk Estimates							
Mixing/Loading Liquids for Groundboom Application (1)	0.5	20	0.0044	19561	0.043	0.0074	1,351
Applicator Risk Estimates							
Groundboom Application (2)	0.0026	3846	0.0024	33417	N/A	N/A	N/A
Mixer/Loader/Applicator Risk Estimates							
Backpack Sprayer (3)	no data	no data	0.0013	61692	2.5	0.0054	1,852
Low Pressure Handwand (4)	0.22	45	0.0013	61692	4.1	0.0087	1,149

Scenario (4) also represents jug application method.

No data means no data are available for hand exposure. See additional PPE scenario.

^a Baseline Absorbed Dermal Dose (mg/kg/day) = (daily dermal exposure (mg/day) x dermal absorption factor 5.0 percent) / 70 kg.

^b Baseline Dermal Absorbed MOE = NOEL (10 mg/kg/day) / daily absorbed dermal dose (mg/kg/day).

^c Baseline Inhalation Dose (mg/kg/day) = daily inhalation exposure (mg/day) / 70 kg.

^d Inhalation MOE = NOEL (mg/kg/day) / Daily Inhalation Dose (mg/kg/day) = Where NOEL = 0.3 mg/L; route-to-route extrapolation = [(0.3 mg/L/day * 1 * 8.46 L/hr * 6 hr * 1) / (0.190 kg)] = NOEL of 80.2 mg/kg/day. Additional mitigation measures are not necessary for inhalation.

^e PPE consists of a single layer of clothing and chemical resistant gloves.

^f PPE Dermal Absorbed Dose (mg/kg/day) = (daily dermal exposure (mg/day) x dermal absorption factor 5.0 percent) / 70 kg.

^g PPE Dermal Absorbed MOE = NOEL (10 mg/kg/day) / daily absorbed dermal dose (mg/kg/day).

Table 5: Exposure Scenario Descriptions for Butralin Uses

Exposure Scenario (Number)*	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
Mixer/Loader Exposure			
Mixing Liquid Formulations (1)	PHED V1.1	80 acres groundboom	Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates; Inhalation = 85 replicates. High confidence in dermal and inhalation data.
			Additional PPE: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates; High confidence in dermal data. PHED data used for baseline and additional PPE, no PFs were necessary.
Applicator Exposure			
Groundboom Application (2)	PHED V1.1	80 acres	Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 29 replicates; Dermal = 32 to 42 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data. PHED data used for baseline, no PFs were necessary.
Mixer/Loader/Applicator Exposure			
Backpack Sprayer (3)	PHED V1.1	1 acre	Baseline: no dermal data; "Best Available" grades: inhalation acceptable grades. Inhalation = 11 replicates. Low confidence in inhalation data.
			Additional PPE: "Best Available" grades: Hands and dermal = grades A, B, C; Hands = 11 replicates, dermal = 9 to 11 replicates, Low confidence in dermal data. PHED data used for baseline inhalation and for dermal additional PPE, no PFs were necessary.
Low Pressure Handwand (4)	PHED V1.1	1 acre	Baseline: "Best Available" grades: Hands, dermal, and inhalation all grades. Hands = 70 replicates; Dermal = 25 to 96 replicates; inhalation = 96 replicates. Low confidence in dermal and inhalation data.
			Additional PPE: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 15 replicates; Dermal = 25 to 96 replicates; Low confidence in dermal data. PHED data used for baseline and additional PPE, no PFs were necessary.

* Jug application is represented by scenario (4).

^a Standard Assumptions based on an 8-hour work day as estimated by the Agency.

^b "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:
 High = grades A and B and 15 or more replicates per body part
 Medium = grades A, B, and C and 15 or more replicates per body part
 Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

Estimated Risk From Handler Exposures

Dermal: The calculations of intermediate-term dermal risk indicate that the MOEs are more than 100 at **baseline** for the spray application with a groundboom sprayer scenario.

The calculations of intermediate-term dermal risk indicate that the MOEs are more than 100 with the addition of chemical-resistant gloves to baseline attire for the following scenarios:

- (1) mixing/loading liquids for groundboom application;
- (2) mixing/loading/applying sprays with a backpack sprayer; and,
- (3) mixing/loading/applying sprays with a low pressure handwand.

Jug application is represented by scenario (3).

Inhalation: The calculations of short-term and intermediate-term inhalation risk indicate that the MOEs are more than 100 at **baseline** for all scenarios.

Risk From Post-Application Exposures

Occupational: Based on relatively low dermal toxicity, EPA concludes that risk due to post-application exposure following applications of the liquid formulation to tobacco would be minimal, provided entry does not occur immediately following applications. The Agency notes that label directions indicate that hand suckering of any suckers that escaped treatment should occur two to three weeks after treatment and that this product should be applied at least 30 days before anticipated harvest dates.

b. Additional Occupational Exposure Studies

Handler Studies

Based on the risk assessment of the current uses of butralin, handler exposure studies are not required at this time.

Post-Application Studies

Based on the risk assessment of the current uses of butralin, post-application exposure studies are not required at this time.

4. Other Exposure and Risk Considerations

The Food Quality Protection Act of 1996 amends both FFDCA and FIFRA by setting a new safety standard for the establishment of tolerances. In determining whether or not a tolerance meets the new safety standard, FQPA directs EPA to consider information concerning: the susceptibility of infants and children to residues of the pesticide in food; the potential for aggregate exposure from dietary as well as non-occupational sources, such as pesticides used in and around the home; and the potential for cumulative effects from a pesticide and other substances that have a common mechanism of toxicity.

Because the use of butralin on tobacco is not a food use and no tolerance has been established, the specific determinations outlined in FQPA are not required for this chemical. However, EPA also believes that for non-food chemicals it should evaluate available data relating to the special sensitivity of infants and children, as well as the potential for aggregate exposures and cumulative effects if infants, children or the general population may be exposed from drinking water or non-occupational uses. The tobacco use of butralin does not result in any drinking water or non-occupational exposure. Therefore, there is no need to consider an additional uncertainty (safety) factor nor conduct an aggregate exposure/risk assessment.

With regard to cumulative risk, butralin is structurally similar to some dinitroaniline compounds. However, EPA has not made a determination regarding a cumulative risk assessment. For the purposes of this Reregistration Eligibility Decision document, the Agency has considered only risks from butralin. However, the contribution of butralin exposure to the exposure from other chemicals with a common mode of toxicity is likely to be minimal. If required, cumulative risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

C. Environmental Assessment

The environmental assessment consists of four sections: Ecological Toxicity, Environmental Fate and Transport, Ecological Exposure and Risk Assessment, and Environmental Risk Characterization. The first and third sections report the ecological toxicity data from laboratory studies, estimates ecological exposure and assesses the effects to nontarget terrestrial and aquatic organisms. The second section depicts the environmental fate and transport data from field and laboratory studies, analyzes the impact to water resources, and details the environmental fate assessment. The section on environmental risk characterization integrates the exposure and effects assessments to determine the extent and potential for risk to the environment.

1. Ecological Toxicity Data

Ecological toxicity studies indicate that butralin is practically nontoxic to terrestrial organisms on an acute oral and subacute dietary basis, but is highly toxic to aquatic organisms on an acute basis. At this time, the Agency does not have sufficient data to adequately assess the ecological toxicity of butralin and is requesting the following studies: chronic toxicity to invertebrates (GLN 72-4b); either a 48-hour embryo-larvae study or 96-hour shell deposition study with oysters (GLN 72-3 b); toxicity to terrestrial (GLN 123-1 a and b) and aquatic (GLN 123-2) plants; and, avian reproduction (GLN 71-4 a and b) with both the mallard duck and bobwhite quail.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of butralin to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Table 6: Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Bobwhite Quail	96	> 2250	160643 Beavers/1986	Practically nontoxic	Yes

Table 7: Avian Acute Dietary Toxicity

Species	% A.I.	LC_{50} ppm	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	98	> 10,000	160644 Fink/1975	Practically nontoxic	Yes
Mallard Duck	98	> 10,000	160645 Fink/1975	Practically nontoxic	Yes

These results indicate that butralin is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements (71-2) are fulfilled.

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed to a pesticide repeatedly or continuously through persistence, bioaccumulation, or multiple applications; or if

mammalian reproduction tests indicate reproductive hazard. The environmental fate data suggest that butralin should be moderately persistent to persistent ($t_{1/2}$ = 3 months to 3 years) and relatively immobile in terrestrial environments. Based upon the persistence of butralin in terrestrial environments, birds are expected to be exposed repeatedly and for a long period of time.

Two avian reproduction studies completed in 1972 were reviewed and classified as supplemental, not-upgradeable. That is, they provided information to be used in the risk assessment, but did not fulfill current guideline requirements. There were numerous guideline deviations in these studies, such as the lack of sufficient treatment levels, inadequate description of testing facilities, and the lack of raw data.

Conclusions: Technical butralin (purity not identified) did not impair the reproductive ability of mallard ducks, with the exception of increased eggshell cracks, at 80 ppm (MRID 44074105). Technical butralin, fed to bobwhite quail for a total of 15 weeks, did not impair the reproductive ability at either the 4 or 80 ppm levels (MRID 44074101). However, these studies are inadequate and the highest tested level (80 ppm) does not adequately represent avian exposure levels expected in the environment according to Kenaga as modified by Fletcher (1994). The guideline requirements, 71-4(a & b), are not fulfilled. The supplemental studies indicate that butralin may adversely affect the reproduction of mallard ducks, therefore a reproduction study with the mallard duck is required. Based on the persistence of butralin, the Agency is also requiring a reproduction study for the bobwhite quail because of the high potential for exposure.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Acute toxicity studies show that butralin is not acutely toxic to the animals tested to date. Therefore, an acute oral LD₅₀ from the Agency's database is sufficient to assess toxicity to mammals. This LD₅₀ is reported below.

Table 8: Mammalian Acute Oral Toxic

Species	LD ₅₀ mg/kg	MRID #	Toxicity Category
Rat (small mammal surrogate)	1049	42112701	Slightly toxic

The available mammalian data indicate that butralin is slightly toxic to small mammals on an acute oral basis (MRID 42112701).

Chronic

Currently, the Agency does not have reproductive mammalian data because chronic data are not required for non-food uses. Tobacco is a non-food use.

(4) Insects

A honeybee acute contact LD₅₀ study is required if new uses will result in honey bee exposure. Based on the use pattern, tobacco, it is unlikely that honeybees will be exposed to butralin, therefore, honeybee testing is not required.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of butralin to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study used a cold-water species (preferably the rainbow trout), and the other used a warm-water species (preferably the bluegill sunfish).

Table 9: Freshwater Fish Acute Toxicity

Species	% A.I.	LC ₅₀ mg/L	MRID No., Author/Year	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	96	0.37	160647, Swigert & Bowman/1986	Highly toxic	Yes
Bluegill Sunfish	96	1.0	160647, Swigert & Bowman/1986	Highly toxic	Yes

The results of the 96-hour acute toxicity studies indicate that butralin is highly toxic to freshwater fish. It should be noted that the LC₅₀ for bluegill sunfish is at the solubility limit for butralin. The guideline requirements (72-1) are fulfilled.

(2) Freshwater Invertebrates

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

Table 10: Freshwater Invertebrate Toxicity

Species	% A.I.	EC ₅₀ mg/L	MRID No., Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Daphnia magna</i>	98.77	0.12	42636101, Evers/1992	Highly toxic	Yes
<i>Daphnia magna</i>	96	Not determined	159513, Forbis & Frazier/1986	N/A	No - supplemental

The results indicate butralin is highly toxic to freshwater aquatic invertebrates. The guideline requirement (GLN 72-2) is fulfilled (MRID 42636101).

Data from an aquatic invertebrate life-cycle test (GLN 72-4 b) is required for butralin because the following criteria have been met:

- the product is expected to be transported to surface water from the intended use site;
- the acute EC₅₀ is less than 1 mg/L; and,
- the GENEEC estimated EEC in water is slightly greater than 0.01 of the acute EC₅₀ value.

Because aquatic invertebrates appear to be more sensitive to butralin than freshwater fish, chronic testing with invertebrates is required instead of chronic freshwater fish testing. It should be noted that the Agency does not have acceptable aquatic metabolism data to confirm the persistence of butralin in aquatic environments, and additional data may be required in the future depending on the results of requested batch equilibrium and field dissipation studies.

(3) Estuarine and Marine Animals

The following table outlines the acute RQs for estuarine/marine organisms:

Table 11: Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate	Species	Acute RQ
Tobacco/ 3.0 lbs a.i./A	Sheepshead minnow (LC50 > 0.18 mg/L)	0.09
Tobacco/ 3.0 lbs a.i./A	Mysid (LC50 = 0.069 mg/L)	0.2

The acute LOC (0.09) for endangered estuarine/marine fish has been exceeded by a small margin. Also, the acute LOC (0.23) for risk that may be mitigated through restricted use has been exceeded for estuarine/marine shrimp by a small margin.

c. Toxicity to Plants

(1) Terrestrial

Most herbicides, including plant growth regulators, require a tier I or tier II data set for terrestrial plant testing, including a seedling emergence and a vegetative vigor study (guideline 123-1 a and b). The registrant has not fulfilled this data requirement and needs to submit seedling emergence and vegetative vigor studies for butralin.

(2) Aquatic

Aquatic plant testing (guideline 123-2) is required for any herbicide, or plant growth regulator, which has outdoor non-residential terrestrial uses that may move off-site of application by runoff or by drift (aerial or irrigation). The registrant has not fulfilled this requirement and needs to submit aquatic toxicity testing for the following species: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

2. Environmental Fate

a. Environmental Fate Assessment

Laboratory studies¹ suggest that the primary routes of dissipation for butralin are aqueous photolysis and to a lesser extent microbial-mediated degradation and volatilization. Other potential routes of dissipation are soil binding, surface water runoff, and foliar interception/dissipation processes.

Based upon available environmental fate data, butralin appears to be moderately persistent to persistent and relatively immobile in terrestrial environments. The importance of the routes

¹ The environmental fate assessment for butralin is based on acceptable as well as supplemental, upgradeable data. Environmental fate data which was found in Agency reviews from the 1970's are regarded as supplemental, non-upgradeable data and are referenced as OPP File Symbol Nos. 264-ELN and -EAL and Pesticide Petition Nos. 4F1431 and 2G1285. Although these earlier 1970 studies and reviews contain useful information, they do not meet current guideline requirements and can not be used in the butralin risk assessment.

of dissipation of butralin is unclear at this time because there is a lack of consistent and comprehensive data on the contribution of individual dissipation routes to the total degradation pathway. The Agency is requesting that the registrant submit additional environmental fate data to confirm the extent of butralin binding to soil/sediment and to assess rates and routes of dissipation for butralin and its degradates under typical use conditions.

Butralin is stable to abiotic hydrolysis and photodegradation on soil ($t_{1/2}$ = 99.6 days). In sunlight irradiated water, butralin photodegrades with a half-life of 13.6 days. The major transformation product (> 10% of applied) is 4-tert-butyl-2,6-dinitroaniline (DNTBA), and possibly 4-tert-butyl-2-nitro-6-nitrosoaniline (DBNNA). The degradate, DBNNA, was identified as a major photodegradate in an earlier aqueous photodegradation study.

Laboratory metabolism studies show that butralin is moderately persistent to persistent ($t_{1/2}$ = 3 months to 3 years) in aerobic mineral soils. The degradate DNTBA has been identified at a maximum of 2% of the applied at 12 months posttreatment. In soil metabolism studies, volatile (^{14}C) residues account for approximately 15% of applied after 12 months. These studies show that > 95% of the volatiles are butralin. Earlier degradation studies in soil and water also show evidence of microbial mediated degradation of butralin.

A half life of 35 days has been observed in an earlier anaerobic soil metabolism study where the majority of the ^{14}C residue was bound to the soil. Supplemental non-upgradeable aquatic metabolism data suggest that butralin degrades in non-sterile water and binds to the sediment. The Agency does not have acceptable data to confirm routes and rates of dissipation of butralin in aquatic and anaerobic soil environments.

Soil mobility studies indicate that butralin is relatively immobile. In acceptable soil column leaching studies, butralin is relatively immobile (0.25% of applied butralin in leachate) in sand, sandy loam, loam, and clay soils. Supplemental, non-upgradeable soil TLC/batch equilibrium studies confirm these results and show that butralin is relatively immobile. The Agency estimates a K_{oc} of 3,219 ml/g for butralin, using a first order linear regression model based on the K_{ow} (Lyman, W.J. 1990). Although there is uncertainty with this estimate, the high value of the estimated K_{oc}

along with the soil column leaching studies suggest that butralin has a relatively high binding affinity to soil. Additional batch equilibrium data are needed to confirm the estimated K_{oc} for butralin and to provide a more accurate quantitative mobility assessment for risk characterization.

Soil metabolism studies indicate that volatilization is a possible route of dissipation even though butralin has a low vapor pressure (5.79×10^{-6} Torr) and low Henry's Constant (7.50×10^6 atm m³/mol). As mentioned above, volatilization of butralin from soil has been observed (approximately 15% of applied butralin during a 12 month study) in a soil metabolism study.

Several field dissipation studies conducted in Georgia, North Carolina, California, and Mississippi indicate that butralin, applied at 1.5-4.0 lb/A, dissipated with half-lives ranging from 10 to 72 days. Only one of these studies is considered supplemental and can be upgraded to meet current guideline requirements. In the Georgia turf study, the registrant calculates a half-life of approximately 73 days in bare ground plots of loamy sand soil and in sandy loam turf plots. Residues of the butralin metabolite DNTBA have been detected only in the 0- to 6-inch soil depth in bareground and turf plots. Other metabolites have not been analyzed in this study.

The registrant has conducted several laboratory fish bioaccumulation studies in microcosms, aquariums, and ponds, all of which show that butralin bioconcentrates in bluegill sunfish, channel catfish, and crayfish. In a more recent acceptable laboratory study, bluegill sunfish bioaccumulated butralin in 39 days of continuous exposure. Bioconcentration factors ranged from 765X, 3410X, and 1870X for edible, non-edible, and whole body tissues, respectively at a nominal butralin concentration of 3.0 µg/L. At 30 µg/L, butralin bioconcentration factors were 734X, 3590X, and 1950X for edible, non-edible, and whole body tissues, respectively. Elimination of butralin residues exceeded 50% by 7-10 days, and 95% by 35 days of depuration.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

Butralin was stable to abiotic hydrolysis in sterile buffered aqueous solutions at pH 4, 7 and 9 at 25°C (MRID 43669401). The data requirement (GLN 161-1) is fulfilled. No additional data are needed at this time.

Photodegradation in Water

Radiolabeled butralin photodegraded in an aqueous solution buffered at pH 7 when irradiated with a filtered xenon sunlamp for 15 days. The registrant calculated the half-life of butralin to be 13.6 days, while the half-life of the dark control samples was calculated to be 138.2 days.

The major transformation product was 4-tert-butyl-2,6-dinitroaniline (DNTBA), which accounted for 31.8% of the applied radiocarbon on day 11 and 23.4% on day 15 in the irradiated samples. In addition, a region of diffuse radioactivity (16% of applied) was observed in the HPLC radiochromatogram which did not contain discernible discrete peaks. The author of the study reported that this diffuse region of radioactivity consisted of highly water soluble components displaying acidic and basic properties and probably resulted from the rupture of the aromatic ring of the major degradate DNTBA with subsequent formation of multiple products (MRID 44064901).

In a supplemental non-upgradeable study, butralin photodegraded under natural sunlight and mercury arc vapor lamp to form 4-tert-butyl-2-nitro-6-nitrosoaniline (76%) and several other minor photolabile transformation products (e.g., DNTBA) (Acc No. 24863). In another supplemental non-upgradeable study, butralin degraded with a half-life of 7.7 days in irradiated buffer solution (pH 7). This study was unacceptable because the dark control also showed degradation (26% in 30 days) (MRID 42620701). In this study, major degradates were identified as 4-tert-butyl-2,6-dinitroaniline (17.4% of applied at 30 days) and 3-nitro-1,2-phenylenediamine (19.3% of applied at 30 days). These degradates were detected in both irradiated and dark control treatments. Additional open literature data indicate that nitroaniline compounds may be intermediate photoproducts from the photodegradation of dinitroaniline compounds (Harris, J. 1990).

The data requirement (GLN 161-2) is not fulfilled. However, the most recent photolysis study (MRID 44064901) is considered supplemental and can be upgraded after the registrant

provides a complete explanation of the differences in metabolites identified among the different aqueous photolysis studies.

(2) Mobility

Photodegradation on Soil

Radiolabeled butralin, at 374 µg/g, photodegraded slowly on sandy loam soil irradiated with natural sunlight for 30 days. Using linear regression, the registrant calculated the half-life to be 99.6 days. Butralin also degraded slowly ($t_{1/2}$ = 112.7 days) in the dark control. At 30 days posttreatment, butralin was 76.7-80.4% of the applied in the irradiated soil, and 78.2-81.4% of the applied in the dark controls. During the experiment, DNTBA and nine other unidentified transformation products were detected (all < 2.3% of the applied) in the irradiated soil and dark controls (MRID 42496201).

A supplemental non-upgradeable study, which assessed the photodecomposition of butralin applied to soil TLC plates and irradiated with natural sunlight, showed that 91% of parent compound remained after 7 days (MRID 50500010).

This data requirement (GLN 161-3) is not required for non-food terrestrial uses.

Photolysis in Air

The data requirement (GLN 161-4) was waived because it is not required to support terrestrial non-food uses. Potential volatilization of butralin into air is expected to be low because of butralin's low vapor pressure (5.79×10^{-6} Torr) and low Henry's Constant (7.50×10^{-6} atm. m³/mol) the Agency's Pesticide One-Liner Database (EFGWB). The Agency notes, however, that volatilization of butralin from soil was observed (15% of applied butralin during a 12 month study) in a soil metabolism study (MRID 43201901).

Aerobic Soil Metabolism

Radiolabeled butralin, at 3.9 µg/g, was persistent (extrapolated half-life of 1126 days or approximately 3 years) in sandy loam soil incubated in the dark at 25°C and 75% field moisture capacity. Radiolabeled butralin was 95.9 - 96.4% of the

applied immediately posttreatment, and decreased to 71.6 - 73.1% at 12 months.

The degradate, 4-tert-butyl-2,6-dinitroaniline (DNTBA), was identified at a maximum of 1.9 - 2.2% of the applied at 12 months posttreatment. Various other degradates, which were present at ≤ 0.02 ppm, were isolated but were not identified. At 12 months posttreatment, volatile (^{14}C) residues were 14.7 - 15.6% of the applied, of which greater than 95% were parent butralin. Unextracted (^{14}C) residues increased to 10.3 - 11.8% of the applied at 12 months (MRID 43201901).

The degradate DNTBA was also identified in an earlier soil metabolism study along with the presence of N-sec-butyl-4-tert-butyl-2-nitroaniline, the mononitro derivative of butralin. Other earlier aerobic soil metabolism studies, submitted by the registrant, indicated that butralin dissipation was predominately dependent on soil binding and oxidative mineralization to CO_2 . Half-lives of butralin ranged from less than 3 months to greater than 245 days. These studies found that the stereoisomers of butralin had similar degradation rates in soil. Additional studies showed that nitrosobutralin, a potential transformation product of butralin, is not persistent in soil (100% loss after 5 days) and does not form in soils with high nitrite concentrations (OPP File Nos. 264-ELN and -EAL and Pesticide Petition Nos. (PP#) 4F1431 and 2G1285¹).

Supplemental, non-upgradeable soil and *in vitro* microbial degradation studies showed different metabolites in soil and fungal extracts. The major metabolite found in soil was the dealkylated derivative of butralin, 4-tertiary butyl-2,6-dinitroaniline, while the major metabolite found in fungal extracts was an oxygenated analog of dibutralin, 3-(4-tert-butylanilino-2,6-dinitro)-2-butanol. (MRID 24824).

The guideline requirement (GLN 162-1) is fulfilled. No additional data are needed at this time.

Anaerobic Soil Metabolism

A half-life of 35 days was observed in a 1974 anaerobic soil metabolism study (MRID 35631) with radiolabeled butralin in silt loam saturated with water. The majority of ^{14}C (56% of applied) was unidentified soil bound radioactivity. In this study, degradation

products of butralin were a dealkylated metabolite (1% of applied) and unidentified polar metabolites (12% of applied).

The data requirement (GLN 162-2) is not fulfilled; however, it is not required for terrestrial non-food uses.

Aquatic Metabolism

Aquatic metabolism data were taken from supplemental non-upgradeable studies on butralin degradation in non-sterile water, accumulation in artificial aquatic ecosystems, and field runoff studies (MRID 42069703, OPP File Nos. 264-ELN and -EAL and PP#4F1431 and 2G1285). The Agency reviewed previous agency reviews for pertinent data relating to the fate of butralin in aquatic environments¹. These aquatic metabolism studies provide limited information regarding the fate of butralin in aquatic environments and cannot be used as supporting data for a risk assessment.

In laboratory studies, butralin in non-sterile water degraded to form four polar metabolites: 2,3 diaminonitrobenzene, 4-tert-butyl-2,6-dinitroacetanilide, N-isopropyl-2-amino-4-tert-butyl-6-nitroaniline, and N-ethyl-2-nitroso-4-tertiary-butyl-6-nitroaniline (OPP File No. 264-ELN).

In artificial aquatic ecosystems, radiolabeled butralin, applied at 2 lbs a.i./A in flooded sediment/test water, was detected at maximum sediment concentration of 23 to 25.50 mg/kg at 7 and 10 days posttreatment and then declined to 4.80 to 6.85 mg/kg at 35 days posttreatment. Butralin water concentrations ranged from 0.14 mg/L to 0.81 mg/L (MRID 42069703). In another artificial aquatic ecosystem study, bluegill sunfish, channel catfish and crayfish were exposed to radiolabeled butralin, applied at 3 lbs a.i./A for 35 days in a static pool. The sediment in the pool was treated with radiolabeled butralin and then aged aerobically for 27 days before flooding. Butralin residues in the water ranged from 0.02 µg/ml to a maximum of 0.06 µg/ml ppm on day 35 of exposure. In the soil, total ¹⁴C-residues were 13.73 µg/g immediately posttreatment, 10.25 µg/g at 30 days and ranged from 8.66 - 9.80 µg/g during the animal exposure period (MRID 42069704).

Runoff studies in Pennsylvania and Mississippi on sites with 3 to 6% slopes showed that butralin, at 3 lbs a.i./A, was detected in adjoining farm pond water and sediment at maximum

concentrations of ≤ 2 $\mu\text{g/ml}$ and ≤ 30 $\mu\text{g/g}$, respectively (PP#4F1431).

Guidelines 162-3 and 162-4 are not required for terrestrial non-food uses.

Soil Column Leaching\Batch Equilibrium

Radiolabeled butralin, at 0.197 $\mu\text{g/g}$, was relatively immobile in 30-cm columns of sand, sandy loam, loam, and clay soil eluted with 20 inches of 0.01 M calcium chloride solution. Trace quantities (0.14-0.25% of applied) of radiolabeled material in the leachates were not identified. In all soil columns, the radiolabeled material was predominantly detected ($> 81.86\%$ of applied) in the 0-6 cm soil layer. The major compound detected in the 0-6 cm soil layer was parent butralin. The degradate 4-tert-butyl-2,6-dinitroaniline, and two unidentified ^{14}C compounds were each $\leq 3.8\%$ of applied (MRID 42842301).

Supplemental, non-upgradeable TLC studies showed that butralin and its metabolites (DNBTA and 2,6-dinitroaniline) were immobile (Helling-Turner mobility classification of 1) on sand, silt loam, and muck soil plates. (OPP File No. 264-EAL).

In a supplemental, non-upgradeable batch equilibrium study, adsorption coefficients (K_d 's) of 2, 6.5, and 90 ml/g for butralin were measured in sand, sandy loam, and clay soil, respectively. These values could not be used to calculate K_{oc} values because the soil organic matter content was not reported (MRID 35622).

The data requirement for an unaged mobility study (GLN 163-1) is satisfied (MRID 42842301). At this time, the Agency is not requiring an aged mobility study. The Agency is, however, requesting additional batch equilibrium data to confirm the estimated K_{oc} for butralin. The Agency estimated a K_{oc} value of 3,219 ml/g using a K_{ow} which was based upon an unvalidated first order regression analysis (Lyman, W.J. 1990).

Volatility

The data requirement (GLN 161-4) was waived because it is not required for terrestrial non-food uses. Potential volatilization of butralin into air is expected to be low because of butralin's low vapor pressure (5.79×10^{-6} Torr) and low Henry's Constant (7.50

* 10^{-6} atm.m³/mol). The Agency notes, however, that volatilization of butralin from soil was observed (approximately 15% of applied butralin during a 12 month study) in a soil metabolism study (MRID 43201901).

Bioaccumulation in Fish

Radiolabeled butralin bioconcentrated in bluegill sunfish which were continuously exposed to nominal butralin concentrations of 3.0 and 30 µg/L for 39 days. For bluegill exposed to a nominal butralin concentration of 3.0 µg/L, bioconcentration factors (BCF) of 765X, 3410X and 1870X were calculated for edible, non-edible, and whole body tissues, respectively. Elimination of accumulated butralin residues exceeded 50% by day 10 and was greater than 95% by day 35.

For bluegill exposed to a nominal butralin concentration of 30 µg/L, BCFs of 734X, 3590X, and 1950X were calculated for edible, non-edible, and whole body tissues, respectively. Elimination of ¹⁴C-residues exceeded 50% by day 7 and was greater than 95% by day 35 of depuration. After 39 days of exposure to 3.0 µg/L, radiolabeled butralin was detected in both viscera (82.2% of TRR) and edible tissues (81.9% of TRR) of bluegill along with several minor metabolites. The study authors concluded that the glutathione pathway was used in the metabolism of butralin by bluegill sunfish (MRID 44081601).

Supplemental, non-upgradeable flow-through accumulation studies at 0.01 and 0.75 mg/L of butralin showed that radiolabeled butralin bioaccumulated in edible portions of bluegill (2200 to 4260X) and in non-edible portions (32,000 to 33,000X). Ninety to ninety-nine percent of the residues were eliminated after 7-35 days of depuration. Butralin was the only compound identified in the edible tissues. At the higher concentration of 0.75 mg/L of butralin, mortality was observed after 19 days of exposure (MRIDs 42069702 and 42069705).

Supplemental, non-upgradeable static accumulation studies, at application rates of 2-3 lbs a.i./A in soil and water, showed that radiolabeled butralin bioaccumulated in edible portions of bluegill (123 to 473X), channel catfish (115 to 1250X), and crayfish (5 to 10X). Bioconcentration factors found in non-edible portions of bluegill ranged between 1561 to 7000X, and in channel catfish they ranged from 1000 to 2682X. Residues were eliminated to < 1-2%

of the highest level in bluegill and catfish after 7-35 days of depuration. Butralin was the only compound identified in fish tissues (MRIDs 42069703 and 42069704).

Field runoff-accumulation studies in Pennsylvania and Mississippi showed that butralin, at 3 lbs a.i./A, bioaccumulated to 150 - 1200X in edible portions of bluegill and catfish, respectively. Bioconcentration factors in non-edible portions of bluegill was 1000X and in channel catfish was 7500X. Maximum concentrations in the water and sediment were 2 µg/L and 30 µg/kg, respectively (PP#4F1431).

The data requirement (GLN 165-4) is fulfilled. No additional data are needed at this time.

(3) Field Dissipation

Terrestrial Field Dissipation

Several field dissipation studies conducted in Georgia, North Carolina, California, and Mississippi indicated that butralin, at 1.5-4.0 lb/A dissipated with half-lives ranging from 10-72 days. None of these studies met guideline requirements for the reasons listed below. The most recent field studies were conducted in tobacco and bare ground in North Carolina and in turf and bare ground in Georgia. The North Carolina study was not acceptable because of low and highly variable recoveries in the frozen storage stability analysis. In addition, the application rate of butralin could not be confirmed, the pattern of decline of butralin in soils planted to tobacco was not established, the concentration data on butralin and the metabolite DNTBA in tobacco plants were not submitted, and only one metabolite was identified.

The Georgia study with turf provided supplemental information, but could not be used to fulfill the guideline requirement. If someone decides to register the turf use, then additional data will need to be submitted concerning the application rate of butralin, storage stability data for butralin beyond 651 days and for the metabolite DNTBA, and the identification of all metabolites at concentrations above 10% of applied.

The Georgia turf study showed that butralin dissipated in Norfolk loamy sand and sandy loam soils with registrant calculated half-lives of approximately 73 days in bare ground plots and in

plots with previously established turf. However, the actual half-lives may be much shorter than the calculated half-lives because butralin residues decreased to less than half of the nominal concentrations by 15 days posttreatment (DPT). Residues of the metabolite DNTBA were detected only in the 0- to 6-inch soil depth in bare ground and turf plots. Maximum DNTBA levels were 0.04 µg/g in bare ground plots at 18 months post-treatment (MPT) and 0.12 µg/g in turf plots at 5 MPT. The soil and turf were not analyzed for other metabolites, such as 3-nitro-1,2-phenylenediamine, 2,6-dinitroaniline, 3-(4-tert-butylanilino-2,6-dinitro)-2-butanol (MRIDs 42069701, 43749801, 43764001).

Supplemental, non-upgradeable field studies in California and Mississippi were conducted on soils planted with crops and treated with butralin at 1.5-4.0 lb/A. In these studies, the reported half-lives of butralin ranged from 42 to 72 days. Metabolites were not identified in these studies (PP#2G1285).

The terrestrial field dissipation data requirement (164-1) is not fulfilled at this time.

(4) Spray Drift

The Droplet Size Spectrum (201-1) and Drift Field Evaluation (202-1) data requirements do not apply for butralin because it is not applied aerially.

c. Water Resources

(1) Ground Water

The Agency evaluates the persistence and mobility of each pesticide for ground water concerns. If data indicate that the parent and/or degradates are persistent and mobile, then a small-scale prospective ground water study may be required. The basic triggering criteria include: weight of the evidence from laboratory and field dissipation studies indicating that the pesticide has properties and characteristics similar to pesticides that are known to leach or have been detected in ground water; movement of the parent or degradates 75-90 centimeters through the soil profile or plow layer in a field dissipation study; reports of detections in ground water from other monitoring studies and information about toxicity. In addition, use patterns, application rates, timing of application, potential acreage treated, depth to ground water, soil

types, hydraulic gradient, and climate are also evaluated as part of the triggering criteria. Persistence, mobility, detections in ground water and toxicity are also used to evaluate a chemical to determine whether its use should be restricted. A compound may be recommended for Restricted Use if it exceeds these criteria.

Persistence and Mobility

Butralin was evaluated for persistence and mobility in relation to its potential to leach to ground water. Below is a summary of that evaluation.

Table 12: Physical and Chemical Characteristics of Butralin Relative to Mobility and Persistence Criteria

Criterion	Characteristic	Ground Water Criteria	Butralin
Persistence	Field dissipation half-life	> 3 weeks or	1.43 to 10.5 wks (10 - 72.6 d)
	Lab-derived aerobic soil metabolism half-life	> 3 weeks or	5 wks to 3 years
	Hydrolysis half-life	< 10% in 30 days or	Stable (pH 4, 7, 9)
	Photolysis half-life (soil)	< 10% in 30 days and	19.6 - 23.3 % in 30 days
Mobility	Soil adsorption: K_d	≤ 5 ml/g or	2-90 ml/g*
	Soil adsorption: K_{oc}	≤ 500 ml/g or	3,219 ml/g** (est. by EPA)
	Depth of leaching in field dissipation study	75 cm	15.2 cm (6")

Shaded cells in column indicates that parameter exceeds trigger for restricted use.

* Qualitative data from soil column leaching studies show that butralin is relatively immobile.

** The K_{oc} was estimated from a first order regression analysis using the K_{ow} for butralin.

Ground Water Detections

EPA's "Pesticides in Ground Water Database" (Hoheisel et al., 1992) does not report any sampling for butralin in the U.S. A search of the Agency records found no other sampling for butralin in ground water.

Butralin is currently not regulated under the Safe Drinking Water Act (SDWA). The Agency's Office of Water has not established a Maximum Contaminant Level (MCL) or Lifetime Health Advisory Level (HAL) for butralin in drinking water.

Ground Water Leaching Index Evaluation

A numerical scale or index was used to assess the leaching potential according to environmental fate properties, soil properties, and soil hydrology. It can be used to compare the relative mobility of different pesticides under the same environmental conditions. A Leaching Index (LI) was developed by the Agency to divide the pesticide mobility index into three discrete classes: low (1), moderate (2), and high (3) potential to leach to ground water.

The Agency used this method to calculate an attenuation factor (AF) for butralin in five different Major Land Resource Areas (MLRA's) using the soil metabolism half-life of 150 days and estimated K_{oc} of 3,219 ml/g. Below are the calculated retardation and attenuation factors for butralin:

Table 13: Retardation and Attenuation Factor

MLRA	Retardation Factor (RF)	Attenuation Factor (AF)
108	2053.09	0
129	1566.00	0
133a	2140.19	0
139	3248.25	0
142	3184.45	0

The Agency compared the calculated attenuation factors of butralin to those calculated for a number of well-known herbicides used in MLRA 108.

Table 14: Comparison of Attenuation Factors (AF) for Various Pesticides

Chemical	AF	Leaching Index	
chlorpyrifos	0.000000	1	Low Risk, may get to ground water in only a small number of wells
butralin	"0"	1	
alachlor	0.000000	2	Moderate Risk, will probably get to ground water in a number of wells
bentazon	0.000110	3	High Risk, will probably reach ground water in a high number of wells
atrazine	0.002165	3	
terbacil	0.44222	3	
tebuthiuron	0.93648	3	

Compared to other pesticides, butralin has a rating of "1" indicating "low risk, butralin may get to ground water in only a small number of wells." From this evaluation, the Agency concluded that butralin ranks very low in its potential to leach to ground water and can essentially be considered a "non-leacher." This assessment is based on an estimated K_{oc}

value for butralin. Additional batch equilibrium data are needed to confirm the leaching potential of butralin.

Tobacco Production

Tobacco production acreage is large, however unlike the large mono-culture crops, it is usually grown in small (less than 1-10 acres), plots widely dispersed over large geographic areas (U.S. Dept. of Commerce, 1992). Much of the use of butralin is expected to be on flue-cured and air-cured tobacco which is grown in the Southeastern U.S., the Mid-Atlantic States, and the mid-southern States². There will be some use on Maryland dark type tobacco which is grown in parts of central and southern Maryland and southern Pennsylvania.

The effect of butralin to the environment would be limited to these tobacco use areas. In addition, this type of use on many small plots distributed over many states, would reduce any potential impact to ground water. The Agency does not anticipate any impact to ground water from butralin use on turf since this use is no longer registered.

Ground Water Conclusions

Butralin is persistent but relatively immobile in terrestrial environments. Based upon qualitative leaching index and mobility studies, butralin is not expected to leach into ground water. Additional batch equilibrium data are needed to confirm the soil binding affinity of butralin. The Agency concludes that use of butralin on tobacco should have minimal impact on ground water.

(2) Surface Water

The current surface water assessment for butralin is an adequate qualitative characterization of the runoff potential for butralin. A more reliable surface water exposure characterization, which is based on PRZM, cannot be adequately determined until the Agency receives additional batch equilibrium data.

² The major tobacco growing regions correspond to the following major land resource areas (MRLA): Southern Coastal Plains (MRLA 133), Southern Piedmont (MRLA 136), Carolina/Georgia Sand Hills (MRLA 137), western edge of the Atlantic Coast Flat Woods (MRLA 153); Kentucky and Indiana Sandstone and Shale Hills and Valley (MRLA 120); Kentucky Bluegrass (MRLA 121), and Highland Rim and Pennroyal (MRLA 122) (Austin, 1972).

The potential for surface water runoff of butralin is expected to be dependent on the cumulative impacts of foliar interception/dissipation, binding on soil/sediment, degradation processes, and site hydrology. Since the current label for butralin (TAMEX-3EC) recommends foliar spray application onto the leaf axial, stalk, and crown of flue-cured and air-cured tobacco, the Agency believes foliar interception and subsequent foliar dissipation processes will affect the magnitude of butralin residues available for surface water runoff. The potential effect of foliar interception may be gauged from unacceptable field dissipation studies on tobacco in which 87% of applied butralin was intercepted by tobacco plants (MRID 43749801). Environmental fate data suggest that direct photolysis will contribute to foliar dissipation of butralin. The impact of foliar interception and subsequent foliar dissipation processes on potential butralin loading into surface waters cannot be fully assessed without data on rates and routes of foliar interception and dissipation of butralin and its transformation products. Butralin residues that are over-sprayed or washed-off from the treated plants are expected to be the only butralin residues available for runoff into surface waters.

Environmental fate studies indicate that butralin is relatively immobile and moderately persistent in mineral soils. In terrestrial environments, the main routes of butralin dissipation appear to be dependent on microbial-mediated degradation ($t_{1/2}$ = 3 months to 3 years) and soil binding (K_{oc} = 3219 ml/g). Acceptable soil column leaching studies and supplemental batch equilibrium/soil TLC studies indicate butralin should be relatively immobile in terrestrial and aquatic environments (Accession No. 35622; MRID 42842301; OPP File No. 264-EAL). These data indicate that butralin will be bound on entrained sediments in surface water runoff. However, the soil binding affinity of butralin cannot be adequately evaluated until the Agency receives confirmatory batch equilibrium data.

The major tobacco growing regions are classified as predominantly upland soils (Udalfs or Udults) and alluvial soils (Fluvents)². These are somewhat freely-drained soils (Soil Survey Staff, 1975). Soils with regional importance are the Psamments in MRLA 137 and poorly drained soils (Aquepts, Aquults) in MRLA 153. Psamments (sandy soils) are expected to be of minimal importance for surface water runoff because of their high water permeability. Although poorly drained soils, as noted in MRLA 153, would be expected to be tile drained for tobacco production, they may serve as groundwater recharge areas from

surface water. These soils are predominately limited to the Atlantic Coast Flat Woods region (MRLA 153).

Based on laboratory aerobic soil metabolism studies and the relatively high estimated K_{oc} , butralin is expected to be persistent and to bind on suspended and bottom sediments in surface waters. Dissolved butralin in the water column should be susceptible to direct photolysis which is dependent on the clarity and depth of the surface water body. Direct aqueous photolysis of butralin is more likely in shallow, clear water bodies with long hydrologic residence times (MRID 44064901). Currently, there are no acceptable data to confirm the fate of butralin in aquatic environments.

Butralin detections in surface water were not reported in STORET. Runoff studies in Pennsylvania and Mississippi on sites 3 to 6% slopes indicate butralin, at 3 lbs a.i./A, was detected in adjoining farm pond water and sediment at a maximum concentration of 2 µg/L and 30 µg/kg, respectively (PP#4F1431). Based on the Tier 1 GENEEC EEC, the peak EEC for butralin is 16.89 µg/L. No maximum contaminant level (MCL) or Lifetime Health Advisory Level (HAL) has been established for butralin.

Expected Aquatic Concentrations: Butralin displays high toxicity to most aquatic organisms tested to date. The Agency calculated generic EECs for butralin application to tobacco (3.00 lbs a.i./A). These EECs are designed as a coarse screen and estimate expected concentrations from a few basic chemical parameters and pesticide label application information. GENEEC is a tier one model which uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a ten hectare field into a one hectare by two meter deep pond.

GENEEC calculates both acute and chronic generic expected environmental concentration (GEEC) values. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before wash off to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body. It is designed to mimic a PRZM-EXAMS simulation.

The following environmental fate parameters were used to calculate the generic EECs:

Table 15: Environmental Fate Parameters

Parameter	Value	Source
Solubility in water	0.3 ppm	EFGWB One-liner
Aerobic soil half-life	stable ¹	MRID 432019-01
Aerobic aquatic half-life data ²	stable	no data
Aqueous photolysis	13.6 days	MRID 440649-01
Hydrolysis half-life	stable	MRID 436694-01
K _{oc}	3,219 ml/g	Regression Equation: ³ logK _{oc} = 0.937 x log(K _{ow})-0.006

¹ The aerobic soil half-life is > 365 days.

² No data are available to assess the degradation rate of butralin in aerobic aquatic environments. Therefore, butralin is assumed to be persistent (or stable) to aerobic aquatic metabolism.

³ Lyman W.J. 1990.

The following table outlines the Generic EECs which were calculated for butralin application to tobacco:

Table 16: Generic Estimated Environmental Concentrations (GEEC) For Butralin

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Tobacco	Broadcast - ground	3.00 (1)	16.89	15.69	11.15	7.70

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC₅₀. The acute effect levels typically are:

- EC₂₅ (terrestrial plants),
- EC₅₀ (aquatic plants and invertebrates),
- LC₅₀ (fish and birds), and
- LD₅₀ (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC) which is the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Table 17: Levels of Concern (LOC) and Associated Risk Presumption

<u>If the</u>	<u>LOC</u>	<u>Presumption</u>
Mammals, Birds		
acute RQ >	0.5	High acute risk.
acute RQ >	0.2	Risk that may be mitigated through restricted use.
acute RQ >	0.1	Endangered species may be affected acutely.
chronic RQ >	1	Chronic risk, endangered species may be affected chronically.
Fish, Aquatic invertebrates		
<u>If The</u>	<u>LOC</u>	<u>Presumption</u>
acute RQ >	0.5	High acute risk.
acute RQ >	0.1	Risk that may be mitigated through restricted use.
acute RQ >	0.05	Endangered species may be affected acutely.
chronic RQ >	1	Chronic risk, endangered species may be affected chronically.
Plants		
<u>If The</u>	<u>LOC</u>	<u>Presumption</u>
RQ >	1	High risk.
RQ >	1	Endangered plants may be affected.

Currently, no separate criteria for restricted use or chronic effects for plants exist.

Butralin use patterns addressed in this assessment: Butralin is registered on flue-cured and air-cured at a use rate of 3.0 lbs a.i./A. For the purposes of this assessment, all types of tobacco will be referred to as "tobacco." This assessment is based primarily on the predominant method of application, boom application to foliage (one application per season). The label also includes individual manual application methods using a handheld dropline, knapsack sprayer or jug application.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Butralin residues found on dietary food items following application are compared to LC₅₀ values to predict hazard. The maximum concentrations of butralin residues which may occur on selected avian dietary food items following a single application of 3.0 lbs a.i./A, the maximum application rate for tobacco, and the corresponding acute risk quotients are provided in the table below:

Table 18: Estimated Environmental Concentrations on Avian Dietary Food Items in PPM and Corresponding Risk Quotients

Food items	EEC	Acute RQ
Short Grasses	720	< 0.07
Long Grasses	330	< 0.033
Broadleaf Plants and Insects	405	< 0.041
Fruits and pods	45	< 0.005

The LOCs have not been exceeded for acute avian risk. Therefore, avian species are not likely to be acutely affected by the use of butralin. Data from supplemental studies, showing a NOEL of 4 ppm, indicate the potential for high chronic risk.

(b) Mammals

Small mammal exposure is addressed using acute oral LD₅₀ values converted to estimate an LC₅₀ value for dietary exposure. The estimated LC₅₀ is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

Table 19: Small Mammal Food Consumption in PPMs (Based on an LD₅₀ = 1049 mg/kg MRID 42112701)

Small Mammal	Body Weight	% of Weight Eaten Per Day	Food Consumed Per Day	Estimated LC ₅₀ Per Day
Meadow vole	46 g	61 %	28.1 g	1,717 ppm
Adult field mouse	13 g	16 %	2.1 g	6,493 ppm
Least shrew	5 g	110 %	5.5 g	953 ppm

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC₅₀ is then compared to the EEC values listed above to calculate a risk quotient. The table below indicates the mammalian dietary risk quotients.

Table 20: Mammalian Dietary Acute Risk Quotients

Small Mammal	RQ
Meadow vole (short grasses)	0.4
Adult field mouse (seeds)	0.06
Least shrew (insects)	0.4

The acute LOC for endangered species has been exceeded by four times the recommended LOC for the meadow vole and the least shrew. Therefore, the use of butralin on tobacco at this use rate may cause adverse effects to herbivorous and insectivorous endangered mammals. Although the LOC for restricted use mitigation has been slightly exceeded, the Agency is not recommending restricted use classification at this time. The actual exposure to small mammals is expected to be reduced because of the directed method of application to the tobacco plant.

Chronic risk to mammals cannot be assessed at this time because chronic mammalian data are not available.

(c) Insects

Honeybees are not likely to be exposed to butralin and are not likely to be adversely affected by its use (Vaughan, A. 1983).

(2) Exposure and Risk to Nontarget Aquatic Animals

(a) Freshwater Fish

The following table outlines the acute RQs for freshwater fish based on EECs calculated in the GENEEC model.

Table 21: Risk Quotients (RQ) for Freshwater Fish

Crop/application rate	Species	Acute RQ
Tobacco/3.0 lbs a.i./A	Rainbow trout $LC_{50} = 0.37$ mg/L	0.046
	Bluegill Sunfish $LC_{50} = 1.0$ mg/L	0.02

The acute LOCs for freshwater fish have not been exceeded.

(b) Freshwater Invertebrates

The following table outlines the acute RQs for aquatic invertebrates.

Table 22: Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate	Species	Acute RQ
Tobacco/3.0 lbs a.i./A	<i>Daphnia magna</i> EC ₅₀ = 0.12 mg/L	0.14

The acute LOC for restricted use (LOC = 0.1) for freshwater invertebrates has been slightly exceeded.

Chronic toxicity to freshwater invertebrates cannot be assessed at this time.

(c) Estuarine and Marine Animals

The following table outlines the acute RQs for estuarine/marine organisms:

Table 23: Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate	Species	Acute RQ
Tobacco/ 3.0 lbs a.i./A	Sheepshead minnow (LC50 > 0.18 mg/L)	0.09
Tobacco/ 3.0 lbs a.i./A	Mysid (LC50 = 0.069 mg/L)	0.2

The acute LOC (0.09) for endangered estuarine/marine fish has been exceeded by a small margin. Also, the acute LOC (0.23) for risk that may be mitigated through restricted use has been exceeded for estuarine/marine shrimp by a small margin.

(3) Exposure and Risk to Nontarget Plants

The Agency does not have adequate data to assess the risk of butralin to nontarget plants. The Agency is requiring that the registrant submit nontarget plant data.

(4) Endangered Species

The following endangered species LOCs have been exceeded: herbivorous and insectivorous endangered mammals and freshwater aquatic invertebrates, and estuarine/marine fish and shrimp. Also, there may be possible reproductive effects to birds.

Acute risk to endangered plant species cannot be determined due to insufficient data.

The Endangered Species Protection Program is expected to be finalized in the near future. Limitations in the use of butralin may be required to protect endangered and threatened species, but these limitations have not been defined yet, and they may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications will most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

b. Water Resources Risk Implication for Human Health

The Agency has no data indicating an undue risk to human health from water resources as a result of butralin use on tobacco.

(1) Ground Water

Butralin is persistent but relatively immobile in terrestrial environments. Based upon qualitative leaching index and mobility studies, butralin is not expected to leach into ground water. Additional batch equilibrium data are needed to confirm the soil binding affinity of butralin. The Agency has concluded that use of butralin on tobacco will have minimal impact on ground water.

(2) Surface Water

Butralin detections were not reported in STORET. Based on the Tier 1 GENECC EEC, the peak EEC for butralin is 16.89 µg/L. A more reliable surface water exposure characterization based on GENECC or PRZM cannot be adequately determined until the additional batch equilibrium data are received and evaluated. No maximum contamination level (MCL) or Lifetime Health Advisory Level (HAL) has been established for butralin. The Agency believes foliar interception and subsequent foliar dissipation processes will affect the magnitude of butralin residues available for surface water runoff. Butralin residues that are oversprayed or washed off from the treated plants are likely to be the only butralin residues available for runoff into surface water.

c. Environmental Risk Characterization

Background Information

Butralin is a post emergent plant growth regulator which is registered to control suckers on flue-cured and air-cured tobacco. Butralin will be applied as an emulsifiable concentrate (36.5%) by direct spraying of the tobacco stalks, leaf axils, and crown using directed, coarse, low pressure spraying techniques. The maximum application rate is 3.0 lbs a.i./A. According to the registrant, the use of butralin is expected to be limited to the southeastern U.S., the mid-Atlantic states and the mid-southern states. In these regions, most of the tobacco is grown on small (less than 1-10 acre) plots which are widely dispersed over large geographic areas.

Aquatic Organisms

Even though laboratory studies show that butralin is highly toxic to fish and invertebrates, the Agency expects that the overall **acute** risk to aquatic organisms in the environment will be low. The risk quotients, which are based upon screening level exposure estimates, indicate that only three LOCs were slightly exceeded (freshwater invertebrates, estuarine\marine fish test\marine shrimp). Furthermore, the estimated EEC values for butralin use on tobacco are conservative because the model does not account for foliar interception/dissipation and aquatic metabolism of butralin. As previously mentioned, the exposure assessment is uncertain because the EECs are based on an estimated K_{oc} value of 3,219 ml/g (Lyman, W.J. 1990). Additional batch equilibrium data are needed to confirm the GENEEC EECs for butralin.

The label for TAMEX-3EC recommends foliar boom or manual spray application over the row, delivering a coarse spray that runs down the stalk and wets suckers in the leaf axils. Butralin may also be applied to individual plants using a handheld dropline, knapsack sprayer or jug application. Butralin residues from foliar over-spray or wash-off from the treated plants are expected to be the only residues available for runoff in surface waters. Although the full magnitude of butralin loading into surface waters cannot be assessed without additional data on rates and routes of foliar interception and dissipation, supplemental terrestrial field dissipation studies suggest that 87% of applied butralin is intercepted by tobacco plants (MRID 43749801). Therefore, the actual amount of butralin reaching surface water is expected to be considerably lower than predicted by GENEEC.

Butralin also has the potential to move into surface waters on entrained sediments and is expected to be bound on suspended and bottom sediment in the aqueous environment. Dissolved butralin in the water column is expected to be degraded by photolysis ($t_{1/2} = 13.6$ days) (MRIDs 44064901 and 00024824). Supplemental runoff studies in Pennsylvania and Mississippi on sites with 3 to 6% slopes indicate butralin, applied at 3 lbs a.i./A, was detected in adjoining farm pond water and sediment at maximum concentrations of ≤ 2 µg/L and ≤ 30 µg/kg, respectively (PP#4F1431).

The following study is required for butralin: either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

The Agency does not have data to assess the chronic effects of butralin to freshwater invertebrates and is requesting an aquatic invertebrate life-cycle test.

(1) Nontarget Plants

The Agency cannot determine the impact of butralin application to nontarget terrestrial and aquatic plants at this time. It can be assumed that butralin, an herbicide, will adversely affect nontarget plants if they are exposed. The Agency is requiring that the registrant submit Tier 2 testing for terrestrial and aquatic plants.

(2) Terrestrial Organisms

Although, environmental fate characteristics indicate that butralin is persistent to moderately persistent (aerobic soil half-life is stable), the overall **acute** risk to terrestrial organisms is expected to be low. No avian LOCs were exceeded; the only acute LOC which was exceeded was for endangered mammals, specifically the meadow vole and the least shrew, and those only by a small margin ($RQ = 0.4$, $LOC = 0.1 - 0.2$). Although the LOC for restricted use mitigation has been slightly exceeded, the Agency is not recommending restricted use classification. The method of application (coarse spray directed onto the plant) is expected to reduce the amount of butralin which will reach potential food items eaten by small mammals in the field.

Supplemental data suggests that butralin may impair the reproductive ability of mallard ducks at 80 ppm. However, the Agency cannot fully assess the chronic affects of butralin to birds without valid data. The supplemental studies only tested at two

levels, the highest being 80 ppm. These test levels do not adequately represent avian exposure according to Kenaga as modified by Fletcher (1994). A mallard reproduction study is required based on an increase in eggshell cracking. A bobwhite reproduction study is also required based on the persistence of butralin in terrestrial environments.

(3) Conclusions

Based upon limited data, the Agency concludes that the overall acute impact on freshwater and terrestrial nontarget organisms and water resources, including ground and surface water, from the use of butralin on tobacco will be minimal. Available ecological toxicity data indicates that there is a "may effect" for endangered species of aquatic invertebrates, including mollusks and crustaceans, for acute effects to estuarine marine fish, for acute effects to mammals, and for possible reproductive effects to birds. Compared to many other pesticides, the amount that the RQ exceeds the LOC for endangered species is relatively low (Consultation Request, 1991). This data also shows that the LOC for restricted use mitigation has been slightly exceeded. However, the Agency is not recommending restricted use classification because of the directed method of application. At this time, the Agency does not have sufficient data to assess the chronic impact of butralin on aquatic and terrestrial nontarget organisms and the acute impact on estuarine and marine invertebrates and nontarget plants. A more complete characterization cannot be made until additional environmental fate and ecological toxicity data are submitted. These include batch equilibrium data to confirm the estimated K_{oc} value, clarification of different metabolites identified in aqueous photolysis studies, additional terrestrial field dissipation data, chronic aquatic invertebrate studies, non-target plant studies, marine/estuarine mollusk studies, and chronic reproduction studies for mallard duck and bobwhite quail.

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 ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to

support reregistration of products containing butralin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing butralin for use on tobacco. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of butralin, 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 butralin and to determine that butralin can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing butralin as the active ingredient for the use on tobacco are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility decision based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that the use of butralin on tobacco is 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 butralin, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered tobacco uses of butralin are eligible for reregistration.

C. Regulatory Position and Labeling Rationale

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

1. Tolerance Reassessment

Existing tolerances of 0.1 ppm are currently established for the herbicide butralin in or on lima beans, cottonseed, southern peas, soybeans forage, soybeans and watermelon (40 CFR §180.358). Products bearing these uses have not been marketed for sometime and the tolerances will be proposed for revocation.

2. Tolerance Revocations and Import Tolerances

As part of EPA's reregistration eligibility decision for butralin, all tolerances cited will be proposed for revocation. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/ regulation on the grounds that the Agency cannot conclude that the tolerance/ regulation is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing butralin tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

Codex Harmonization

Codex harmonization is not a concern in this reregistration case since butralin food use registrations have been canceled and no RfD is established. Butralin is classified as a non-food use pesticide.

3. Potential Risks to Infants and Children/Aggregate Exposure /Cumulative Effects

In determining whether infants and children are particularly susceptible to the toxic effects of a pesticide, EPA considers the completeness and reliability of the toxicity data base, the nature of the effects observed in toxicity studies, and other information. Based on current data requirements, only one developmental study is usually required for non-food use chemicals. However, because butralin at one time had food uses, a developmental study in a non-rodent species and a two generation reproduction study are also available for evaluation. There was no evidence of pre or post natal sensitivity in any of these three studies. The developmental effects and effects on offspring occurred at dose levels that were equal to or greater than the maternal NOELs. Thus, the Agency has concluded that there is no special sensitivity to infants and children from butralin exposure.

In addition, the Agency believes there is little likelihood of direct exposure to infants and children since butralin has no food uses and its only use, on tobacco, will not result in drinking water exposure nor would the tobacco use result in any non-occupational exposures. The Agency does not have concerns for prenatal exposures based on the adequate MOEs for handlers and the lack of special sensitivity seen in the developmental and reproduction studies.

In examining aggregate exposure, EPA takes into account available information concerning exposures from dietary sources, drinking water and non-occupational sources. As noted in the preceding paragraph, the only source of butralin exposure is occupationally related.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of butralin and whether it is appropriate to consider exposure from butralin with other compounds in order to address cumulative effects. However, based on the high MOEs for butralin and its lack of dietary sources, drinking water and non-occupational exposures, the contribution of butralin exposures to the risks of other compounds with a common mode/mechanism of toxicity is likely to be minimal.

4. Occupational Labeling Rationale/Risk Mitigation

All butralin pesticide products are intended for occupational use. There are currently no butralin products intended for homeowner use.

The Worker Protection Standard (WPS)

On August 21, 1992, the Agency issued worker protection regulations affecting all pesticide products whose labeling reasonably permits use in the production of agricultural plants on any farm, forest, nursery or greenhouse. In general, products within the scope of the Worker Protection Standard (WPS) had

to bear complying labeling when sold or distributed by the registrant after April 21, 1994.

The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted entry intervals (REI), and notification are interim. The interim WPS handler PPE requirements are based solely on the acute dermal and inhalation toxicity and skin and eye irritation potential of the end-use product. The interim WPS restricted-entry intervals for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. "Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The WPS retained more stringent PPE, REI, and notification requirements from existing labeling. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. During reregistration, the Agency reviews risks resulting from WPS uses as well as from all other occupational and residential uses.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators)

Occupational handler exposures and risks are evaluated jointly. As a result of the reregistration evaluation of the acute and other adverse effects of butralin, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all butralin end-use products. The risks to handlers are adequately mitigated with the addition of chemical-resistant gloves for most handler scenarios. Therefore, the Agency is requiring that all handlers wear chemical-resistant gloves.

Entry Restrictions

As a result of the reregistration evaluation of the acute and other adverse effects of butralin, the Agency has determined that the risks from post-application exposures to butralin by workers warrant the minimum WPS REI of 12 hours following applications of the liquid formulation to tobacco. Furthermore, since EPA has determined that the risks from adverse effects following such applications are minimal, EPA is establishing the minimum WPS early-entry PPE of coveralls, chemical-resistant gloves, shoes and socks. At this time, butralin is not a candidate for a 4-hour REI, since there are no chemical-specific post-application exposure data and there is a dermal NOEL of 10 mg/kg/day.

Worker Notification

Butralin is not classified as toxicity category I for select acute dermal toxicity or skin irritation potential and is not classified as a severe skin sensitizer. EPA has no special concerns about butralin for adverse effects where a single exposure can trigger the effect and EPA has not established an unusually long restricted-entry interval. Therefore, at this time, EPA is not requiring a WPS "double" notification statement on the labeling of butralin end-use products.

Other Labeling Requirements

The Agency is requiring additional end use labeling statements addressing application restrictions and user safety requirements.

5. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects.

6. Environmental Assessment

Based upon available data, the Agency concludes that risk to freshwater and terrestrial organisms and water resources will be minimal. No additional label statements are required. Certain additional confirmatory data are being required.

7. Restricted Use Classification

Butralin does not require and is not being considered for restricted use.

8. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level.

Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary 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.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of butralin for the above eligible uses has been reviewed and determined to be substantially complete. However, additional confirmatory data are required to fulfill the requirements listed below. Some of these requirements were levied in the Phase 2 and Phase 4 Data Call-In Notices (DCI). Only the data requirements that have not been previously levied by the Agency will be included in the generic DCI included as an attachment to this RED document:

- Avian reproduction with quail data, GLN 71-4(a)
- Avian reproduction with duck data, GLN 71-4(b)
- Estuarine/Marine toxicity mollusk, GLN 72-3(b)
- Life cycle with freshwater invertebrate, GLN 72-4(b)
- Seedling germination/seedling emergence, GLN 123-1(a)
- Vegetative vigor, GLN 123-1(b)
- Aquatic Plant Growth, GLN 123-2
- Leaching/adsorption/desorption, GLN 163-1

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an herbicide for use on tobacco"

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under:

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. All end-use product labels [e.g. multiple active ingredient (MAI) labels, SLN's, and products subject to generic data exemption] must be amended such that they are consistent with the basic producer labels. See Appendix A for appropriate rates and restrictions for those supported uses.

a. Occupational Protection

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain butralin, the handler personal protective equipment requirements set forth in this section must be incorporated on all butralin product labels. Any conflicting PPE requirements on current labeling must be removed. There are currently no multiple-active-ingredient end-use products that contain butralin.

Products Intended Primarily for Occupational Use (WPS)

Minimum (Baseline) PPE Requirements The minimum (baseline) PPE for all occupational uses of butralin end-use products is:

"Applicators and other handlers must wear:
--long-sleeve shirt and long pants,
--chemical-resistant gloves*, and
--shoes plus socks."

* For the glove statement, use the statement established for butralin through the instructions in Supplement Three of PR Notice 93-7.

Actual end-use product PPE requirements: The PPE, if any, that would be established on the basis of the acute toxicity category of each end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in labeling: The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

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

Restricted-entry interval: A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see tests in PR Notices 93-7 and 93-11) on all end-use products.

Early-entry personal protective equipment (PPE): The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves, and
-- shoes plus socks.

Placement in labeling: The REI and early-entry PPE must be inserted into the standardized REI and early-entry PPE statements required by Supplement Three of PR Notice 93-7.

b. Additional Labeling Requirements

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

Application Restrictions

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

User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

C. Existing Stocks

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

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

VI. APPENDICES

Case 2075 [Butralin] Chemical 106501 [N-sec-Butyl-4-tert-butyl-2,6-dinitrobenzamine butralin]

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NON-FOOD/NON-FEED

NON FOOD/NON FEED

Use Group: TERRESTRIAL NON-FOOD CROP

65

APPENDIX A REPORT

[illegible]

444444

HEADER ABBREVIATIONS

PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

EC : EMULSIFIABLE CONCENTRATE

ABBREVIATIONS

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

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APPLICATION RATE

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DCNC      : Dosage Can Not be Calculated
No Calc   : No Calculation can be made
W         : PPM calculated by weight
V         : PPM Calculated by volume
U         : Unknown whether PPM is given by weight or by volume

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Case 2075 [Butralin] Chemical 106501 [N-sec-Butyl-4-tert-butyl-2,6-dinitrobenzamine butralin]

APPLICATION RATE (CONT.)

nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

C46 : Do not apply through any type of irrigation system.

CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

H01 : — day(s) preharvest interval.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION.

h : hour(s)

A : acre
lb : pound
plant :

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Butralin covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Butralin 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 Butralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	C	40979802, 41225203
61-2A	Start. Mat. & Mnfg. Process	C	40979802, 41225203
61-2B	Formation of Impurities	C	40979802, 41225203
62-1	Preliminary Analysis	C	40979801, 41225202
62-2	Certification of limits	C	40979801, 41225202
62-3	Analytical Method	C	40979801, 41225202
63-2	Color	C	40979801, 41225201, 41225202, 41784101, 42616401
63-3	Physical State	C	40979801, 41225201, 41225202, 41784101, 42616401
63-4	Odor	C	40979801, 41225201, 41225202, 41784101, 42616401
63-5	Melting Point	C	40979801, 41225201, 41225202, 41784101, 42616401
63-6	Boiling Point	C	40979801, 41225201, 41225202, 41784101, 42616401
63-7	Density	C	40979801, 41225201, 41225202, 41784101, 42616401
63-8	Solubility	C	40979801, 41225201, 41225202, 41784101, 42616401
63-9	Vapor Pressure	C	40979801, 41225201, 41225202, 41784101, 42616401
63-10	Dissociation Constant	C	40979801, 41225201, 41225202, 41784101, 42616401
63-11	Octanol/Water Partition	C	40979801, 41225201, 41225202, 41784101, 42616401

Data Supporting Guideline Requirements for the Reregistration of Butralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	pH	C	40979801, 41225201, 41225202, 41784101, 42616401
63-13	Stability	C	40979801, 41225201, 41225202, 41784101, 42616401
<u>ECOLOGICAL EFFECTS</u>			
71-1A	Acute Avian Oral - Quail/Duck	C	160643
71-2A	Avian Dietary - Quail	C	160644
71-2B	Avian Dietary - Duck	C	160645
71-3	Wild Mammal Toxicity	C	42112701
72-1A	Fish Toxicity Bluegill	C	160647
72-1C	Fish Toxicity Rainbow Trout	C	160647
72-2A	Invertebrate Toxicity	C	42636101
<u>TOXICOLOGY</u>			
81-1	Acute Oral Toxicity - Rat	C	42112701
81-2	Acute Dermal Toxicity - Rabbit/Rat	C	42660701
81-3	Acute Inhalation Toxicity - Rat	C	42488201
81-4	Primary Eye Irritation - Rabbit	C	42488201
81-5	Primary Dermal Irritation - Rabbit	C	42020702
81-6	Dermal Sensitization - Guinea Pig	C	42660601
82-1A	90-Day Feeding - Rodent	C	43626401, 43652701
82-2	21-Day Dermal - Rabbit/Rat	C	40419601
82-4	90-Day Inhalation - Rat	C	42633601

Data Supporting Guideline Requirements for the Reregistration of Butralin

REQUIREMENT		USE PATTERN	CITATION(S)
83-3A	Developmental Toxicity - Rat	C	40419601, 40419602, 40419603, 41742003, 42156101, 42156102, 42156103
83-3B	Developmental Toxicity - Rabbit	C	40419601, 41742002, 42156104
83-4	2-Generation Reproduction - Rat	C	92014039, 00154259
84-2A	Gene Mutation (Ames Test)	C	40121101, 40121102, 40551909
84-2B	Structural Chromosomal Aberration	C	40551910
84-4	Other Genotoxic Effects	C	00078460, 40121103, 40350901
85-1	General Metabolism	C	42743201
<u>ENVIRONMENTAL FATE</u>			
160-5	Chemical Identity	C	40979802, 41225203
161-1	Hydrolysis	C	43669401
162-1	Aerobic Soil Metabolism	C	43201901
163-1	Leaching/Adsorption/Desorption	C	42842301
165-4	Bioaccumulation in Fish	C	42069702, 42069703, 42069704, 42069705, 44081601

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

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

**GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE**

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6 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 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and six 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 Sheets
- 2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The 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: 703-605-6000).

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

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines 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 did 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 6. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

Option 4. Submitting an Existing Study

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, “*Raw data*” means any laboratory

worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

- b. Health and safety studies completed after May 1984 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 submission of 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 documents 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 a 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:
 - a). Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

- b). Fulfill the commitment to develop and submit the data as required by this Notice; or
 - c). Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

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

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

- 1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
- 2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
- 3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled 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 canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

BUTRALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Butralin. 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) a list of registrants receiving this DCI (Attachment 5) and (7) the Cost Share and Data Compensation Forms in replying to this Butralin Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the data base for Butralin are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Butralin 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 Butralin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

RE: Butralin

BUTRALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Butralin. 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 3), (4) a list of registrants receiving this DCI (Attachment 5), (5) the Cost Share and Data Compensation Forms in replying to this Butralin Generic Data Call In (Attachment D). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Butralin are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on Butralin are needed. These data are needed to fully complete the reregistration of all eligible Butralin 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 Tom Luminello at (703) 308-8075.

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

Tom Luminello, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Butralin

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Regulatory Information Division, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
- Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
- Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.
- Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

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

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

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

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

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

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption.

You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

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

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

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 initialed 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 canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response 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. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include deletion of uses or 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, Regulatory Information Division, Mail Code 2137, 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 REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.
- Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
- Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum,

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

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

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

- Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.
- Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume/minor use data waivers in the Data Call-In Notice and I request a low volume/minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
- Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume/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 canceled

EPA'S BATCHING OF BUTRALIN PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products, the Agency has batched products which can be considered similar for purposes of acute toxicity. Batching was not done for Butralin since there are only two products.

LIST OF REGISTRANTS SENT THIS DATA CALL-IN

Richard J. Otten, Agent of Record
CFPI
5116 Wood Valley Drive
Raleigh, North Carolina 27613

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

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 all 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.



United States Environmental Protection Agency
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

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)	

United States Environmental Protection Agency
Washington, DC 20460



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

**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief, Regulatory Information Division, Mail Code 2137, 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)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

☐ [] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

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

Signature

Date

Name and Title (Please Type or Print)

APPENDIX E - LIST OF AVAILABLE RELATED DOCUMENTS

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

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Internet using World Wide Web on <http://www.epa.gov/oppsrrd1/REDs/>, or contact C.P. Moran at (703) 308-8590.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for Butralin.

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

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

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

1. The Label Review Manual.
2. EPA Acceptance Criteria.

