United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(H-7508W)

EPA 738-R-93-018
September 1993

EPA Reregistration Eligibility Document (RED)

BUTYLATE

Printed on Recycled Paper

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

NOV 26 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division

representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Judy Loranger at (703)-308-8056.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-F-93-014
September 1993

EPA R.E.D. FACTS

Butylate

Pesticide Reregistration

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

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

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

Use Profile

Butylate is a selective herbicide registered solely for use on corn crops including field corn, sweet corn and popcorn, to control grassy and broadleaf weeds and nutsedge. Formulations include emulsifiable concentrates, granular and encapsulated forms. Butylate is applied with ground equipment and is incorporated into the soil immediately after application.

Regulatory History

Butylate was first registered as a pesticide in the U.S. in 1967. EPA issued a Data Call-In (DCI) Notice in 1981, and a Registration Standard in September 1983 (NTIS PB85-147304), which required additional product chemistry, toxicology, ecological effects and environmental fate data. The Agency issued a second DCI in October 1990, requiring submission of product chemistry, ecotoxicity, toxicology, environmental fate, residue chemistry and exposure information.

Currently, there are 14 active registered products which contain the active ingredient butylate. Between 6 and 15 million pounds of butylate are applied annually, treating 2 to 7% of the field corn grown in the U.S. Butylate is most commonly used in combination with the herbicides atrazine and/or cyanazine. Butylate/atrazine products are classified as Restricted Use Pesticides due to ground water concerns.

Human Health Assessment

Toxicity

Based on results of acute toxicity studies, butylate has been placed in Toxicity Category I for primary eye irritation. (Category I indicates the greatest and Category IV the lowest degree of acute toxicity.) It has been placed in Category III for acute oral and dermal toxicity, dermal irritation, and acute inhalation toxicity. EPA is requiring acute and subchronic neurotoxicity studies for butylate because it is chemically related to several pesticides which have shown neurotoxicity in long-term animal studies.

A chronic toxicity study using rats showed decreased body weight gain and liver effects in high-dose males. A study with Beagle dogs showed decreased body weight, increased platelet count, increased thyroid weight and liver effects at high doses.

Butylate does not appear to be carcinogenic in the mouse. In a study using rats, a significant increase in benign lesions was found in the livers of males at the highest dose tested. The Agency has classified butylate as a "Group E" carcinogen (evidence of non-carcinogenicity for humans).

In developmental toxicity studies, no teratogenicity was found in rats. Although maternal toxicity was observed at the highest dose level, no developmental effects were noted at any dose in rabbits. A reproductive toxicity study using rats showed kidney effects and changes in blood, organ weights and liver cells at the highest dose level.

Butylate is not mutagenic. Metabolism studies show that it is rapidly and completely metabolized and excreted, does not bioaccumulate, and does not produce metabolites of toxicological concern.

Dietary Exposure

People may be exposed to butylate residues when consuming treated corn. Tolerances or maximum residue limits of 0.1 ppm have been established for butylate in or on corn grain (including popcorn), fresh corn (including sweet corn), and corn forage and fodder (please see 40 CFR 180.232). The Agency has reassessed these tolerances and found that no changes are needed.

Residues of butylate do not concentrate in processed food or feed. Therefore, no food or feed additive tolerances have been required. Since it is metabolized rapidly, finite residues of butylate are not expected in meat, milk, poultry or eggs. There are no residues of concern to be regulated in rotational crops.

Plant metabolism studies indicate that no residues of intact butylate are found in corn at harvest. Storage stability studies show that residues of butylate in corn grain stored frozen remain stable for up to one year, but decline by about 50% within 2 to 3 years.

EPA conducted a chronic dietary exposure assessment for butylate using a Reference Dose (RfD) of 0.05 mg/kg body weight/day, using tolerance-level residues, and assuming 100% of the crop was treated. A "worst case" Theoretical Maximum Residue Concentration (TMRC) was estimated for the overall U.S. population and 22 subgroups. The TMRC for the general population was found to represent 0.1% of the RfD, and the TMRC for the most highly exposed subgroups (non-nursing infants and children 1 to 6 years old) represents 0.3% of the RfD for each subgroup.

Occupational and Residential Exposure

There is potential for dermal and inhalation exposure among workers involved in mixer/loader/applicator and soil incorporation activities. However, butylate is of low toxicity so worker exposure studies are not needed. Further, since butylate is incorporated into soil well before plants are mature, post-application exposure is unlikely and reentry data are not needed.

Human Risk Assessment

EPA has concluded that the human health risks from current, low-level exposure to butylate are minimal due to its low acute toxicity and because it is not believed to cause cancer in humans.

Environmental Assessment

Environmental Fate

The available data indicate that butylate is highly volatile and degrades moderately rapidly under aerobic conditions. Once in the atmosphere, butylate may be transported in fogs, mists and rainwater. Runoff to surface water may follow rainfall.

Based on these properties, EPA has additional questions regarding runoff into surface water (do concentrations of butylate exceed the Levels of Concern for fish?), persistence (would butylate residues remain at high levels long enough to present a chronic risk to terrestrial animals ?), volatility (what is the amount and nature of residues in air from volatilization of butylate as a result of normal agricultural use?), and ground water (is degradation sufficiently rapid to preclude leaching to ground water?). The Agency is requiring field dissipation studies with volatilization measurements and aged leaching data to confirm it's assessment of butylate's environmental fate.

Ecological Effects

Technical butylate is practically nontoxic to birds, highly toxic to freshwater fish, slightly toxic to freshwater invertebrates and relatively nontoxic to honey bees. Available data indicate a potential for chronic risk to birds and mammals, but butylate residues are not expected to persist long enough to allow chronic exposure. Runoff, spray drift and volatility from sprinkler application can be expected to reach plants in adjacent fields. Thus, butylate may pose a hazard to endangered or threatened species.

Ecological Effects Risk Assessment

Based on available use and exposure information, EPA calculated risk quotients to assess the acute and chronic risks of butylate granular and spray formulations to small mammals, birds and aquatic organisms. When the risk quotient is greater than the LOC, the species exposed may be at risk.

Regarding acute exposure, LOC triggers were exceeded for small mammals and birds. However, based on mitigating factors including butylate's use patterns, its low acute toxicity to birds, and the feeding habits and preferences of small mammals, the Agency has concluded that minimal acute risks actually exist for nonendangered species.

LOC chronic risk triggers also were exceeded for small mammals and birds, but only immediately after application of butylate granules. The Agency concludes that actual chronic risks are unlikely based on environmental fate data and mitigating factors including butylate's volatility, its use patterns (it is soil incorporated or watered in immediately after application), and the feeding habits of small mammals and birds, who would not likely consume enough granules per day required to reach the LEL over an extended period.

Neither acute nor chronic risks to aquatic organisms appear likely. Acute risks to nontarget insects also are unlikely. However, since butylate is a herbicide, risks to nontarget plants are likely.

Endangered Species

Potential acute risks exist for nontarget endangered mammals, freshwater vertebrates and amphibians. There also is a possibility of chronic risks to endangered mammals and birds, as well as risks for endangered plants, which may impact endangered insects. EPA is working with the U.S. Fish and Wildlife Service to develop a program to avoid jeopardizing the continued existence of identified species by the use of pesticides. When this program goes into effect, endangered species labeling will be required.

Additional Data Required

The generic data base for butylate is substantially complete. However, for confirmatory purposes, EPA is requiring additional generic studies including product chemistry, storage stability, aged leaching, terrestrial field dissipation with volatilization measurements, seed germination/seedling emergence, vegetative vigor, aquatic plant growth, droplet size, spray drift and acute and subchronic neurotoxicity.

EPA also is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling for reregistration of pesticide products containing butylate.

Product Labeling Changes Required

All end-use butylate products must comply with EPA's current pesticide product labeling requirements. In addition:

- **Effluent Discharge Statement**

All end-use or manufacturing-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following effluent discharge labeling statement, modified to include a fish toxicity statement:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

- **Worker Protection Standard (WPS) Requirements**

Any product whose labeling permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery or greenhouse) must, within the deadlines specified, comply with the labeling requirements of:

- PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and
- PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7."

Unless specifically directed in the RED document, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the PR Notices.

Labels must be revised to comply with the WPS requirements --

- After April 21, 1994, for products distributed or sold by the primary registrant or any supplementally registered distributors, and
- After October 23, 1995, for products distributed or sold by any person.

- **Restricted Use Pesticides**

The 2 registered butylate/atrazine combination products, classified as Restricted Use Pesticides due to ground water concerns, must retain current label precautions regarding toxicity and protection of ground and surface water.

- **Personal Protective Equipment (PPE)**

The following PPE labeling is required for all end-use products:

Applicators and other handlers must wear:

- *Long-sleeved shirt and long pants*
- *Chemical-resistant or waterproof gloves*

- *Shoes plus socks*

Registrants must compare these PPE requirements with those on current labeling (if any), and retain the more protective. For guidance, please see Supplement Three of PR Notice 93-7.

- **Entry Restrictions**

A 12-hour restricted entry interval (REI) is required for all uses on all butylate end-use product labels. This REI should be inserted into the standard REI statement required by PR Notice 93-7.

The PPE for early entry should be that required for applicators (see above), except:

- No apron or respirator (if on the label) is required, and
- "Coveralls" must be specified instead of "long-sleeved shirt and pants."

This information should be inserted into the standard early entry PPE statement required by PR Notice 93-7.

- Sole Active Ingredient Products - Registrants must adopt these entry restrictions, and remove any conflicting entry restrictions from their labels.
- Multiple Active Ingredient Products - Registrants must compare these entry restrictions with those on current labeling, and retain the more protective.

- **Protection of Aquatic Organisms**

The Environmental Hazard Section of the label must include the following statements:

- For Granular End-Use Products:

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

- For Non-Granular End-Use Products:

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

Regulatory Conclusion

The use of currently registered pesticide products containing butylate as labeled and specified in the RED document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Products containing butylate as the sole active ingredient may be reregistered once the generic and product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products also containing other active ingredients may be reregistered only when the other active ingredients are determined to be eligible for reregistration.

For More Information

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

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

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

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

REREGISTRATION ELIGIBILITY DECISION DOCUMENT

BUTYLATE

LIST A

CASE 0071

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

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BUTYLATE REREGISTRATION ELIGIBILITY TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas liquid chromatography
HDT	Highest Dose Tested
K+CWHR	Kernel plus cob with husk removed
LC_{50}	An experimentally derived estimate of the median lethal concentration. The median lethal concentration is that concentration of a chemical in the inspired air which, when respired will kill 50% of the sampled population. It is expressed as the mass of a substance per unit volume of air.
LD_{50}	An experimentally derived estimate of the median lethal dose. The median lethal dose is that mass of a chemical which, when administered by any route, will kill 50% of the sampled population. It is expressed as mass of a substance per unit mass of the animal.
LD_{lo}	Lethal Dose-low. The lowest dose at which lethality has been observed, either experimentally or following accidental exposure.
LEL	Lowest Effect Level
LOC	Level of concern
LOEL	Lowest Observed Effect Level

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

MATC	Maximum Allowable Toxic Concentration
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Manual
PPE	Personal Protective Equipment
ppm	Parts Per Million
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TGAI	Technical Grade of the Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TEP	Typical End-Use Product

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide butylate. Butylate is a soil incorporated herbicide produced by Zeneca Inc. and is registered for use on field corn, sweet corn and popcorn to control grass, broadleaf weeds and nutsedge. Butylate formulations include emulsifiable concentrates, a granular form, and a microencapsulated form. Butylate is applied with ground equipment and is incorporated into the soil immediately after application. In certain geographic areas, butylate is registered for application into center pivot irrigation systems, injection into the soil before or at planting, fall application before the ground freezes, or soil application and incorporation between the rows after corn emergence. Butylate is cleared for use with compatible fluid fertilizers and for impregnation on certain dry bulk fertilizer formulations.

Butylate was initially registered as a pesticide in 1967 by the Stauffer Chemical Company. A Registration Standard was issued in September 1983 (NTIS PB85-147304). This Registration Standard summarized the available data supporting the reregistration of products containing butylate used for control of grassy and broadleaf weeds and nutsedge prior to emergence, and with preplant, at-planting, and postplanting applications. The Registration Standard also required additional product chemistry, toxicology, ecological effects and environmental fate data. An October 24, 1990 Data Call-In Notice (DCI) required the submission of product chemistry, ecotoxicity, toxicology, environmental fate, residue chemistry and exposure information. The Agency has now completed its review of the butylate data base including the data submitted in response to the 1983 Registration Standard and the 1990 DCI.

The Agency has determined that the uses of butylate as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. However, for confirmatory purposes, the Agency is requiring that additional generic data be submitted. These data include product chemistry, storage stability for crop field trials, aged leaching and terrestrial field dissipation studies with volatilization measurements. The Agency is also requiring that other generic data be submitted. These data, which include acute and subchronic neurotoxicity, seed germination/seedling emergence, vegetative vigor, aquatic plant growth and droplet size and spray drift, are not part of the target database for the reregistration of butylate.

Based on the results of its reregistration review, the EPA has concluded that all registered uses of butylate are eligible for reregistration. The Agency has classified butylate as a Group E carcinogen (signifies evidence of non-carcinogenicity in humans). A reference dose of 0.05 mg/kg/day has been established based on a NOEL of 5 mg/kg/day, with an uncertainty factor of 100, for increased liver weights in male dogs in a long-term feeding study. The dietary risk assessment is based on a worst-case scenario, assuming treatment of 100% of acreage and highest legal residue values which result in an overestimation of exposure and risk. Even using these values, dietary exposure is estimated to be minimal. There are tolerances established for corn grain (including popcorn), fresh corn (including sweet corn) and corn forage and fodder (including sweet corn, field corn, and popcorn). A reassessment of tolerances is included in this

document and there are no changes in the previously established tolerances. The Agency has concluded that human health risks from exposure to butylate are minimal due to its low acute toxicity and current classification as non-carcinogenic to humans. Available data indicate that technical butylate is practically nontoxic to birds, highly toxic to freshwater fish, slightly toxic to freshwater invertebrates and relatively nontoxic to honey bees.

Before reregistering the products containing butylate, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable, the Agency may reregister a product based on whether or not it meets the requirements in Section 3(c)(5) of FIFRA. Those products which contain other active ingredients may be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for 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.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of butylate. The document consists of six sections. Section I is the introduction. Section II describes butylate, 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 butylate. Section V discusses the reregistration requirements for butylate. 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.[1]

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[1] EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** butylate
- **Chemical Name:** S-ethyl diisobutylthiocarbamate
- **CAS Registry Number:** 2008-41-5
- **OPP Chemical Code:** 041405
- **Empirical Formula:** $C_{11}H_{23}NOS$
- **Trade and Other Names:** Sutan +, R-1910, Gennate Plus, Sutazine +
- **Basic Manufacturer:** Zeneca, Inc.

B. Use Profile

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

Type of Pesticide:

A soil-incorporated herbicide

Mechanism of action:

Inhibits growth in the meristematic region of leaves of grass by unknown mechanism

Use Groups/sites:

- Terrestrial food and feed crop: field corn, popcorn, sweet corn, forage/silage

Target Pests:

- Barnyardgrass; crabgrass; giant, green, and yellow foxtail; goosegrass; seedling johnsongrass; and nutsedge

Formulation Types Registered:

- Emulsifiable concentrate (89.6%, 88.2%, 85.1%, 78.0%, (77.3%, 74.2% butylate formulations)

- Granular (10% butylate formulation)

- Microencapsulated (48.2% butylate formulation)

- Technical grade (97.0% technical butylate formulation)

- Emulsifiable concentrate combination product of butylate and atrazine (56.8% butylate), atrazine is suspended in a butylate EC

- Granular combination product of butylate and atrazine (18% butylate)

Method and Rates of Application:

Type of Application - ground (broadcast or band)

Equipment - boom sprayer, soil injection equipment, center pivot irrigation, and granule application

Rates - Butylate is applied as a preemergent, preplant, at plant, postplant or fall application at the following maximum active ingredient rates to corn, popcorn and sweet corn:

Emulsifiable concentrate- applied at 6.30 lbs ai/A
Granular- applied at 4.08 lbs ai/A
Microencapsulated- applied at 5.994 lbs ai/A

C. Estimated Usage of Pesticide

Between 6 to 15 million pounds of butylate are applied annually, treating 2 to 7% of the field corn grown in the United States. No more than 200,000 pounds of butylate is applied to sweet corn. Butylate is applied to less than 13% of sweet corn acreage. Data are unavailable for popcorn. These estimates are derived from a variety of published and proprietary sources available to the Agency.

D. Data Requirements

Data requested in the September 1983 Registration Standard for butylate included studies on product chemistry, toxicology, ecological effects and environmental fate. These data were required to support the uses listed in the Registration Standard. The 1990 DCI required the submission of product chemistry, ecotoxicity, toxicology, environmental fate, residue chemistry, and exposure data. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Butylate was initially registered by the Stauffer Chemical Company in 1967. Butylate is a selective herbicide registered solely for use on corn (field, sweet, and popcorn) for control of grassy and broadleaf weeds and nutsedge. Butylate is most commonly used in combination with atrazine and/or cyanazine. Butylate formulations include granular forms, emulsifiable concentrates and an encapsulated form. The wettable powder formulation and one of the two granular formulations are sold as package mixes with atrazine. Registered products containing butylate as the sole active ingredient are not classified as restricted use at this time. The butylate-atrazine products are currently classified as restricted use due to groundwater concerns.

Butylate is applied with ground equipment and is incorporated into the soil immediately after application. In certain geographic areas, butylate is registered for application into center pivot irrigation systems, injection into the soil before or at planting, fall application before the ground freezes, or soil application and incorporation between the rows after corn emergence. Butylate is cleared for use with compatible fluid fertilizers, and for impregnation on certain dry bulk fertilizer formulations.

Data Call-In (DCI) notices were issued in 1981 for butylate requiring chronic feeding, oncogenicity, reproduction and teratology studies. A Registration Standard for butylate was issued on September 30, 1983 (NTIS #PB85-147304) which evaluated the studies submitted as a result of the 1981 DCIs. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and 1990 Data Call-In.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color:	Pale yellow
Physical State:	Liquid
Odor:	Rubbery sweet
Boiling Point:	107-109°C at 5 mm Hg
Density:	0.9397 g/ml at 20°C
Solubility:	4.4 X 10^{-3} g/ml of water at 20°C; miscible with organic solvents
Vapor Pressure:	12.9 μm Hg at 25°C., 6.8 μm Hg at 20°C
Octanol/Water Partition Coefficient	1.4 x 10^4 at 25°C
pH:	5.5 at 22°C
Stability:	Stable at elevated temperatures (53°C) for two weeks. Stable to sunlight, to moisture, metals and metal ions
Oxidizing/reducing Action:	Reacted with oxidizing agent but not reducing agent
Flammability:	Did not flash at 106°C
Explodability:	Not thermally explodable up to 250°C
Storage Stability:	Stable at ambient temperature for 2 years
Viscosity:	4.81 centistokes at 25°C
Corrosion Characteristics:	Noncorrosive to stainless steel, carbon steel, borosilicate glass, soft glass, and aluminum

The Agency has evaluated the product chemistry data base and has concluded that available preliminary analysis data are not fully acceptable and additional data must be submitted. Although this preliminary analysis data gap exists, the Agency considers the requirement of this study as confirmatory and not critical to the reregistration eligibility decision. The data requirements and the data gaps are given in Appendix B.

B. Human Health Assessment

1. Toxicology Assessment

At the time of the Registration Standard the following studies were required:

Acute inhalation (rat) study
90 day non-rodent feeding study
Chronic non-rodent toxicity study
Rat and mouse oncogenicity studies
Rat and rabbit developmental toxicity studies
2-Generation reproduction study
Gene mutation study
Chromosomal aberration study
Other genotoxic effects study
General metabolism study

A Data Call-In notice dated 10/24/90 required the submission of a dermal sensitization study, an acute inhalation study and a 90 day mammalian neurotoxicity study. The Agency has reviewed the registrant's data waiver request for the 90 day mammalian neurotoxicity study and concludes that this study and an acute neurotoxicity study are still required. However, these requirements are not part of the target database for butylate and do not affect the reregistration eligibility decision. These studies are required to support the continued registration of butylate products. The data requirements and data gaps are given in Appendix B. Summaries of available studies are provided below.

a. Acute Toxicity

The table below summarizes the toxicity results and categories for technical grade butylate.

TEST	RESULTS	TOX CATEGORY
Acute Oral LD_{50} (1)	Males > 3500 mg/kg females > 4000 mg/kg	III
Acute Dermal LD_{50} (1)	LD_{50} > 2000 mg/kg	III
Acute Inhalation LC_{50} (2)	LC_{50} = 2.85 mg/L	III

1. MRIDs 00063486, 00149316
2. MRID 42389401

The following table is derived from manufacturing use product data considered toxicologically similar to butylate technical and is for informational purposes only.

TEST	RESULTS	TOX CATEGORY
Primary Eye Irritation (1)	Corneal opacity noted after 21 days	I
Primary Dermal Irritation (2)	erythema and edema after 24 hours, still present after 72 hours	III
Dermal Sensitization (3)	Skin sensitizer	Not applicable

1. MRID 00063487
2. MRIDs 00063487, 00149316
3. MRID 42123903

Acute Neurotoxicity

An Acute Neurotoxicity Special Study (Guideline 81-8) is a new requirement. This study is needed, because butylate is chemically related to several thiocarbamate pesticides which have shown neurotoxicity in long-term repeated dose studies in rats and/or dogs. The lack of evidence of neurotoxicity in a chronic rat study of butylate at 400 mg/kg/day does not provide sufficient evidence that butylate may not be neurotoxic. This study is not part of the butylate target database.

b. Subchronic Toxicity

90 Day Feeding-Rodent

Two rat feedings studies were reviewed and deemed unacceptable. However, a 2-year rat feeding study described below satisfies this requirement.

90-Day Feeding - Nonrodent

A 13 week dog feeding study was reviewed and found to be unacceptable because of procedural deficiencies. However, an acceptable 1-year dog study described below satisfies this requirement.

21-Day Dermal

Technical butylate was applied five days/week to normal and abraded skin sites of New Zealand white rabbits as a ten percent solution (20 mg/kg ai) and a 20 percent solution (40 mg/kg ai) . Treated areas showed erythema, dryness, fissuring, and sloughing. Congestion was reported in kidneys and lungs of treated animals, but no supportive histopathology for these observations was found by the investigators. (MRID 00026312)

Subchronic Neurotoxicity (Mammalian)

A waiver request for this requirement was denied, because butylate is chemically related to several thiocarbamate pesticides that have shown neurotoxicity in long-term repeated dose studies in rats and/or dogs.

c. Chronic toxicity

Chronic Rodent

An acceptable rodent study is available in the rat. Sprague-Dawley rats ingested butylate technical at levels of 50, 100, 200, or 400 mg/kg/day for 24 months. The systemic no-effect level was determined to be the lowest dose tested, 50 mg/kg/day, based on decreased body weight gain at the next higher dose, 100 mg/kg/day, and above. In addition, increased incidence of periportal hepatocellular hypertrophy was recorded in high-dose (400 mg/kg/day) males. (MRID 00125678)

Chronic Nonrodent

An acceptable nonrodent study is available in the dog. Beagle dogs were given gelatin capsules containing 0, 5, 25, or 100 mg/kg butylate daily for 12 months. A systemic no-effect level was determined to be 5 mg/kg/day, based on increased relative liver weight in males treated at the next higher dose, 25 mg/kg/day. In addition, high-dose (100 mg/kg/day) males and females showed decreased body weight, increased platelet count, increased alkaline phosphatase activity, and increased thyroid/parathyroid weight; hepatocellular vacuolization/vesiculation was also recorded in two males at this dose. (MRID 40389101)

d. Carcinogenicity

The carcinogenicity data requirement for studies in two species is satisfied by adequate studies in the mouse (MRID 00035844) and rat (MRID 00125678).

In the first study, CD-1 mice were fed butylate (in corn oil) for 24 months at levels providing daily intakes of 0, 20, 80, or 320 mg/kg/day. Although dose-related non-neoplastic changes were found in livers and kidneys at 80 and 320 mg/kg/day, no increase in neoplastic lesions was recorded at any dose in either sex. Butylate does not appear to be carcinogenic in the mouse. (MRID 00035844)

The second study was a combined chronic toxicity/carcinogenicity study in Sprague-Dawley CD rats fed butylate at levels up to equivalent intakes of 400 mg/kg/day. In addition to periportal hypertrophy, a significant increase in neoplastic nodules (benign lesions) was found in the livers of males at the highest dose tested, 400 mg/kg/day. (MRID 00125678)

The carcinogenicity of butylate was evaluated on 10/15/92 by the OPP Peer Review Committee which classified butylate as Group E - evidence of noncarcinogenicity for humans.

e. Developmental Toxicity

Developmental toxicity data requirements, listed as data gaps in the 1983 Registration Standard, have since been satisfied by adequate studies in rats (MRID 00131032) and rabbits (MRID 40389102).

Butylate technical, administered orally by gavage to Sprague-Dawley (CD) rats at doses of 0, 40, 400, or 1000 mg/kg/day caused decreased body weight gain and increased relative liver weight in dams. Decreased fetal body weight

and increased skeletal effects were found at 400 mg/kg/day and above, but increased resorptions only at the highest dose tested. No teratogenicity was found at any dose. The maternal and fetotoxic no observed effect level (NOEL) was determined to be the 40 mg/kg and the embryotoxic NOEL, 400 mg/kg.

In the rabbit study, butylate was administered at oral doses of 0, 10, 100, or 500 mg/kg/day. Maternal toxicity (decreased body weight gain and increased ovarian weight) was observed only at the highest dose tested (hence the maternal NOEL was set at 100 mg/kg), but no developmental effects were noted at any dose.

f. Reproductive Toxicity

The data requirement for a reproduction study with butylate has been satisfied with an adequate two-generation study in rats fed butylate technical at levels of 0, 200, 1000 or 4000 ppm (MRID 00160548).

Decreased food consumption in parental males and decreased body weight in parental females during gestation and lactation were observed at 1000 ppm (50 mg/kg/day), while decreased body weight in F_2a (second generation) pups and decreased absolute brain weight in F_1b (first generation) male weanlings were noted at the same level.

Increased incidences of dilated renal pelvis and retinal folds were observed in the F_1b animals but only at 4000 ppm (200 mg/kg/day). Other treatment related systemic and reproductive effects were noted at the highest dose tested, including hematological and organ weight changes, as well as increased hepatocyte vacuolization. The maternal and developmental NOELs were found to be 200 ppm and 1000 ppm, respectively.

g. Mutagenicity

Acceptable studies are available which report that technical butylate does not induce gene mutations in Ames testing in bacteria (MRIDs 00149317 and 00162707) or in mouse lymphoma cell (MRID 00162707), even at doses producing severe toxicity. The same preparation was also negative for chromosome damage in mouse lymphoma L5178Y cells (MRID 00162709), as well as negative for DNA repair in yeast cells (MRID 00149317) and mouse lymphoma cells (MRID 00162709), and negative for transforming capacity in BALB/3T3 cells (MRID 00162710).

h. Metabolism

A total of five reports on the metabolism of butylate in rats have been submitted. Together, the reported studies satisfy the metabolism data requirements for butylate. They indicate that butylate is rapidly and completely metabolized and excreted. No evidence of bioaccumulation was observed and no metabolites of toxicological concern were identified. (MRIDs 43680, 43681, 43682, 00250645 and 41037301)

i. Reference Dose

A RfD of 0.05 mg/kg/day has been established for butylate based on a NOEL of 5 mg/kg/day for increased liver weights observed in males at 25 mg/kg/day in a long-term feeding study in dogs and an uncertainty factor of 100. An ADI (Acceptable Daily Intake) has not been established by the World Health Organization.

2. Exposure Assessment

a. Dietary

At the time of the Registration Standard, only field and confined rotational crop studies were required. The 10/24/90 Data Call-In notice required the submission of the following studies on corn, the only registered crop:

Residue analytical method in plants
Storage stability
Magnitude of the residue in processed foods
Confined rotational crop

The residue chemistry data base for butylate is substantially complete with the exception of storage stability data that must still be submitted. The storage stability data are considered confirmatory. The Agency has concluded that this requirement is not critical to the reregistration eligibility decision. The data requirements and data gaps are shown in Appendix B. Summaries of available studies are provided below:

Plant Metabolism

The parent compound butylate is the residue of concern. Studies with corn seedlings conducted under hydroponic conditions and corn grown under simulated field conditions indicate that butylate is rapidly absorbed from soil by the roots, translocated to shoots, and metabolized via oxidation to sulfoxides followed by transfer of the dialkycarbamoyl moiety to glutathione. Glutathione

conjugates are metabolized further to cysteine and 3-thiolactic acid conjugates. These compounds are then conjugated with malonic acid and glucose. No residues of intact butylate or of diisobutylamine have been found in corn at harvest. (MRID s 00020555, 00020558, 00021594, 00021781, 00021822, 00021849, and 00129398)

Animal Metabolism

Greater than 99% of [^{14}C]butylate administered to laboratory animals (rodents), is rapidly metabolized to water-soluble compounds which are readily eliminated by excretion (in urine and feces). Metabolism occurs via sulfoxidation, hydrolysis, and conjugation (major pathway), and via oxidation and degradation (minor pathway). No metabolites of toxicological concern were identified. Data from ruminant and poultry metabolism studies are not required because of limited potential exposure from residues of butylate on livestock feed items, and also because of a lack of evidence that residues of butylate exist in laboratory animals. There is no reasonable expectation of finite residues of butylate in meat, milk, poultry, and eggs with respect to 40 CFR 180.6 (a)(3) and no tolerances for animal feed items are required. (MRID 00129397)

Residue Analytical Methods - Plants and Animals

An adequate enforcement method is available for determination of residues of butylate in or on corn grain, forage, and fodder. The enforcement method (Method A of PAM Vol. II; Sec. 180.232) is a GLC method with microcoulometric detection and a limit of detection of 0.04 ppm. This enforcement method has undergone successful Agency method validation on corn grain. Since no tolerances exist for animal commodities, enforcement methods for residues of butylate in animal commodities are not required. (MRID 00022848, 00023535, 00024324, 00024776, 00025676; 00063485, 00064183, 00068699, 00074451, 05002372, 05010440, 05013158, 05018944, 42126302)

Storage Stability

The available storage stability data (MRID 41812205) indicate that residues of butylate are stable in corn grain stored frozen for up to 1 year. Residues in corn grain stored for 2 and 3 years decline by approximately 50%. A portion of the samples of corn grain used to provide data supporting the established tolerances were stored for intervals in excess of 1 year. Reassessment of the 0.1 ppm tolerance includes the assumption that residues of butylate have declined 50% during storage. The registrant has been required (DCI dated 10/24/90) to submit the sample storage conditions and intervals for those samples deemed to be useful for tolerance reassessment. The registrant has submitted preliminary storage stability data from samples of milled corn grain, where the

recovery was 85% of the nominal residue (0-day sample). The adequacy of this study will be determined when the final report for this study is submitted in September 1993. The required storage stability data can be considered confirmatory and does not affect the reregistration eligibility of butylate.

Magnitude of the Residue in Plants

The available residue data from crop field trials provide sufficient information to reassess the 0.1 ppm tolerances for residues of butylate in/on corn grain, fresh corn, and corn forage/fodder. This assessment includes the assumption that residues of butylate may decline up to 50% in samples stored in excess of 1 year. Residues of butylate in or on about 250 samples of corn grain or whole ears and about 200 samples of field corn forage and fodder were nondetectable (<0.02 to <0.05 ppm). A portion of these samples was stored for up to 3 years. Assuming a 50% residue decline in samples of corn grain, forage, and fodder stored for periods longer than 1 year, residues of butylate are not expected to exceed the established 0.1 ppm tolerance. (MRID 00020547, 00020548, 00020564, 00021749, 00021751, 00021753, 00021755, 00021759, 00021766, 00021769, 00021783, 00021784, 00021787, 00021794, 00021803, 00021856, 00022846, 00023534, 00023727, 00023816, 00023817, 00023818, 00023819, 00024775, 00026259, 00026260, 00026315, 00026316, 00026974, 00035840, 00037762, 00041699, 00090889, 00093145, 00093221, 00093222, 00098255, 00109470, 00117892, 42406401)

Processed Food/Feed

Corn grain and sweet corn cannery waste processing studies indicate that residues of butylate do not concentrate in processed food/feed items. No food/feed additive tolerances are required. (MRID 42126301 and 42448701)

Confined Rotational Crops

The confined rotational crop study is adequate to satisfy this guideline requirement. There are no terminal residues of concern to be regulated in rotational crops; thus, tolerances on rotational crops need not be established. No additional residue characterization or field rotational crop studies (GLN 165-2) are required, and no specific plantback intervals are needed. The parent compound, butylate, was not identified in any plant tissue extract. Two metabolites were identified and confirmed in plants from the 30-day rotational interval. The Agency has concluded that the butylate metabolites, identified in plants rotated to butylate-treated soil, are not of toxicological concern. Hydrolysis of the non-extractable fractions yielded residues in hydrolysates and post-hydrolysis solids predominantly in the 10 ppb range. Residues resulting in rotational crops do not require regulation. (MRID 42694001)

b. Occupational and Residential

At the time of the Registration Standard, no exposure studies were required. The 10/24/90 Data Call-In notices stated that dermal and exposure studies were reserved pending the review of required toxicology data.

Although there is a potential for dermal and inhalation exposure for workers involved with mixer/loader/applicator and soil incorporation activities, butylate does not meet Agency criteria for additional testing based on available toxicity studies. In addition, since butylate is soil incorporated well before the plants are mature, the potential for postapplication exposure during tasks such as sweet corn harvesting or seed corn detasseling is unlikely. Because butylate does not meet EPA's exposure or toxicity criteria, postapplication/reentry data are not required to support the reregistration of this chemical.

3. Human Risk Assessment

a. Dietary

A chronic dietary exposure assessment has been conducted using the following parameters:

1. Toxicological Endpoint: This assessment used a Reference Dose (RfD) of 0.05 mg/kg body weight/day, based on a No Observed Effect Level (NOEL) of 5.0 mg/kg body weight/day and an uncertainty factor of 100. The NOEL was taken from a long-term feeding study in dogs which demonstrated increased liver weights in males at the next dose, 25 mg/kg/day.

2. Residue Information: Food uses in this analysis are the published tolerances on corn commodities. Published tolerances for this chemical are listed in the Tolerance Index System (TIS) and 40 CFR §180.232.

This assessment used tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 subgroups. The TMRC represents a worst case estimate. The TMRC for the general population from all published tolerances is 5.8×10^{-5} mg/kg body weight/day, representing 0.1% of the RfD. The most highly exposed subpopulations are non-nursing infants (< 1 year old) and children (1-6 years old). Assuming tolerance level exposures, the TMRCs are 1.39×10^{-4} and 1.43×10^{-4} mg/kg/day, respectively, representing 0.3% of the RfD for each subgroup. At this time, there are no pending or temporary tolerances for butylate.

b. Occupational and Residential

The Agency has concluded that human health risks from exposure to butylate are considered to be minimal due to its low acute toxicity and current classification as non-carcinogenic to humans. No occupational or residential exposure data have been required.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

The Registration Standard required the following environmental fate studies:

Hydrolysis
Photodegradation in water
Terrestrial field dissipation
Fish accumulation

The 10/24/90 Data Call-In notice required the submission of the following studies:

Photodegradation in soil
Aerobic soil metabolism
Anaerobic soil metabolism
Leaching/adsorption/desorption
Volatility (Laboratory)
Terrestrial field dissipation
Droplet size spectrum
Drift field evaluation

Two additional field dissipation studies with volatilization measurements, aged leaching, and spray drift and droplet size data are required to confirm the reregistration eligibility of butylate. Although data gaps exist, these requirements are not critical to the reregistration eligibility decision. The data requirements and data gaps are given in Appendix B. Summaries of available studies are provided below:

1. Hydrolysis

Butylate did not hydrolyze significantly in pH 5, 7, and 9 sterile aqueous buffered solutions containing 1% acetonitrile incubated in the dark at $\pm$ 25 °C. (MRID 40389111)

2. Photodegradation in water

Butylate does not degrade significantly in sterile aqueous pH 7 buffered solutions while being irradiated continuously for 30 days with a xenon arc lamp. (MRID 40389111)

3. Photodegradation in air

A photodegradation in air study is not required at this time. If the volatility measurements required in the field dissipation studies indicate a concern, the Agency will reconsider the need for this test.

4. Photodegradation on soil

Butylate degraded slowly on loam soil that was irradiated outdoors in California at approximately 25°C, with an average of 82% of the butylate remaining undegraded after 30 days of irradiation. No degradation of butylate occurred in the dark control during the same period. Two minor degradates, butylate sulfoxide and butylate sulfone, were identified in the irradiated soil. Because butylate is soil-incorporated, photodegradation is not likely to be an important route of dissipation in the environment. (MRID 42123905)

5. Aerobic soil metabolism

Butylate degraded with a reported half-life of 23.9 days in sandy loam soil that was incubated for 245 days in darkness at 24°C. The decline in butylate soil residues was due primarily to volatilization (47% of the applied radioactivity was present as volatilized parent at day 28) with aerobic soil metabolism of secondary importance. The nonvolatile degradates identified were butylate sulfoxide, diisobutylformamide, oxazolidinone, hydroxyisobutyl butylate, butylate S-acid, butylate N-acid, and diisobutylamine. At the end of the study, $^{14}CO_2$ and organic [^{14}C]volatiles (of which >93% were butylate) totaled 21.16 and 57.94% of the applied, respectively; ^{14}C-bound residues comprised 9% of the radioactivity. (MRID 41812201)

6. Anaerobic soil metabolism

Butylate degraded with a half-life of 63.6 days in anaerobic (flooding plus nitrogen atmosphere) sandy loam soil that was incubated in the dark at 24°C for up to 60 days following 20 days of aerobic incubation. The decline in butylate soil residues was due primarily to

volatilization (about 60% of the decline in soil residues during the anaerobic incubation period was due to volatilization of parent) with anaerobic soil metabolism of secondary importance. The nonvolatile degradates identified were butylate sulfoxide, diisobutylformamide, oxazolidinone, hydroxyisobutyl butylate, butylate S-acid, butylate N-acid, and diisobutylamine. The predominant volatilized compound was undegraded butylate. (MRID 41812201)

7. Leaching and adsorption/desorption

Based on batch equilibrium experiments, butylate was determined to be mobile to moderately mobile in Keeton sandy loam, Columbia loamy sand, Sorrento loam, and Atterberry silt loam soils. The respective Freundlich K_{ads} values reported for these soils were 1.48, 4.84, 7.28, and 5.47. These results are for parent butylate only and do not assess the mobility of degradation products. Aged leaching data are required as confirmatory data to assess the mobility of butylate degradation products. (MRID 41812202)

8. Laboratory volatility

Butylate readily volatilized from moist sandy loam soil with 53.1% of the applied radioactivity volatilized by 25 hr posttreatment. Butylate comprised >95% of the volatilized residues. During the experiment, the soil was maintained at 25°C and 75% of field moisture capacity, with a continuous flow of humidified air. (MRID 42123906)

9. Terrestrial field dissipation

In two studies found to be supplemental (MRIDs 41812203 and 41812204), butylate dissipated with half-lives of 12-13 days from the upper 6-7 inches of sandy loam soil that was treated with a soil-incorporated application of butylate at 6 lb a.i./A. Neither butylate nor monitored degradates were detected deeper than 9 inches.

These studies are considered supplemental for the following reasons:

(a) Butylate is used exclusively as a corn herbicide, but the studies were conducted in California which is not a major corn-growing region. The studies' results, therefore, may not be representative of butylate's dissipation under typical use conditions.

(b) Adequate freezer storage stability data for degradates were not presented.

(c) One study (MRID 41812204) was initiated during July when air and soil temperatures were elevated and therefore the dissipation reported is probably not representative of the compound's typical use. Butylate is normally applied during or near corn planting time (April - May). The other study (MRID 41812203) cannot be used toward fulfillment of the data requirement because the time zero soil samples did not confirm the application rate. As confirmatory data, two field dissipation studies are required.

10. Bioaccumulation in fish

The studies submitted provide supplemental information regarding the bioaccumulation in fish. These studies are considered supplemental because degradates were uncharacterized. [^{14}C]Butylate residues accumulated in bluegill sunfish continuously exposed to [^{14}C]butylate at 0.12-0.16 ppm, with maximum mean bioconcentration factors of 180x for edible tissues, 630x for nonedible tissues, and 410x for whole fish; by day 14 of the depuration period, 98-99% of [^{14}C]butylate residues were eliminated from the fish tissues. (MRIDs 40843901 and 40657401).

11. Spray Drift and Droplet Size

Droplet size spectrum (201-1) and spray drift evaluation (202-1) data are needed to support the chemigation application method for butylate. The registrant may elect to satisfy both data requirements through the Spray Drift Task Force, provided the Agency does not require these data in advance of the Task Force's final report (currently scheduled for 1994).

b. Environmental Fate Assessment

A comprehensive environmental fate assessment includes: 1) how a chemical dissipates; 2) identification of significant environmental degradation products if degradation occurs during dissipation and 3) analysis of where the residues are most likely to persist (e.g., in the atmosphere, ground water, surface water, target plants). The existing data base for butylate is sufficient to draw preliminary conclusions about its dissipation in the environment. However, there are uncertainties associated with these conclusions and therefore additional data are required to confirm this preliminary assessment.

Laboratory studies demonstrate what specific processes and relative rates may be involved with the dissipation of the chemical and the major environmental degradates. Field studies confirm the laboratory studies and examine how the competing dissipation processes affect the overall dissipation rate.

A preliminary assessment from acceptable laboratory data is that volatilization is an important (and perhaps the major) route of butylate dissipation. Partially satisfactory field dissipation studies provide indirect evidence that substantial volatilization occurs under actual use conditions. At present, however, there is no information related to the amount or nature of residues resulting from volatilization during normal agricultural use. It is not possible to quantify the extent of volatilization in the absence of field volatility data. Mineralization to CO_2 occurs also, but this appears to be secondary to volatilization as a dissipation pathway.

Based on the available data, it can be concluded that butylate is highly volatile and degrades moderately rapidly under aerobic conditions. Aerobic soil metabolism indicated that much of the applied butylate volatilized during the course of the study. The remaining butylate degraded to CO_2. The moderate value of the calculated Henry's Constant (8.26×10^{-6} atm-m^3/mol), combined with the compound's volatility, indicate that once in the atmosphere, butylate may be transported in fogs, mists, and rainwater. Because butylate is often applied to bare ground as a preemergence herbicide or shortly after planting, and because it is mobile to moderately mobile in soil, runoff to surface water may follow a rainfall event. Based on these demonstrated properties, there were several issues that require attention.

The first issue is run-off into surface water. The aquatic Estimated Environmental Concentration (EEC) was based upon models developed for two different scenarios. These were used to determine whether the concentrations of butylate would exceed the Levels of Concern for fish. Field studies would increase the certainty of the aquatic EEC by verifying the model.

With regard to the fish accumulation study, the Agency believes that no more data should be required for this guideline study for the following reasons:

1. 98-99% of the ^{14}C butylate residues were eliminated from the fish tissue within 14 days. Therefore, butylate is unlikely to be a major bioaccumulator.

2. Although there are unidentified residues in fish, this is unlikely to present a human health problem because:

a. Butylate is classified as a group E carcinogen, meaning that there is evidence of noncarcinogenicity for humans.

b. The Agency has concluded that at the current tolerance level exposures, the TMRCs for the most highly exposed subpopulations, non-nursing infants and children aged 1-6, are 1.39×10^{-4} and 1.43×10^{-4}, representing 0.3 % of the Rfd. Thus, there is little concern that residues in fish tissue will pose non-cancer risk.

The second issue relates to volatility of butylate. As stated above, butylate may be transported in mists, fogs and rainwater. The volatile component of the field dissipation study would provide basic information relating to butylate in air. At present, no field data exist relating the amount or the nature of residues in air from volatilization of butylate as a result of normal agricultural use.

The last issue relates to groundwater. As stated above, the data indicate that the major routes of dissipation are volatilization of butylate and degradation to CO_2. Some of the intermediate compounds appear to be structurally related to compounds that may be mobile. Degradation and volatility may not be sufficiently rapid to preclude leaching into ground water: however, these situations will most likely be rare. Dissociation constants developed for intermediate compounds on soils would help confirm that little or no leaching of residues will occur.

In summary, preliminary conclusions can be made about the dissipation of butylate in the environment. However, there are uncertainties associated with these conclusions. Consequently, the following data are required to confirm the assessment of the environmental fate of butylate but are not critical to the reregistration eligibility decision:

1. A minimum of two field dissipation studies are required. These two studies are to be conducted in major corn-producing regions where butylate is commonly used and must reflect typical corn cultivation practices. Because it is available in emulsifiable concentrate (EC), flowable concentrate (FC), granular, and microencapsulated formulation and because formulation may influence dissipation, the studies need to address the effect of formulation on the field dissipation of butylate. Therefore, at least one field dissipation study must be conducted with the

EC or FC and the second study must use either the granular or microencapsulated formulation. Volatilization measurements (which may be acceptable to satisfy the requirement for the field volatility study) are needed in all field dissipation studies because it appears to play a significant role in the environmental fate of butylate.

2. Aged leaching data are necessary to assess the mobility of butylate degradation products. Because of the volatility issue and the relatively slow formation of degradates under aerobic soil conditions, batch equilibrium studies using radiolabeled synthesized degradates are required to assess degradate mobility.

3. Spray drift data are required but may be fulfilled through the Spray Drift Task Force.

2. Ecological Effects

At the time of the Registration Standard cold and warm water fish acute LC_{50} studies were required. (The remaining ecological effects studies were either acceptable or not required). The 10/24/90 Data Call-In notice required the submission of the following studies:

Estuarine/marine toxicity - fish
A fish early lifestage study
Seed germination/seedling emergence
Vegetative vigor
Aquatic plant growth

The nontarget plant studies (seed germination, seedling emergence, vegetative vigor and aquatic plant growth) are not required as part of the target database for butylate and do not effect the reregistration eligibility decisions. These plant studies are required to support the continued registration of butylate products. The data requirements and data gaps are given in Appendix B. Summaries of available studies are provided below.

a. Ecological Effects Data

(1) Terrestrial Data

A. Effects to Nontarget Birds

(i). Avian Single-Dose Oral LD_{50}

AVIAN ACUTE ORAL TOXICITY			
SPECIES	% A.I.	LD_{50} (mg/kg)	CONCLUSIONS
Mallard Duck	98	>4640	Practically nontoxic

There is sufficient information from the study cited above to characterize technical grade butylate as practically nontoxic to birds when exposed orally to a single dose. (MRID 00025060)

(ii). Avian Dietary

AVIAN SUBACUTE DIETARY TOXICITY			
SPECIES	% A.I.	LC_{50} (ppm)	CONCLUSIONS
Bobwhite Quail (1)	98.1 Tech	>5620	Practically nontoxic
Mallard duck (2)	98.1 Tech.	>5620	

1. MRID 00131300
2. MRID 00131299

The studies listed above are sufficient to characterize technical butylate as practically nontoxic when exposure is through the diet to upland game birds (bobwhite quail) and waterfowl (mallard duck).

(iii). Avian Reproduction

Based upon the available mammalian reproduction data, the use pattern (typical application, preplant with incorporation into bare soil), and the available environmental fate data, avian reproduction tests are not required at this time. If future environmental fate data (i.e., for microencapsulated or granular formulations) indicate significant persistence of butylate, the Agency will reconsider the need for these tests.

(2) Aquatic Organism Data

A. Acute Toxicity to Freshwater Fish

(i). Effects of Technical Butylate to Freshwater Fish

FRESHWATER FISH ACUTE TOXICITY TECHNICAL BUTYLATE			
SPECIES	% A.I.	LC_{50} (ppm)	CONCLUSIONS
Bluegill sunfish (1)	98.2	6.4	The LC_{50} values for freshwater fish range from 0.21-7.0 ppm. Using the data from the most sensitive species, bluegill sunfish, technical butylate is classified as highly toxic to freshwater fish.
Rainbow trout (2)	98.2	7.0	
Bluegill sunfish (3)	98	0.21	
Bluegill sunfish (3)	98	0.47	
Rainbow trout (3)	98	2.10	

1. MRID 00149318
2. 00149319
3. 40098991

Using the data from the most sensitive species, bluegill sunfish, there is sufficient information to characterize technical butylate as highly toxic to freshwater fish.

(ii). Effects of Butylate Formulations to Freshwater Fish

FRESHWATER FISH ACUTE TOXICITY BUTYLATE FORMULATIONS			
SPECIES	% A.I.	LC_{50} (ppm)	CONCLUSIONS
Rainbow trout (1)	79.23 (Sutan 6E)	5.2	Moderately toxic
Bluegill Sunfish (1)	79.23 (Sutan 6E)	7.2	
Bluegill Sunfish (2)	Sutan 4S Microencap-silated	>500	Practically nontoxic
Rainbow trout (2)	Sutan 4S Microencap-silated	>700	

1. MRID 00021835
2. MRID 00020532

There is sufficient information to characterize a 79.23 percent emulsifiable concentrate formulation as moderately toxic to coldwater and warmwater fish. A 48 percent microencapsulated formulated product was found to be practically nontoxic to fish.

B. Fish Early Life-Stage

A fish early life stage study (MRID 42214302) and an addendum (MRID 42773601) were reviewed and found to be scientifically-sound but do not meet the guideline requirements for a fish early life-stage test because of study defects. Although flawed, this study shows that the maximum allowable toxic concentration for technical butylate was greater than 0.30 ppm and less than 0.51 ppm. The study can be used to conduct a risk assessment, therefore, the Agency will not require another study to support the presently registered corn use.

C. Acute Toxicity to Freshwater Invertebrates

FRESHWATER INVERTEBRATE ACUTE TOXICITY			
SPECIES	% A.I.	LC_{50} (ppm)	CONCLUSIONS
Daphnia magna	98	11.9	Slightly toxic

There is sufficient information to characterize technical butylate as slightly toxic to freshwater aquatic invertebrates.
(MRID 00021841)

D. Acute Toxicity to Estuarine/Marine Organisms

ACUTE TOXICITY ESTUARINE ORGANISMS			
SPECIES	% A.I.	LC_{50} ppm	CONCLUSIONS
Sheepshead Minnow	98.4	2.6	Moderately Toxic

A 96-hour LC_{50} study was conducted to determine the acute toxicity of butylate to estuarine and marine fish. The guideline requirement for technical grade acute testing using an estuarine/marine fish has been satisfied. (MRID 42214301) Technical butylate was found to be moderately toxic to sheepshead minnow.

(3) Non-Target Insects Data

ACUTE TOXICITY NONTARGET INSECTS			
SPECIES	% A.I.	LD_{50} μg/bee	CONCLUSIONS
Honeybee	TGAI	>29	Relatively nontoxic

There are sufficient data to characterize butylate as relatively nontoxic to honey bees. (MRID 00036935) Therefore, the guideline requirement for the honey bee acute contact LD_{50} study has been fulfilled.

(4) Non-Target Plants Data

Seven studies were evaluated under this topic and were found to be unacceptable due to either solubility problems or reporting deficiencies. Phytotoxicity testing is required because the pesticide may pose a hazard to endangered or threatened species. Runoff, spray drift and volatility from center pivot sprinkler application can be expected to reach plants in adjacent fields. Seed germination, seedling emergence, vegetative vigor, and aquatic plant growth studies are required. These studies are not required as part of the target database for butylate and do not affect the reregistration eligibility decision. These studies are required to support the continued registration of butylate products.

b. Ecological Effects Risk Assessment

This section consists of numerous risk assessments each covering a different combination of endpoint and exposure scenario. Each risk assessment includes a risk quotient which combines the toxicity and exposure information. For each quotient there is an established value above which the risk is considered to be at a high level of concern (LOC). The generic risk quotients and their respective LOC's for each risk assessment are provided in the table below. Note that the same risk quotients are used for non-endangered and endangered species, but the acute LOC is lower for endangered species.

Endpoint/Scenario	Risk Quotient	Nonendangered LOC	Endangered LOC
Mammalian acute (granular)	LD_{50}/ft^2	0.5	0.1
Mammalian acute (spray)	EEC/LC_{50}	0.5	0.1
Mammalian chronic (granular)	EEC/LEL	1.0	1.0
Mammalian chronic (spray)	EEC/LEL	1.0	1.0
Avian acute (granular)	LD_{50}/ft^2	0.5	0.1
Avian acute (spray)	EEC/LC_{50}	0.5	0.1
Avian chronic (granular)	EEC/LEL	1.0	1.0
Avian chronic (spray)	EEC/LEL	1.0	1.0
Aquatic acute	EEC/LC_{50}	0.5	0.05
Aquatic chronic	EEC/LEL	1.0	1.0
Non-target insects & plants	NOT QUANTIFIED	N/A	N/A

The narrative sections below provide the derivation and value of the appropriate risk quotients for butylate and an interpretation of its significance.

1. Mammalian Acute Risk Characterization

A. Granular Formulation Exposure

Because data are unavailable for determining the acute toxicity of butylate to nontarget mammals, the Agency is using data from acute oral toxicity studies in rats as surrogate data to calculate and define acute mammalian risks. The Agency is assuming that deer mice, a representative small mammal, has similar sensitivity as rats to butylate through acute oral exposure . LD_{50} values of 3500 mg/kg and 5431 mg/kg, for male and female rats, respectively, were used.

Based on available use and exposure information, the Agency has calculated that a maximum estimated environmental concentration (EEC) of 66 mg ai/ft^2 is possible through use of granular butylate at 6.3 lb ai/A, the maximum allowable label rate.

For a deer mouse weighing 0.0184 kg this is equivalent to 3587 mg ai/ft^2/kg.

This results in a risk quotient of:

3587/3500 = 1.0 LD_{50}'s/ft^2 for male deer mice
and
3587/5431 = 0.7 LD_{50}'s/ft^2 for female deer mice

These are both greater than the established level of concern (LOC) for granular formulations of 0.5 LD_{50}/ft^2".

Based on these calculations, it appears that small mammals may be at risk from use of granular butylate. It is important to note, however, that because of the mitigation factors listed below, it is unlikely that the use of butylate will pose a hazard to nonendangered small mammals.

(1) Butylate is soil incorporated immediately after application which should reduce exposure to small mammals except, possibly, at turn row areas;

(2) Small mammals would be required to consume high numbers of granules, from approximately 597 to 926 granules, to achieve the risk quotients of 1.0 and 0.7 LD_{50}'s/ft^2.

(3) Small mammals such as deer mice, are not likely to ingest granules, either selectively or accidently as birds may, unless the granules were to prove attractive to them.

B. Spray Formulation Exposure

This risk assessment is based upon dietary exposure.

Preliminary EEC's from generic residue data indicate that an application rate of 6.3 lb ai/A would result in residues of 788 ppm (typical) up to 1512 ppm (maximum) on short grasses. A deer mouse consuming 0.0036 kg food/day would receive 2.8 to 5.4 mg butylate/day at these concentration levels.

This is equivalent to 154 to 293 mg/kg of butylate/day for a .0184 kg deer mouse.

The level of concern for dietary exposure is exceeded when the expected dietary intake exceeds 1/2 the LD_{50}. In this case, the dietary exposure is well below 1/2 the LD_{50} for both males and females (given in Section A above). This indicates that acute risks to mammals from dietary exposure following the use of butylate spray formula are unlikely.

2. Mammalian Chronic Risk Characterization

A. Granular Formulation Exposure

The Agency has assumed that the deer mouse and rat have similar sensitivities to chronic oral butylate exposures. A 2-generation rat reproduction study resulted in a lowest effect level (LEL) of 50 mg/kg/day (described in Section III B1f).

As described in the section on acute mammalian risk for granular formulations, the maximum EEC from use of granular butylate is 664 mg ai/ft^2, which is equivalent to 3587 mg/kg/ft^2 for an animal with the weight of a deer mouse.

This results in a risk quotient of

$$3587/50 = 72$$

This is much greater than the established LOC of 1.0. However, the Agency concludes that chronic risks to mammals are unlikely to be great based upon the mitigating factors discussed in the paragraph above under mammalian acute risk characterization. Further, the available environmental fate data indicate butylate is highly volatile and likely to volatilize substantially under actual use conditions thereby mitigating chronic risks. However, if future environmental fate data indicate significant persistence of butylate, the Agency will reexamine the chronic mammalian risks at that time.

B. Spray Formulation Exposure

The LEL of 50 mg/kg cited in the above section on granular formulation exposure is equivalent to 256 ppm for an animal with the weight and food consumption of a deer mouse (provided in the section on acute mammalian risk).

As stated in the section on acute mammalian risk, preliminary EECs of 788 to 1512 ppm have been calculated for butylate on short grasses.

This would result in a risk quotient of

788/256 = 3.1

to 1512/256 = 5.9

which exceed the established LOC of 1.0 for chronic risk.

However, residues on short grasses are not particularly appropriate to the deer mouse diet. More appropriate food items evaluated in the same generic data base as the short grasses are fruits, forage, and insects. EECs based on these items are 44-365 maximum and 9-208 typical.

These EECs lead to a range of risk quotients

from 9/256 = 0.04

to 365/256 = 1.4

Although the risk quotients based upon maximum residues even on these items exceed the LOC, it is questionable whether the residues would persist at these levels long enough to constitute chronic exposure. The available fate data indicate that butylate is highly volatile and likely to volatilize substantially under actual use conditions. At present, it is unlikely that small mammals exposed to chronic exposures will be at risk. However, if future environmental fate data indicate significant persistence of butylate, the Agency will reexamine the chronic mammalian risks at that time.

3. Avian Acute Risk Characterization

A. Granular Formulation Exposure

As stated in the ecological effects data section, the only avian oral LD_{50} available is >4640 mg/kg from a study in the mallard duck. The value 4640 mg/kg is used to quantitate acute oral toxicity to all birds.

The EEC for granular formulation is 66 mg ai/ft^2, as already stated for mammalian risk.

For a small bird such as a field sparrow (weighing 0.014 kg) this is equivalent to 4714 mg ai/kg/ft^2.

This results in a risk quotient of:

4714/4640 = 1.0

which exceeds the LOC of 0.5. The LOC would not be exceeded for any birds as large as or larger than a robin.

Even though the calculated quotient exceeds the LOC for small birds, the Agency has concluded that minimal acute risks exist for nonendangered avian species exposed to granular butylate because: (1). all LD_{50} values are "greater than" values and it is not known what the LD_{50} actually is and (2). the mallard LD_{50} value indicates that the compound is "practically non-toxic".

B. Spray Formulation Exposure

The available avian subacute dietary toxicity data show the dietary LC_{50} for both bobwhite quail and mallard duck to be in excess of 5620 ppm of the diet. This analysis assumes that the LC_{50} is equal to 5620 ppm for a bird the size of a bobwhite quail.

For a much smaller bird such as a field sparrow which consumes an amount of food equal to approximately 33% of its body weight (as opposed to approximately 9% for the quail) this is equivalent to an LC_{50} of 1501 ppm.

The EECs for birds range from 44-1512 (maximum) to 9-788 (typically), depending on the food item.

This could result in a maximum risk quotient of

1512/1501 = 1.0

for a small bird such as the field sparrow.

However, the EECs for the food items most likely to be consumed by field sparrows (weed seeds and insects) are 365 ppm or less.

This would result in a risk quotient of

$$365/1501 = 0.24$$

which is below the LOC for acute risk.

The risk quotient for a mallard, which is more likely to consume grasses is based upon a higher LC_{50}.

i.e. $\frac{1512}{5620} = 0.27$

This also fails to exceed the LOC.

The Agency concludes, therefore, that acute risks to birds from spray formulations will be minimal.

4. Avian Chronic Risk Characterization

Because no chronic data on birds are available, the Agency has used the rat reproduction study, already cited in the mammalian chronic risk section.

The LEL of 50 mg/kg found for rats is assumed for birds.

A. Granular formulation exposure

For granular formulations the EEC of 66 mg ai/ft^2 used for the granular risk assessments set forth in earlier sections applies.

As stated in the avian acute risk section, this is equivalent to 4714 mg ai/kg/ft^2 for a small bird such as a field sparrow.

This results in a risk quotient of

$$4714/50 = 94.3$$

for small birds.

For a much larger bird such as a mallard (weighing about 1 kg), the equivalent exposure would be 66 mg ai/kg/ft^2 and the corresponding risk quotient is: $66/50 = 1.3$

Both of these exceed the established LOC of 1.0 for chronic risk.

However, since butylate appears highly volatile and is, furthermore, soil incorporated or watered in immediately following applications, it is unlikely that birds will consume sufficient number of granules to achieve LEL daily throughout their reproductive cycle.

Therefore, the Agency concludes that high chronic risk to birds from granular butylate is unlikely. However, if future environmental fate data indicate significant persistence of butylate, chronic avian risks will be reexamined at that time.

B. Spray Formulation Exposure

Again, the LEL of 50 mg/kg from the rat reproduction study is assumed to apply to birds.

This is equivalent to 149 ppm in the diet for a small bird such as a field sparrow and to 1,000 ppm for a much larger bird such as a mallard.

The dietary EECs are described in previous section and range from 9 to 1512 ppm, depending on the food item.

For the high end of this EEC range (1512 ppm) the risk quotients range from

1512/149 = 10. for a field sparrow

down to 1512/1000 = 1.5 for a mallard.

However, only the mallard is likely to eat the grasses to which this EEC applies.

As explained in the section on acute risks, the EECs for the foods likely to be consumed by a field sparrow are 365 ppm or less. This results in a risk quotient

of 365/149 = 2.4

for the field sparrow.

All of these risk quotients are above the LOC of 1.0 for chronic risk.

However, given the apparent volatility of butylate, it is unlikely that birds will consume foods with residues high enough to achieve the LEL throughout their reproductive cycle.

Therefore the Agency concludes that chronic risk to birds from butylate spray formulation is unlikely. However, if future environmental fate data for the microencapsulated or granulated formulations indicate significant persistence of butylate, the chronic avian risks will be reexamined at that time.

5. Aquatic Risk Characterization

Acute. Of the aquatic species tested (see the section on aquatic organism data) the most sensitive species is the bluegill sunfish, with a lowest LC_{50} of 0.21 ppm or 210 ppb. This LC_{50} is used for the aquatic acute risk assessment.

The Estimated Environmental Concentration for butylate in aquatic environments was derived from models developed for two different scenarios: 1) corn grown on Loring Silt Loam in Mississippi; and (2) corn grown on Fatette Silt Loam in Iowa. Using estimates from these two sites, acute EEC's were calculated to range from 70 to 76 ppb.

This results in a maximum acute risk quotient of

$$76/210 = 0.4$$

which is well below the LOC of 0.5 for acute risk to non-endangered species. It is, therefore, unlikely that acute risks exist for non-endangered freshwater fish, invertebrates or marine species.

Chronic risks. The MATC of 0.39 ppm (390 ppb) from the fathead minnow study is used to quantitate chronic aquatic toxicity.

The chronic EECs derived from the model described above range from 30 to 34 ppb.

This results in a risk quotient of

$$34/390 = 0.09$$

This is below the aquatic chronic LOC of 1.0 for non-endangered species.

The Agency concludes that chronic risks to non-endangered aquatic species are unlikely. However, as discussed in the environmental fate section, these EEC calculations are based upon very limited environmental fate data and will be reconsidered when the confirmatory field dissipation studies are reviewed.

6. Nontarget Insects Risk Characterization

Based on the available honey bee toxicity data (acute contact LD_{50} = > 29 ug/bee) and the presently registered use patterns for butylate (typically: one application preplant followed by incorporation or watering in; applications are usually to bare ground; and no applications are made during crop bloom (tasseling)) the acute risks to nontarget insects are unlikely.

7. Nontarget Plant Risk Characterization

There is insufficient data to characterize risks to nontarget plants. The presently available studies lack pertinent data, which need to be submitted. For other species the studies need to be redone. However, since butylate is a herbicide, it is assumed that risks to nontarget plants are likely.

8. Endangered Species Risk Characterization

The risk quotient for endangered species is calculated in the same way as for non-endangered species. However the LOC is lower for endangered species acute risk. The table below summarizes the risk quotients calculated in earlier sections for non-endangered species and compares them to the corresponding LOCs for endangered species (taken from the table at the beginning of this section.) Endpoint/scenario combinations where the risk quotient exceeds the LOC are marked in the table below with an asterisk.

Endpoint and Scenario	Butylate Risk Quotient Value	LOC for Endangered Species
*Mammalian acute (granular)	0.7 - 1.0	0.1
Mammalian acute (spray)	0.03 - 0.08	0.1
*Mammalian chronic (granular)	72	1.0
*Mammalian chronic (spray)	0.04 - 5.9	1.0
*Avian acute (granular)	1.0	0.1
*Avian chronic (granular)	1.3 - 94	1.0
*Avian chronic (spray)	1.5 - 10	1.0
*Aquatic (fish) acute	0.4	0.05
Aquatic (fish) chronic	0.09	1.0

PLANTS NOT QUANTIFIED BUT EXPECTED TO BE AT RISK

A high level of concern is reached when the risk quotient exceeds the LOC for endangered aquatic and terrestrial organisms.

Using the above LOCs and considering butylate's presently registered use patterns, potential acute risks exist for nontarget endangered mammals, birds and freshwater vertebrates. Although there are mitigating factors, as discussed above under the acute risk characterization for non-endangered mammals, endangered mammals may be more sensitive and, therefore, acute risks may exist. Because of the sensitivity of freshwater vertebrates to butylate, potential risks may exist for endangered amphibians.

There also may be a possibility of chronic risks to mammals and birds. Food habits, use patterns, and butylate's volatility are mitigating factors, but the possibility that endangered mammals and birds are more sensitive to butylate than non-endangered ones may offset these mitigating factors. In addition, because butylate is a herbicide, risks are likely for endangered plants and this may impact endangered insects. EPA is working with the US Fish and Wildlife Service and other Federal and state agencies to develop a program to avoid jeopardizing the continued existence of the identified species by the use of pesticides. When the Endangered Species Protection Program is published in the Federal Register and

subsequent guidance to registrants is given, endangered species labeling amendments may be required on affected end use products. Labeling statements for end use products will likely refer users to county specific bulletins specifying detailed limitations on use to protect endangered species.

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 butylate 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 butylate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of butylate, 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 butylate and to determine that butylate can be used without resulting in unreasonable adverse effects to human health and the environment. The Agency therefore finds that all products containing butylate as the sole active ingredient are eligible for reregistration. However, those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients have been determined to be eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient butylate, the Agency has sufficient information on the health effects of butylate and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency concludes that products containing butylate and registered for use on field corn, sweet corn and popcorn are eligible for reregistration.

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

2. Eligible and Ineligible Uses

The Agency has determined that the uses of butylate on field corn, sweet corn and popcorn are eligible for reregistration. These are the only registered uses of butylate.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances for residues of S-ethyl diisobutylthiocarbamate in or on food and feed commodities are currently expressed in terms of parent compound only (40 CFR 180.232).

Sufficient crop field trial data are available to ascertain the adequacy of the established tolerances of 0.1 ppm for residues of butylate in or on field corn grain (including popcorn), sweet corn kernels plus cob with husk removed (K+CWHR), field corn forage and fodder (including popcorn), and sweet corn forage and fodder. Sufficient data also indicate that residues of butylate do not

concentrate upon processing; therefore, no food/feed additive tolerances are required. There are no established or proposed Codex maximum residue limits (MRL) or other international tolerances for residues of butylate.

The Agency is requiring that the entry in 40 CFR 180.232 be amended by replacing the chemical name "S-ethyl diisobutylthiocarbamate" with the acceptable common name "butylate." The term negligible residues should be deleted from the tolerance expression. The tolerances listed in 40 CFR 180.232 should be modified to reflect current commodity definitions as follows:

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition
Corn grain (including popcorn)	0.1	0.1	Corn, field, grain Corn, pop, grain
Fresh corn including sweet corn (kernels plus cob with husk removed)	0.1	0.1	Corn, sweet (K + CWHR)
Corn forage and fodder including sweet corn, field corn, and popcorn)	0.1	0.1	Corn, field, fodder Corn, field, forage Corn, pop, fodder Corn, pop, forage Corn, sweet, forage

2. Labeling Rationale

The Worker Protection Standard (WPS) for Agricultural Pesticides -40 CFR Parts 156 and 170, established an interim restricted-entry interval of 12 hours for butylate based on the results of acute dermal toxicity, skin irritation and eye irritation toxicity testing. The Agency considers the 12-hour restricted entry interval for this chemical a prudent risk-mitigation measure to protect workers. Therefore, the Agency retains the 12 hour REI and will allow workers to enter areas treated with butylate during the REI only in the few narrow exceptions allowed in the WPS.

The Agency considers the use of a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves a prudent risk-mitigation measure to protect handlers and early-entry workers from exposure to butylate. Therefore, the Agency requires that all products that contain butylate bear personal protective equipment requirements for handlers and early-entry workers that are at least as protective as these items. If the end-use product labeling already bears personal protective equipment requirements that are more protective than these items, the more protective requirements must be retained.

All manufacturing-use or end-use products that may be contained in effluent discharged to waters of the United States or municipal sewer systems must bear required labeling.

3. Endangered Species Statement

The Agency does have concerns regarding exposure of endangered animals and plants to butylate. At the present time, EPA is working with the U.S. Fish and Wildlife Service and other Federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species by the use of pesticides. When the Endangered Species Protection Program is implemented and subsequent guidance is given, endangered species labeling amendments may be required on affected end-use products. Labeling statements for end use products will likely refer users to county specific bulletins specifying detailed limitations on use to protect endangered species.

Specific label language is outlined in Section V, Labeling Requirements.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of butylate for the above eligible uses has been reviewed and determined to be substantially complete. However, additional confirmatory information is needed to fulfill data requirements for the studies listed below.

Product chemistry
Storage stability
Aged leaching
Terrestrial field dissipation with volatilization measurements
Seed germination/seedling emergence
Vegetative vigor
Aquatic plant growth
Droplet size and spray drift
Acute and subchronic neurotoxicity

2. Labeling Requirements for Manufacturing-Use Products

All manufacturing-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement in the "Environmental Hazards" section. Please note that this effluent discharge statement has been modified to include a required fish toxicity statement.

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

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 within 8 months after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data

meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

Worker Protection Standard Requirements

Any product whose labeling reasonably permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery, or greenhouse) must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by any person.

<u>Atrazine-Butylate Combination Products</u>

The Agency requires that the two restricted use butylate-atrazine combination products retain the label precautions that are currently on these products due to toxicity and ground and surface water concerns for atrazine compounds.

Personal Protective Equipment Requirements

The following personal protective equipment (PPE) labeling is required for all end-use products:

"Applicators and other handlers must wear:
-Long-sleeved shirt and long pants
-Chemical-resistant or waterproof gloves (see instructions below)
-Shoes plus socks"

The glove statement for butylate is the statement established through the instructions in Supplement Three of PR Notice 93-7.

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

Entry Restrictions: A 12-hour restricted entry interval (REI) is required for all uses on all end-use products. All uses are within the scope of the WPS (see PR Notice 93-7). This REI should be inserted into the standardized REI statement required by PR Notice 93-7. The personal protective equipment (PPE) for early entry should be the PPE required for applicators of butylate, except no apron or respirator (if any is on label) is required and "coveralls" must be specified for early-entry workers instead of "long-sleeved shirt and long pants." This PPE should be inserted into the standardized early entry PPE statement required by PR Notice 93-7.

Sole-active ingredient: End-use products that contain butylate must adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed.

Multiple-active ingredient: End-use products that contain butylate must compare the entry restrictions set forth in this section to the entry restrictions on current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

The Environmental Hazard Section is to include:

Granular End-Use Products
"This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark.

Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Non-granular End-Use Products

"This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

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 Document (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 on a case-by-case basis, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell butylate 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.

APPENDIX A

Table of Use Patterns
Subject to Reregistration

APPENDIX A - Use patterns subject to reregistration for: CASE 0071, BUTYLATE

SITE Application Type, Application Timing, Application Equipment CORN: FIELD OR FORAGE/SILAGE OR POP OR SWEET	Maximum Application Rate (ai)	Form	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Hours)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
Soil incorporated treatment, Preplant (Fall) or Postplant or Preemergence, Ground equipment	6.3 lb/A	EC or FM/L or MCAP	(1)	(1)	Not Applicable	12	Some states listed with specific directions	AZ; 10 southernmost CA counties (except field and silage corn in Kern County)	Do not use on corn seed stock. For silage corn in the Southeastern U.S., do not seed small seeded grains after corn harvest until September. Max application rate should not be used on blow sands & the light soils of the Eastern Coastal States
Soil incorporated treatment, Preplant or Postplant or Preemergence, Center pivot irrigation	6.14 lb/A	EC	(1)	(1)	Not Applicable	12	Western Plains States	Arizona; 10 southernmost CA counties (except field and silage corn in Kern County)	Do not use on corn seed stock.
Soil incorporated treatment, Postplant, Ground equipment	3 lb/A	G	(1)	(1)	Not Applicable	12	Some states listed with specific directions	Arizona; 10 southernmost CA counties (except field and silage corn in Kern County)	Do not use on corn seed stock. For silage corn in the Southeastern U.S., do not seed small seeded grains after corn harvest until September.
Soil incorporated treatment, Preplant, Ground equipment	4.08 lb/A	G	1	1	Not Applicable	12	North Central, Northeast and Midwest Corn Growing Areas	Arizona; 10 southernmost CA counties (except field and silage corn in Kern County)	Do not use on corn seed stock. Do not plant any crop except corn until the following year. Do not use on blow sands and light soils in the Eastern Coastal States.

SITE Application Type, Application Timing, Application Equipment **CORN: FIELD OR FORAGE/SILAGE OR POP OR SWEET**	Maximum Application Rate (ai)	Form	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Hours)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
Soil injection treatment, At planting or Preplant, Soil injector equipment	3.14 lb/A	EC	(1)	(1)	Not Applicable	12	Southeast	All other areas	Do not use on corn seed stock. For silage corn, do not seed small seeded grains after corn harvest until September.
CORN: FIELD OR FORAGE/SILAGE OR SWEET									
Soil incorporation treatment, Preplant, Granule applicator	4 lb/A	G	(1)	(1)	Not Applicable	12	Some states listed with specific directions	Arizona; 10 southernmost CA counties (except field and silage corn in Kern County)	Do not use on corn seed stock. For silage corn in the Southeastern U.S., do not seed small seeded grains after corn harvest until September.

Abbreviations used

Header: max. = maximum; min. = minimum; apps. = applications; ( ) = implied
Form: EC = emulsifiable concentrate; FM/L = form not identified/liquid; G = Granular; MCAP = microencapsulated
Rate: ai = active ingredient; lb = pound; A = acre

The maximum of one application is implied in label instructions for butylate as a single active ingredient, but is not strictly stated.

APPENDIX B

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide butylate covered by this Reregistration Eligibility Decision. It contains generic data requirements that apply to butylate 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 Butylate

REQUIREMENT		USE PATTERN	CITATION
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	00020545, 00026325, 00043679, 00063484, 42123902, 42764702
61-2	Start. Mat. & Mnfg. Process	ALL	00063484, 42123901, 42764701
61-3	Formation of Impurities	ALL	00063484, 42123901, 42764701
62-1	Preliminary Analysis	ALL	00063484, 42123902, 42764702, DATA GAP
62-2	Certification of Limits	ALL	00063484, 42123902, 42764702
62-3	Analytical Method	ALL	00023535, 00025676, 00064183, 05018944, 42123902, GS-0071-001, GS-0071-006, 42764702
63-2	Color	ALL	00026324, 00063484, 42182201
63-3	Physical State	ALL	00020535, 00026324, 00063484, 42182201
63-4	Odor	ALL	00063484, 42182201
63-6	Boiling Point	ALL	00063484, 42182201
63-7	Density	ALL	00021822, 00063484, 42182201
63-8	Solubility	ALL	00063484, 42182201
63-9	Vapor Pressure	ALL	00063484, 42182201

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Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
63-11	Octanol/Water Partition	ALL	42182201
63-12	pH	ALL	00026324, 00063484, 42182201
63-13	Stability	ALL	00063484, 42182201
63-14	Oxidizing/Reducing Action	ALL	42182201
63-15	Flammability	ALL	42182201
63-16	Explodability	ALL	42182201
63-17	Storage Stability	ALL	42182201
63-18	Viscosity	ALL	42182201
63-20	Corrosion Characteristics	ALL	42182201

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral-Quail/Duck	AB	00025060, GS-071-002
71-2A	Avian Dietary (LC_{50}) - Quail	AB	00021835, 00131300
71-2B	Avian Dietary (LC_{50}) - Duck	AB	00020530, 00131299
72-1A	Fish Acute (LC_{50}) - Bluegill (TGAI)	AB	00149318, 40098001
72-1B	Fish Acute (LC_{50}) - Bluegill (TEP)	AB	00021835, 00020532
72-1C	Fish Acute (LC_{50}) - Trout (TGAI)	AB	00149319, 40098001
72-1D	Fish Acute (LC_{50}) - Trout (TEP)	AB	00021835, 00020532
72-2A	Aquatic Invertebrate (EC_{50})	AB	00021841, 05001497
72-3A	Estuarine/marine toxicity fish	AB	42214301
72-4A	Fish Early Lifestage	AB	42214302, 42773601
123-1A	Seed germination and seedling emergence	AB	42123909 DATA GAP
123-1B	Vegetative Vigor	AB	42123904 DATA GAP
123-2	Aquatic Plant Growth	AB	42123910, 42123911, 42123912, 42123913, 42123914, DATA GAP

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
141-1	Honey bee acute contact LD_{50}	AB	00036935

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	AB	00063486, 00149316
81-2	Acute Dermal Toxicity	AB	00063486, 00149316
81-3	Acute Inhalation - Rat	AB	00063488, 42389401
81-4	Primary Eye Irritation - Rabbit	AB	00063487
81-5	Primary Dermal Irritation - Rabbit	AB	00063487, 00149316
81-6	Dermal Sensitization	AB	42123903
81-8	Acute Neurotoxicity	AB	DATA GAP
82-1A	90-Day Feeding - Rodent	AB	Satisfied by 2 year rat study (00125678)
82-1B	90-Day Feeding - Non-rodent	AB	Satisfied by 1 year dog study (40389101)
82-2	21-Day Dermal-Rabbit/Rat	AB	00026312
82-5B	90-Day Neurotoxicity - Mammal	AB	WAIVER DENIED, DATA GAP
83-1A	Chronic Toxicity - Rodent	AB	00035844, 00125678
83-1B	Chronic Toxicity - Non-rodent	AB	40389101
83-2A	Oncogenicity - Rat	AB	00125678

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
83-2B	Oncogenicity - Mouse	AB	00035844
83-3A	Developmental Toxicity - Rat	AB	00131032
83-3B	Developmental Toxicity - Rabbit	AB	40389102
83-4	2-Generation Reproduction - Rat	AB	00160548
84-2A	Gene Mutation	AB	00149317, 00162707
84-2B	Structural Chromosomal Aberration	AB	00162709
84-4	Other Genotoxic Effects	AB	00162710, 00162708
85-1	General Metabolism	AB	00043680, 00043681, 00043682, 41197301 129397, 129398

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
ENVIRONMENTAL FATE			
161-1	Hydrolysis	AB	40389111
161-2	Photodegradation - Water	AB	40389111
161-3	Photodegradation- Soil	AB	42123905
162-1	Aerobic Soil Metabolism	AB	00026320, 00043683, 00043684, 41812201
162-2	Anaerobic Soil Metabolism	AB	00043684, 41812201
163-1	Leaching/Adsorption/Desorption	AB	00027139, 00027140, 00043683, 41812202 DATA GAP
163-2	Laboratory Volatility	AB	00043683, 42123906
164-1	Terrestrial Field Dissipation	AB	00021848, 00023814, 41812203, 41812204 DATA GAP
165-4	Fish Accumulation	AB	00020535, 40657401, 40843901

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
RESIDUE CHEMISTRY			
165-1	Confined Rotational Crop	AB	42694001
165-2	Field Rotational Crop	AB	WAIVED
171-4A	Nature of Residue - Plants	AB	00020555, 00020558, 00021594, 00021781, 00021822, 00021849, 00129398
171-4B	Nature of Residue - Animals	AB	
171-4 C/D	Residue Analytical Method Plant and Animal	AB	00022848, 00023535, 00024324, 00024776, 00025676, 00063485, 00064183, 00068699, 00074451, 05002372, 05010440, 05013158, 05018944, 42126302, PP#7F0621
171-4E	Storage Stability	AB	41812205 - DATA GAP
171-4K	Magnitude of the Residue -Corn grain (field, pop, and sweet)	AB	00020547, 00020548, 00020564, 00021749, 00021751, 00021753, 00021755, 00021759, 00021766, 00021769, 00021783, 00021784, 00021787, 00021794, 00021803, 00021856, 00022846, 00023534, 00023727, 00023816, 00023817, 00023818, 00023819, 00024775, 00026259, 00026260, 00026315, 00026316, 00026974, 00035840, 00037762, 00041699, 00090889, 00093145, 00093221, 00093222, 00098255, 00109470, 00117892

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Butylate

REQUIREMENT		USE PATTERN	CITATION
	-Corn forage and fodder	AB	00020547, 00020564, 00021749, 00021751, 00021753, 00021755, 00021759, 00021766, 00021769, 00021783, 00021784, 00021787, 00021803, 00021856, 00022846, 00023534, 00023727, 00023816, 00023817, 00023818, 00023819, 00024775, 00026259, 00026260, 00026315, 00026316, 00026974, 00035840, 00037762, 00041699, 00090889, 00093145, 00093221, 00093222, 00098255, 00109470, 00117892, 42406401
171-4l	Magnitude of the Residue in processed food/feed	AB	42126301, 42448701
EXPOSURE			
201-1	Droplet Size Spectrum	AB	DATA GAP
202-1	Drift Field Evaluation	AB	DATA GAP
231	Estimation of Dermal Exposure	AB	WAIVED
232	Estimation of Inhalation Exposure	AB	WAIVED

APPENDIX C

BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting Reregistration

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 this Reregistration Eligibility Decision. 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 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 identifying number which 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 a 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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42764702 Farina, L. (1993) Analysis and Certification of Product Ingredients in SUTAN Selective Herbicide: Lab Project Number: RR 91-061B RES. Unpublished study prepared by Zeneca Ag Products, Western Research Center. 79 p.

42773601 Sankey, S. (1993) Butylate: Fish Early Life-Stage Toxicity Test Guideline Reference 72-4A: Addendum # 1 to MRID # 42214302 Response to EPA Review Comments: Lab Project Number: BRIX-051393: 051393. Unpublished study prepared by ICI PLC, Brixham Lab. 9 p.

APPENDIX D

List of Available Related Documents

APPENDIX D

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Butylate RED Fact Sheet (included in this RED)

4. PR Notice 91-2 (Included in this RED) Pertains to the Label Ingredient Statement

Federal publications on butylate are available and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

1. Guidance for the Reregistration of Pesticide Products Containing Butylate as the Active Ingredient (The 1983 Registration Standard): NTIS Stock No. PB85-147304

2. Pesticide Fact Sheet (No. 6) for butylate: NTIS Stock No. PB87-108940

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

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

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

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anna E. Lindsay

Anna E. Lindsay, Director
Registration Division (H-7505

APPENDIX E

Pesticide Reregistration Handbook

United States
Environmental Protection
Agency

Office of
Pesticide Programs

October 1991

EPA

Pesticide Reregistration Handbook

How to Respond to the Reregistration Eligibility Document (RED)

Printed on Recycled Paper

PESTICIDE REREGISTRATION HANDBOOK

HOW TO RESPOND TO THE

REREGISTRATION ELIGIBILITY DOCUMENT (RED)

OFFICE OF PESTICIDE PROGRAMS

ENVIRONMENTAL PROTECTION AGENCY

OCTOBER 1991

Printed on Re

PRODUCT REREGISTRATION HANDBOOK

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PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its uses and its regulatory history; describes EPA's decision concerning the eligibility of the uses of the chemical for reregistration; and explains the scientific and regulatory bases for this decision. EPA's reviews of the data by scientific discipline are available upon request.[1] Appendices to the RED contain: (1) a Data Dall-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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[1] EPA's science reviews and information on the registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

--whether all of the product specific data and labels/labeling are acceptable,

--whether all of the uses on the label/labeling are eligible,

--whether all of the active ingredients in the product are eligible, and

--if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be **reregistered.** Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as **amendments** in order to implement label changes required by the RED.

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. **All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1** summarizes how and when to respond to the RED. A step-by-step explanation follows.

Step 1. Are Expedited Label Changes Required? In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. **If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED.** If expedited label changes are not required, go to Step 2.

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

and sign the form. In Section II, insert the phrase **"Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)."** Applications for expedited label changes will be processed as applications for amended registration. **Use only an original application form with a red identifier number in the upper right-hand corner.**

b. **Five (5) copies of revised draft label and labeling.** Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? **If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.**

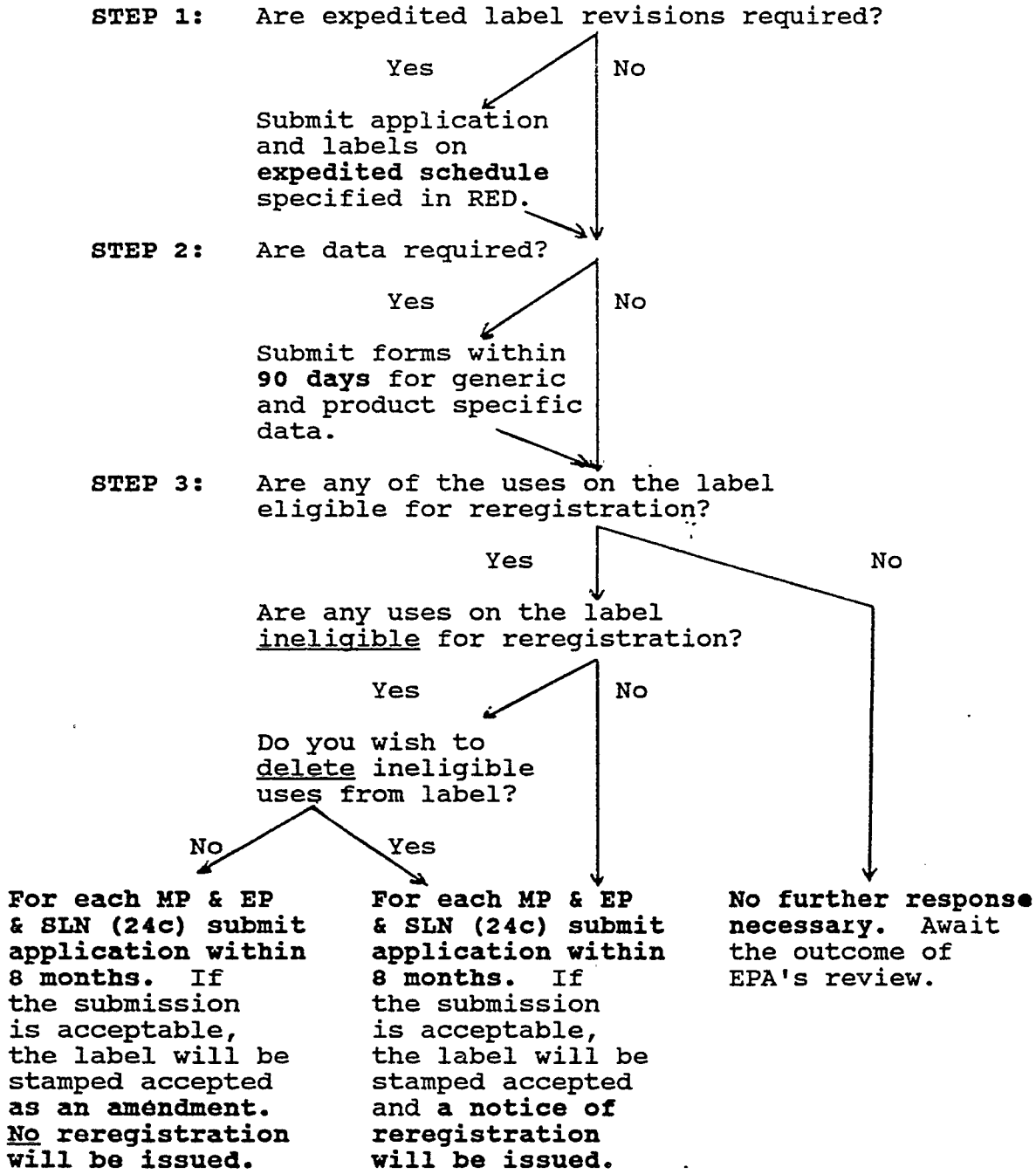
Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. **If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) and special local needs registrations (SLNs), must submit the items below for each product within 8 months of the date of issuance of the RED:**

a. **Application for Reregistration (use EPA Form 8570-1).** Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase **"Application for Reregistration." Use only an original application form with a red identifier number in the upper right-hand corner.**

b. **Five (5) copies of revised draft label and labeling.** Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are **ineligible uses** on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).



c. **Product Specific Data. You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.**

d. **Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 85).** Two completed and signed CSF forms must be submitted for the **basic formulation** and for **each alternate formulation.** If CSFs are not provided for the alternate formulas, they will **not** be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. **Certification With Respect to Citation of Data (EPA Form 8570-31).** This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

B. When No Response is Needed

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.

C. Where to Respond

By U.S. Mail:

Document Processing Desk **(insert distribution code)**
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk **(insert distribution code)**
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing **generic data**. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing **product specific data or labeling**. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.

Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Dall-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

B. Product Specific Data

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

1. Product Chemistry

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

a. Data

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together a being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

b. Inert Ingredients

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, **a product containing a List 1 inert ingredient will <u>not</u> be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient.** However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert <u>may</u> be reregistered <u>if</u> it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

2. <u>Acute Toxicity</u>

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each baatch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

3. Product Performance

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to EPA for review before tests are initiated.

a. Efficacy Data Submission Waiver Policy

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;

2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;

3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;

4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

C. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). **Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier.** Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

C. Sample Label Formats--General Use & Restricted Use

D. Label Regulations (40 CFR 156.10)

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

EPA Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by Weight	14. Certified Limits % by Weight a Upper Limit	b Lower Limit	15. Purpose in Formulation
	16. Typed Name of Approving Official			17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 2-85) Previous editions are obsolete.

Original and second copy to EPA. Third copy to Applicant

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

l. 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.

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

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

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

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

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

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

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

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

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

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

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

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

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

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

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

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

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

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

1. **All uses restricted.** The following statements must be placed in a black box at the top of the front panel of the label and labeling:

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.

   b. The **reason** for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.

   c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification." The RED will specify what statement must be used.

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

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

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

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

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

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in

accordance with PR Notice 83-2, March 29, 1983.

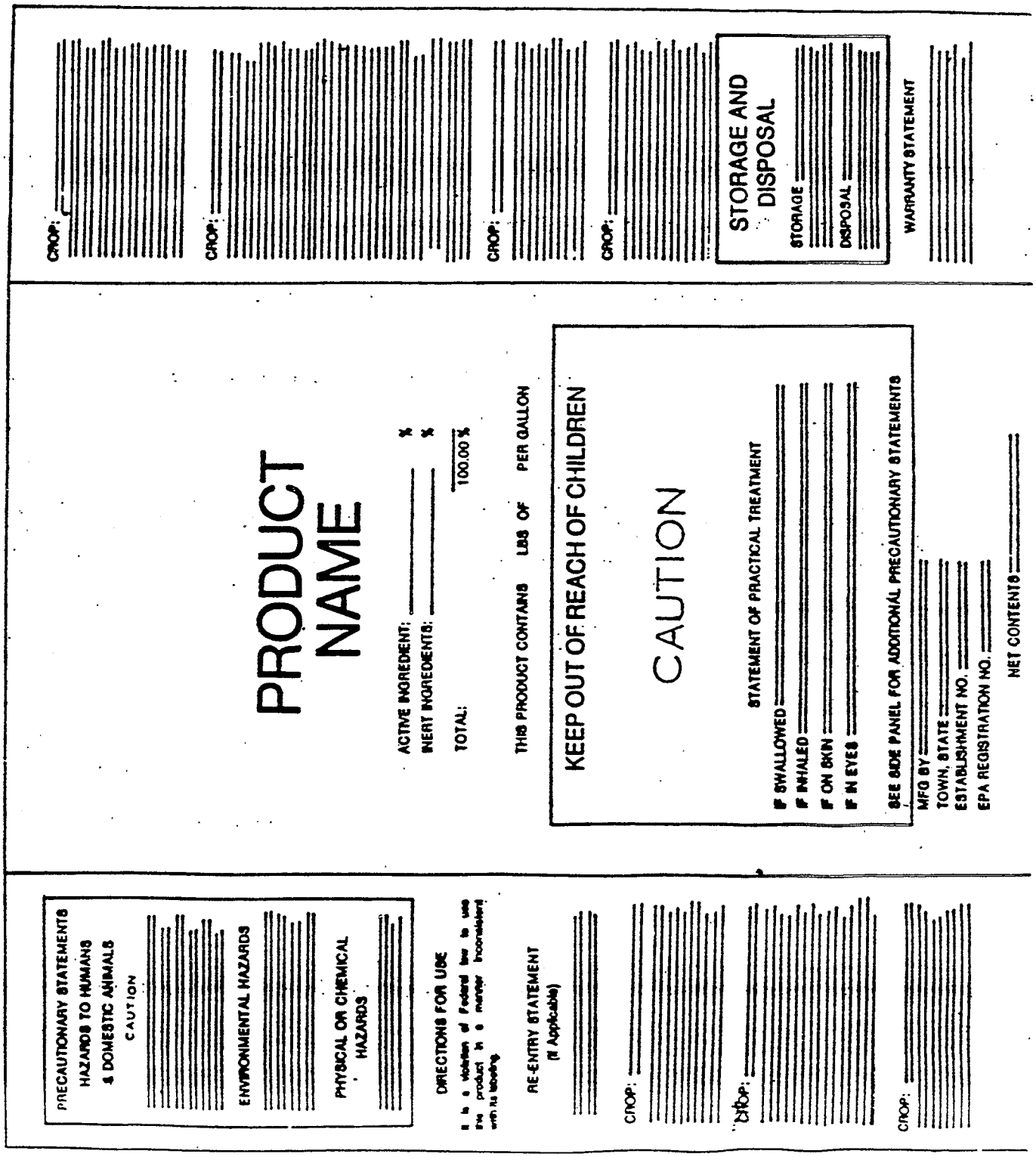
Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10(i)(2)]

COLLATERAL LABELING

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

LABEL FORMAT FOR UNCLASSIFIED PRODUCTS



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
Due to (insert reason*)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

(*for example, "Due to high acute toxicity.")

PRODUCT NAME

ACTIVE INGREDIENT: _____ %
INERT INGREDIENTS: _____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER—POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED UCE

submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, E 'A will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136–136y.

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regu-

lations in this Part. The contents of a label must show clearly and prominently the following:

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

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

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

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

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

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

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

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

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

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

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

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

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

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

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

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

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

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

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

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

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

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

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

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

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

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

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

tent of the packages in a shipment fall below the stated average content.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such

that it is approved for use on infants or small children, may the Administrator waive this requirement.

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

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

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

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

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

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988]

APPENDIX F

Generic Data Call-In

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

DATA CALL-IN NOTICE

CERTIFIED MAIL

NOV 26 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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 A through F; or

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment C, 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 B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment D).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 3-31-96).

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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:

Attachment A - Data Call-In Chemical Status Sheet
Attachment B - Data Call-In Response Form
Attachment C - Requirements Status And Registrant's Response Form
Attachment D - List Of All Registrants Sent This Data Call-In Notice
Attachment E - EPA Acceptance Criteria
Attachment F - 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 Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, 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 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose 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 data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, Attachment B and the Requirements Status and Registrant's Response Form, Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 identified in Attachment A.

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

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

2. 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, 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 on the Requirements Status and Registrant's Response Form.

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 and Emergency Response Branch, Registration Division, (703) 557-2126.

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, must bear an amended label.

3. 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:

a. 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;

b. 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

c. 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 B 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 product specific data.

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 the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the

registrations of both your 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.

4. Satisfying the Data Requirements of this Notice There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), 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 timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency

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

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

Option 3, Offer to Share in the Cost of Data Development -- If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment E. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that

offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " '[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report

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

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

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

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

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

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does

contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For 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.

III-D REQUESTS FOR DATA WAIVERS

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 inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 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 as low volume pesticides 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:

a. (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.

b. 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.

c. 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.

d. (i). 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 onducting the testing needed to fulfill each of these data requirements.

(ii). 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.

e. For each of the next ten years, a year-by-year fore- cast 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.

f. 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.

2. Request for Waiver of Data -- Option 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 corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also 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 do not apply 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.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

c. otherwise take appropriate steps to meet the requirements stated in this Notice,

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing

stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Peter Caulkins for
Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrants Response Form
D - List of Registrants Receiving This Notice
E - EPA Acceptance Criteria
F - Cost Share and Data Compensation Forms

ATTACHMENT A

Generic DCI Chemical Status Sheet

BUTYLATE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have products containing butylate.

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 butylate. 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 B), (3) the Requirements Status and Registrant's Response Form (Attachment C), (4) a list of registrants subject to this DCI and List of Products Subject to this generic DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this butylate Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for butylate are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on butylate are needed on certain technical/manufacturing use 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 butylate products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of butylate, please contact Ms. Judy Loranger at (703) 308-8056.

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

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

Ms. Veronica Dutch
Special Review and Reregistration Division
Office of Pesticide Programs, H7508W
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Butylate

ATTACHMENT B

Generic Data Call-In Response Form Instructions
(Form A included in registrants copy only)

SPECIFIC INSTRUCTIONS FOR THE DATA CALL-IN RESPONSE FORM

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1 -4 will 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.

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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, 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

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. 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. 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. You do not need to complete any

item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

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

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

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

Item 6b. Check this Item if the data call-in is a generic data call-in 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.

Item 7a. Check this item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is a end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

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

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

ATTACHMENT C

Requirements Status and Registrants' Forms (Form B) plus Instructions

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

Generic Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, 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

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. 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.

Item 6. This item identifies the code associated with the use pattern of the pesticide. 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. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EP	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 identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date of your receipt of the Data Call-In Notice.

Item 9. 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.

1. (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.

2. (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.

3. (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 submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study 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.

5. (Upgrading a Study) I am submitting or citing 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.

6. (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. I am providing the Agency's classification of the study.

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

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.

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 an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, 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.

Item 10. 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. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address

2. Case # and Name
0071 Butylate
Chemical # and Name 041405
Butylate

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
62-1 *	Preliminary Analysis					all	TGAI	6 mos.	
82-5(b) *	90-day neurotox-mammal		Y			AB	TGAI	24 mos.	
123-1(a) *	Seed germ/seedling emerg					AB	TGAI	12 mos.	
123-1(b) *	Vegetative vigor					AB	TGAI	12 mos.	
123-2 *	Aquatic plant growth					AB	TGAI	12 mos.	
163-1 *	Leach/adsorp/desorption					AB	* See gdln comment	12 mos.	
164-1 *	Terrestrial field dissipation		Y			AB	TEP	24 mos.	
171-4(e) *	Storage stability					AB	TEP	3 mos.	
201-1 *	Droplet size spectrum					AB	TEP	12 mos.	
202-1 *	Drift field evaluation					AB	TEP	12 mos.	
81-8-SS *	Acute Neurotoxicity					AB	TGAI	12 mos.	
	Protocol	Y						3 mos.	

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0071 Butylate
Chemical # and Name
041405 Butylate

GUIDELINE	COMMENT
62-1	Analysis is needed for one confidential ingredient after consultation with the Agency.
82-5(b)	This neurotoxicity study is now required because butylate is chemically related to several thiocarbamate pesticides that have shown neurotoxicity in long-term repeated dose studies in rats and/or dogs.
123-1(a)	Phytotoxicity testing is required because this pesticide may pose a hazard to endangered or threatened species. Runoff, spray drift and volatility from center pivot sprinkler application can be expected to reach plants in adjacent fields. The following Tier II nontarget plants studies are required as confirmatory data: 123-1a, 123-1b and 123-2.
123-1(b)	Refer to the footnote for 123-1a.
123-2	Refer to the footnote for 123-1a.
163-1	Aged leaching data are required as confirmatory data to assess the mobility of butylate degradation products. Because of the nature and rate of butylate degradation, radiolabeled synthesized degradates may be necessary.
164-1	Two field dissipation studies must be conducted in major corn-producing regions where butylate is commonly used and must reflect typical corn cultivation practices. These studies must contain volatilization measurements because volatility appears to play a significant role in the environmental fate of butylate. One field dissipation study must be conducted with the EC or FC and the second study must be conducted with either the granular or microencapsulated formulation.
171-4(e)	Based on available storage stability studies that report a 50% decline in residues, the Agency has concluded that additional storage stability data are required to confirm that the residues do not exceed the 0.1 ppm tolerance.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0071 Butylate
Chemical # and Name
041405 Butylate

GUIDELINE	COMMENT
201-1	This study is required to support the chemigation application method for butylate.
202-1	This study is required to support the chemigation application method for butylate.
81-8-SS	This neurotoxicity study is now required because butylate is chemically related to several thiocarbamate pesticides that have shown neurotoxicity in long-term repeated studies in rats and/or dogs.

ATTACHMENT D

List of all Registrant(s) sent this DCI
(Included in registrants copy only)

ATTACHMENT E

EPA Acceptance Criteria

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Name of technical material tested (include product name and trade name, if appropriate)
2.___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3.___ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%
4.___ Purpose of each active ingredient and each intentionally-added inert
5.___ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6.___ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
7.___ Description of each beginning material in the manufacturing process
    _____ EPA Registration Number if registered; for other beginning materials, the following:
    _____ Name and address of manufacturer or supplier
    _____ Brand name, trade name or commercial designation
    _____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity
8.___ Description of manufacturing process
    _____ Statement of whether batch or continuous process
    _____ Relative amounts of beginning materials and order in which they are added
    _____ Description of equipment
    _____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained
    _____ Statement of whether process involves intended chemical reactions

8. (continued)

____ Flow chart with chemical equations for each intended chemical reaction
____ Duration of each step of process
____ Description of purification procedures
____ Description of measures taken to assure quality of final product

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

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 1, 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement of Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration, and certified limits.
3. Name and upper limit for all impurities present at $\geq$ 0.1% and those toxicologically significant impurities present at <0.1%.
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental or internal code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

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

1. Number of representative samples analyzed for all active ingredients and all impurities at $\geq$ 0.1%.

2. Degree of accountability or closure in analyses in item #1.

3. Chemical names of toxic impurities which were analyzed for levels <0.1%.

4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.

5. Statement of precision and accuracy of method(s) in item #4.

6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.

7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.

8. Proposed upper certified limit for each impurity present at >=0.1% and certain toxicologically significant impurities at <0.1% with brief explanation of how limits were determined.

9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).

10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

___ Verbal description of coloration (or lack of it)

___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

___ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"

___ Based on visual inspection at about 20-25° C

63-4 Odor

___ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"

___ Observed at room temperature

63-5 Melting Point

___ Reported in C°

___ Any observed decomposition reported

63-6 Boiling Point

___ Reported in C°

___ Pressure under which B.P. measured reported

___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

___ Measured at about 20-25° C

___ Density of technical grade active ingredient reported in g/ml <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

___ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide

___ Measured at about 20-25° C

___ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

___ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)

___ Experimental procedure described

___ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

___ Experimental method described

___ Temperature of measurement specified (preferably about 20 - 25° C)

63-11 Octanol/water Partition Coefficient

___ Measured at about 20-25° C

___ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)

___ Data supporting reported value provided

63-12 pH

___ Measured at about 20 - 25° C

___ Measured following dilution or dispersion in distilled water

63-13 Stability

___ Sensitivity to metal ions and metal determined

___ Stability at normal and elevated temperatures

___ Sensitivity to sunlight determined

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

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

1. Description of color.
2. Description of physical state.
3. Description of odor.
4. Indication of melting point (in C°).
5. Indication of boiling point (in C°).
6. Indication of density, bulk density, and specific gravity.
7. Indication of solubility.
8. Indication of vapor pressure.
9. Indication of dissociation constant.
10. Indication of octanol/water partition coefficient.
11. Indication of PH.
12. Description of stability.

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig
81-7	Acute Neurotoxicity in the Hen

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, end-use product, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing and for at least 14 days.
7. Summarization of body weights
8. Summarization of gross necropsy
9. Significance of changes from the Acceptance Criteria

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc)

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

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

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

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. The number of animals/sex/dose
3. Weight range of animals
4. Verification of single, dermal exposure
5. Duration of dermal exposure
6. Statement of vehicle control
7. Doses tested and results
8. Preparation of application site
9. Area of application site (percent body surface)
10. Occlusion of test material on application site
11. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
12. Summarization of body weights
13. Summarization of gross necropsy
14. Significance of changes from Acceptance Criteria

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. Statement of the inhalability of test substance
3. The number of animals/sex/dose
4. Duration of inhalation exposure
5. Number of chamber air changes/hour and the percent oxygen content of chamber air
6. Ranges for chamber air temperature and relative humidity
7. Air flow rate
8. Analytical concentrations of test material in breathing zone
9. Results of aerosol particle-size determination
10. Doses tested (or limit dose of 5mg/L or highest attainable)
11. Individual observations on day of dosing and for at least 14 days.
12. Summarization of body weights
13. Summarization of gross necropsy
14. Significance of changes from Acceptance Criteria

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive, cause severe dermal irritation or has a pH of <2 or >11.5
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual daily observations afterwards, until eyes are normal or for 21 days
10. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD 50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for day of dosing and individual daily observations thereafter
12. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

dose your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if material is corrosive or has pH <2 or >11.5.
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

81-7 Acute Neurotoxicity in the Hen

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Study performed on an organophosphate cholinesterase inhibiting compound.
2.____ Technical form of the active ingredient tested.
3.*___ Positive control utilized.
4.____ Species utilized, domestic laying hen 8-14 months of age.
5.____ Dosing oral by gavage or capsule (dermal or inhalation may be used).
6.____ An acute oral LD is determined.
7.____ Dose tested equal to an acute oral LD or a limit test of 5000 mg/kg.
8.*___ Dosed animals may be protected with atropine and/or 2-PAM.
9.____ Sufficient test animals so that at least 6 survive.
10.____ Negative (vehicle) control group of at least 6 hens
11.*___ Positive control of at least 4 hens. (if used)
12.____ Test dose repeated if no signs of delayed neurotoxicity observed by 21 days after dosing.
13.____ Observation period 21 days after each dose.
14.____ Individual daily observations.
15.____ Individual body weights.
16.____ Individual necropsy not required.
17.____ Histopathology performed on all animals. Tissue to be fixed in sin preferably using whole animal perfusion techniques. At least three sections of each of the following tissues:
    _____brain, including medulla oblongata
    _____spinal cord; upper cervical, mid-thoracic and lumbro-sacral regions
    _____tibial nerve; proximal regions and branches
    _____sciatic nerve

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

ATTACHMENT F

Cost Share and Data Compensation Forms

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-9

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

Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develp 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 a offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on al 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 name above, and that the statements that I have made o 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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

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
Chemical Name	EPA Chemical Number

I Certify that:

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

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

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

APPENDIX G

Product Specific Data Call-In

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

DATA CALL-IN NOTICE

CERTIFIED MAIL

NOV 26 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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 product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

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

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 3-31-96).

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

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

The Attachments to this Notice are:

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - List of Registrants(s) sent this DCI
F - EPA Acceptance Criteria
G - 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. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, 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 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you 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. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment B and Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). 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 A.

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

If you 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.

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select 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 timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

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

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

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

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-

guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

2. Failure to submit on the required schedule an acceptable proposed or final protocol if 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 if 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 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 (if applicable), including the incorporation of any changes required by the Agency following review.

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent

distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on 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 A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment B and Attachment C) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment A. If the voluntary cancellation option is chosen, only the Data Call-In Response Form need be submitted.

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

Sincerely yours,

Peter Cowlbeck for

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - List of Registrants Sent This DCI
F - EPA Acceptance Criteria (refer to Attachment E, EPA Acceptance Criteria for Generic DCI)
G - Cost Share and Data Compensation Forms

ATTACHMENT A

Product Specific DCI Chemical Status Sheet

BUTYLATE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have products containing butylate.

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 butylate. 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 B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this butylate Product Specific Data Call-In (Attachment G). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of butylate, please contact Ms. Judy Loranger at (703) 308-8056.

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

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

Ms. Veronica Dutch
Special Review and Reregistration Division
Office of Pesticide Programs, H7508W
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Butylate

ATTACHMENT B

Product Specific Data Call-In Response Forms (Form A) plus Instructions

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11.Self-explanatory.

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

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

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0071 Butylate	PRODUCT SPECIFIC

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Form B) plus Instructions

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the

agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

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

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

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

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

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

Items 10-13. Self-explanatory.

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

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

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

2. Case # and Name
0071 Butylate
EPA Reg. No. NNNNNN-NNNNN

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

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descrip of starting materials,(1,2) production & formulation proc					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

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

2. Case # and Name
0071 Butylate
EPA Reg. No. NNNNNN-NNNNN

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

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	12 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,36,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-2	Acute dermal (1,2,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
	toxicity-rabbit/rat								
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0071 Butylate

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

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

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0071 Butylate

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

ATTACHMENT D

EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration

ATTACHMENT D

EPA'S BATCHING OF BUTYLATE END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone

else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table I indicates 1 batch including 2 products containing the active ingredient butylate.

Table I.

Batch No.	EPA Reg. No.	% Butylate	Formulation
1	34704-702	85.1	Emulsifiable Concentrate (EC)
	10182-222	85.1	EC

Table II lists 12 products that were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table II.

EPA Reg. No.	% Butylate, And Other Active Ingredient	Formulation
10181-181	78.06	EC
10182-182	10.0	Granular
10182-192	88.2	EC
10182-201	18.0 5.7 Atrazine	Granular
10182-211	77.3	EC
10182-236	48.2	Pellet/tablet
10182-248	56.8 13.9 Atrazine	EC
10182-249	74.0	EC
10182-269	97.0	Technical
10182-286	89.6	EC

EPA Reg. No.	% Butylate, And Other Active Ingredient	Formulation
10182-288	85-1	EC
34704-633	10.0	Granular

ATTACHMENT E

EPA Acceptance Criteria
(Refer to Generic DCI Acceptance Criteria Attachment E)

ATTACHMENT F

List of Registrants sent this DCI
(Included in registrants copy only)

ATTACHMENT G

Product Specific Data Call-In Cost Share and Data Compensation Forms

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0107
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
Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develp 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 name 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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-9

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
Chemical Name	EPA Chemical Number

I Certify that:

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

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

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	