United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA738-R-97-013 December 1997

Reregistration Eligibility Decision (RED)

THIOBENCARB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case thiobencarb which includes the active ingredient S-[(4-chlorophenyl)methyl]diethyl carbamothioate. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1997 contains the Agency's evaluation of the data base of the 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 "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative C.P. Moran at (703) 308-8009. Please address any questions on required generic data to the Special Review and Reregistration Division representative Dennis Deziel at (703)308-8173.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

THIOBENCARB

LIST B

CASE 2665

TABLE OF CONTENTS

THIOBENCARB REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

James Saulmon	Herbicide and Insecticide Branch
Yuen-Shaung Ng	Science Information and Analysis Branch
Edward Brandt	Economic Analysis Branch
Neil Anderson	Herbicide and Insecticide Branch
Michael Yanchulis	Herbicide and Insecticide Branch

Environmental Fate and Effects Risk Assessment

Nick Mastrota	Environmental Risk Branch II
James Breithaupt	Environmental Risk Branch II
David Wells	Environmental Risk Branch II
Robert Hitch	Environmental Risk Branch II

Health Effects Risk Assessment

Paul Lewis	Risk Characterization and Analysis Branch
Stephen Dapson	Toxicology Branch II
David Miller	Chemistry and Exposure Branch II
Brian Steinwand	Chemistry and Exposure Branch II
Alan Nielson	Reregistration Branch II

Registration Support Risk Assessment

Daniel Kenny	Fungicide-Herbicide Branch
Joanne Miller	Fungicide-Herbicide Branch

Risk Management

Dennis Deziel, Team Leader	Reregistration Branch I

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

ABSTRACT

This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of pesticide products containing the active ingredient thiobencarb S-((4-chlorophenyl)methyl) diethylcarbamothioate. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products.

Thiobencarb is a thiocarbamate herbicide that is applied primarily to rice (95%), as well as to lettuce, celery and endives to control grasses and broadleaf weeds. Thiobencarb is sold in the United States by Valent U.S.A. Corporation. There are five registered products.

Thiobencarb was first registered for use on rice in 1982. In 1991, thiobencarb was issued regional tolerances for use on celery, endives, and lettuce in the state of Florida. Thiobencarb is applied as a liquid and granular (California only) using fixed-wing aircraft, helicopter, granular tractor-drawn spreader, and groundboom sprayer.

The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration. However, to mitigate risks for certain uses, the Agency has determined that the following actions must be taken in regard to thiobencarb:

1. **Prohibit application of thiobencarb south of the Intracoastal Waterway in Louisiana,** based on the high risk of chronic effects to fish and freshwater invertebrates, including shrimp and mollusks, and the high risk of causing acute effects to freshwater and invertebrates. This affects approximately 10,000 acres of rice, less than 5 percent of total rice acreage in Louisiana.

2. **Prohibit application of thiobencarb within two (2) miles inland from the shorelines of Galveston and Matagorda Bays in Texas,** based on the high risk of chronic effects to fish and freshwater invertebrates, including shrimp and mollusks, and the high risk of causing acute effects to freshwater and invertebrates. This affects approximately 2,000-5,000 acres of rice, about 1 percent of total rice acreage in Texas.

3. **Institute a 14-Day holding period following thiobencarb application to rice fields**, where weather permits, due to the risks associated with thiobencarb and thiobencarbsulfoxide residues in runoff and receiving waters.

4. **Continue use of thiobencarb on vegetable crops (currently celery, endives and lettuce) and rice in Florida**, a decision which will be reassessed with the completion of ongoing environmental monitoring studies in Florida (Fall 1998).

The generic data base supporting the reregistration of thiobencarb for the above eligible uses has been reviewed and determined to be substantially complete. Additional data for occupational exposure, ecological effects and environmental fate are being required to confirm the Agency's risk assessment and conclusions.

In establishing or reassessing tolerances, the Food Quality and Protection Act of 1996 (FQPA) requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effect from a pesticide and other compounds with a common mechanism of toxicity. The FQPA further directs the Agency to consider potential for increased susceptibility of infants and children to the toxic effects of pesticide residue. The Agency considers the appropriateness of an additional uncertainty factor, which can be applied in situations where available data indicate infants and children may have an increased sensitivity to the pesticide. In general, the data base for thiobencarb does not indicate a potential for increased toxicological sensitivity from either pre- or post-natal exposures. No developmental toxicity was observed in either the rat or the rabbit developmental toxicity studies, nor was there evidence in the two-generation reproduction study of developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. Therefore, the Agency has determined that an additional uncertainty factor is not warranted.

Regarding aggregate risks, the Agency considered chronic exposure through the diet, including drinking water (thiobencarb has no residential uses). The estimated aggregate risks from these exposures do not exceed the Agency's levels of concern. EPA does not have, at this time, available data to determine whether thiobencarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on common mechanism of toxicity, thiobencarb does not appear to produce a toxic metabolite produced by other thiocarbamate compounds. For the purposes of this tolerance action, therefore, EPA has not assumed that thiobencarb has a common mechanism of toxicity with other substances.

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

I. INTRODUCTION

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Thiobencarb
- **Chemical Name:** S-((4-chlorophenyl)methyl)diethylcarbamothioate
- **Chemical Family:** Thiocarbamate
- **CAS Registry Number:** 28249-77-6

- **OPP Chemical Code:** 108401

- **Empirical Formula:** $C_{12}H_{16}CINOS$

- **Trade and Other Names:** Bolero
  Bencarb
  Saturn
  B 3015
  IMC 3950

- **Basic Manufacturer:** Valent U.S.A. Corporation

B. Use Profile

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

For thiobencarb:

Type of Pesticide: Systemic Herbicide

Mode of Action: Inhibits shoots of emerging seedlings

Use Sites: Rice, lettuce, celery, and endive

Target Plants: Broadleaf weeds, grasses, and sedge

Specific types: Hemp sesbania, redstem, purple ammannia, teaweed, southern naiad, ducksalad, mud plantain, fall panicgrass, texas millet, hurrahgrass, annual bluegrass, foxtail, johnsongrass, jointvetch, sicklepod, watergrass, gulf cockspur, goosegrass, little barley, sprangletop, red rice, panicum, paragrass, broadleaf signalgrass, cheat, downy brome, crabgrass, junglerice, barnyardgrass, spikerush, fimbristylis miliaceae, roughseed bulrush, horned beakrush, waterwort, mexicanweed, texasweed, woolly croton, redstem filaree, carolina foxtail, pitted morningglory, mustard, shepherdspurse, flatsedge, smallflower umbrellaplant, gooseweed, chickweed, lambsquarters, dayflower, eclipta, dandelion, morningglory, pigweed, purslane, waterplantain, arrowhead, alligatorweed, redroot pigweed, redstem, sprangletop, cheat, crabgrass, spikerush, fimbristylis miliaceae, mustard, lambsquarters, dayflower, pickerelweed, buttercup, waterhyssop, false pimpernel, redweed, and marestail

Formulation Types Registered:

TECHNICAL GRADE		
ACTIVE INGREDIENT:	Liquid 97.40%	
END USE PRODUCT:	Emulsifiable Concentrate	84.00%
GRANULAR:	10.00%	

Method and Rates of Application:

Equipment - Aircraft; Boom sprayer; Ground; Low pressure ground sprayer; Low volume ground sprayer; Sprayer.

Method - Soil treatment; Spray; Water application.

Rate -

Rice	2 to 4lbs a.i./acre
Lettuce	6lbs a.i./acre
Endive	6lbs a.i./acre
Celery	6 to 8lbs a.i./acre

Timing - Early-postemergence; Post-emergence; Post-transplant; Preemergence; Seed bed.

Use Practice Limitations:

Do not apply directly to water (Liquid formulation). Do not apply through any type of irrigation system. Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction) For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

Site/Application Limitations: For celery, endives (escarole), and lettuce provide for a 60-day preharvest interval

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of thiobencarb. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Approximately 1.22 million pounds of thiobencarb are applied annually on 465,000 acres (460,000 of which is rice). Based on data from the National Agricultural Pesticide Impact Assessment Project, four states -- Arkansas, Louisiana, California, and

Texas -- accounted for 88 percent of the total rice planted in the United States in 1993, and 89 percent of the total rice production for that year. The percentage of total rice treated in Arkansas, Louisiana, California, and Texas with thiobencarb was 14.1 percent. The average rate for thiobencarb used on rice was 2.85 lb. AI/acre.

D. Regulatory History

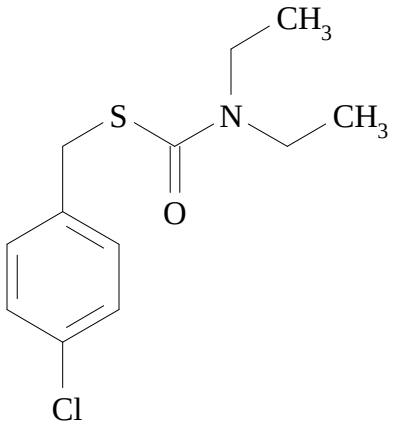
Thiobencarb is the common name for S-[(4-chlorophenyl)methyl]diethyl carbamothioate. Thiobencarb was first registered for use on rice in 1982. In 1991, thiobencarb was issued regional tolerances for use on celery, endives, and lettuce in the State of Florida.

Currently, there are five products containing thiobencarb registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act. They consist of one technical (manufacturing use) product containing 97.4% active ingredient, two emulsifiable concentrate end-use products each containing 84.0% active ingredient, and two granular end-use products each containing 10.0% active ingredient.

The Agency issued a Data Call-In as part of the Phase 4 reregistration in August 1991. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data that were submitted voluntarily by the registrant or in response to the Data Call-In Notice attached to this document.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment



Empirical Formula: $C_{12}H_{16}ClNOS$

Molecular Weight: 257.8

CAS Registry No.: 28249-77-6

Thiobencarb is a pale yellow liquid with a boiling point of 126-129° C. Thiobencarb is readily soluble in most organic solvents and slightly soluble in water.

B. Human Health Assessment

1. Toxicology Assessment

At present, the available toxicological database for thiobencarb is adequate and will support reregistration eligibility for the currently registered uses. Table 1 lists the toxicity studies and their results for thiobencarb.

a. Acute Toxicity

Thiobencarb has been tested for acute toxicity by the oral, dermal and inhalation routes of exposure. The results obtained in these studies, which are listed in Table 2, satisfy the acute toxicity data requirements.

Table 1. Acute Toxicity Values for Technical Thiobencarb.

Test	Results	Toxicity Category	Purity
Oral LD_{50} - rat	Males: LD_{50} = 1033 (924-1155) mg/kg Females: LD_{50} = 1130 (1033-1247) mg/kg (MRID 42130701)	III	96.0%
Dermal LD_{50} - rabbit	LD_{50} > 2000 mg/kg (both sexes) (MRID 42130701)	III	96.0%
Inhalation LC_{50} - rat	LC_{50} > 42.8 mg/L (1 hour) (MRID 00040585, 00134976	IV	95.1%
Eye Irritation - rabbit	Slight irritation (MRID 00040581)	III	95.1%
Dermal Irritation - rabbit	Slight irritation (MRID 00040583, 00081900)	IV	95.1%
Dermal Sensitization - guinea pig	Not a sensitizer (MRID 00161699)	NA	84.0%

Table 2. Data At A Glance: Thiobencarb Hazard Toxicity.

DATA AT A GLANCE	**THIOBENCARB HAZARD TOXICITY**							
GENERAL TOXICITY INFORMATION:	➤ **Carcinogenicity Classification**: **Group D** (Not Classifiable as to human carcinogenicity) ➤ **Reference Dose (RfD)**: **0.01 mg/kg/Day** ➤ **Uncertainty Factor**: **10** (interspecies extrapolation) **x 10** (intraspecies extrapolation) = **100**							
GLN #	**STUDY**	**MRID #**	**LC_{50} (mg/L)**	**LD_{50} (mg/kg)**	**TOXICITY (category)**	**NOEL (mg/kg/day)**	**LOEL (mg/kg/day)**	**ENDPOINT/ RESULTS**
ACUTE								
81-1	Acute Oral (rat)	42130701	N/A	1033 (M) 1130 (F)	III (Caution)			Oral toxicity;
81-2	Acute Dermal (rabbit)	42130701	N/A	2000 (M/F)	III (Caution)			Dermal toxicity;
81-3	Acute Inhalation (rat)	00040585 00134976	42.8	N/A	IV (Non-toxic)			Inhalation Toxicity;
81-4	Primary Eye Irritation (Rabbit)	00040581			III (Caution)			Slight Irritation;
81-5	Primary Dermal Irritation (rabbit)	00081900			IV (Non-toxic)			Slight Irritation;
81-6	Dermal Sensitization (guinea pig)	00161699						Not a sensitizer;
81-7	Acute Neurotoxicity (rat)	42987001 43148202				100	500	Gait abnormalities, decreased sensory responses, decreased body temperature, and decreased motor activities;
81-7	Acute Neurotoxicity (systemic tox.)	42987001 43148202				100	500	Increased clinical signs and gait abnormalities;
84-2	Gene Mutation (Ames)	00041174 00084131 00135285						Result: Negative; non-mutagenic;
84-2	Structural Chromosone Aberration (dominant lethal)	0084133						Result: Negative; non-mutagenic;
84-2	Structural Chromosone Aberration (Clastogenicity)	40352401						Result: Negative; non-mutagenic;
84-4	Other Genotoxic Effects (micronucleus test in mice)	40352402						Result: Positive; Significant incidence of increases in the micronuclei;
85-1	General Metabolism Study	42340302						Result: No significant sex-related or dosegroup differences in absorption, urinary or fecal excretion, or radioactivity excretion were observed;
85-2	Dermal Absorption (rats)	41215311						Result: dermal absorption factor of 60.2%, observed at 10 hours.

GLN #	STUDY	MRID #	LC_{50} (mg/L)	LD_{50} (mg/kg)	TOXICITY (category)	NOEL (mg/kg/day)	LOEL (mg/kg/day)	ENDPOINT/ RESULTS
SUB-CHRONIC								
82-2	21-Day Dermal (rat)	42893001				Not Observed	40	Skin irritation;
82-2	Dermal (Systemic Tox.)	42893001				40	160	Decreases in body weight and food consumption;
82-4	90-Day Neurotoxicity (rat)	43001001				> 100	Not Estab.	Increased clinical signs, decreased body weights, increased liver and kidney weights;
82-4	Neurotoxicity (systemic tox.)	43001001				**2**[1]	20	Increased clinical signs, decreased body weights, increased liver and kidney weights;
CHRONIC								
83-1	2-Year Feeding Chronic Toxicity (rat)	00154506				**1**[2]	5	Decreased body weight gains, food consumption, food efficacy and increased blood urea nitrogen;
83-1	2-Year Feeding Chronic Toxicity (non rodent)	00144742				8	64	Increased liver and kidney weights and decreased hematological and clinical chemistry parameters;
83-1	Chronic Toxicity (Plasma Cholinesterase)	00144742				1	8	Biologically significant depression in cholinesterase activity;
83-1	Chronic Toxicity (erythrocyte cholinesterase)	00144742				8	64	Biologically significant depression in cholinesterase activity;
83-1	Chronic Toxicity (Brain Cholinesterase)	00144742				$\underline{<}$ 64	> 64	Biologically significant depression in cholinesterase activity;
83-2	Oncogenicity (mouse) (carcinogenicity)	00086004				3 (M) 5 (F)	14 (M) 19 (F)	Histopathological changes in the liver;
83-3	Teratogenicity (rat) (developmental)	00115248 00086873 00093691				**25**[3]	150	Increased skeletal anomaly observations, increased incidents of reduced ossification, and increased number of runts;
83-3	Teratogenicity - rat (maternal toxicity)	00115248 00086873 00093691				25	150	Decreased body weight gains and decreased food efficiency;
83-3	Teratogenicity (rabbit)	00164313				$\underline{>}$ 200	> 200	Increase in absolute and relative liver weights;
83-3	Teratigenicity - rabbit (maternal toxicity)	00164313				100	200	Increased liver weights;
83-4	2-Generation Reproduction (rat)	40446201 40908571				$\underline{>}$ 100	> 100	Histopathological changes of the liver and kidney;
83-4	Reproduction -rat (parental/systemic toxicity)	40446201 40985701				2	20	Histopathological changes of the liver and kidney;

[1] NOEL, supported by the NOEL established in the multigenerational reproduction study, is significant for factoring intermediate-term occupational or residential exposure (1 week to several months).

[2] NOEL used to calculate thiobencarb Reference Dose (RfD), multiplied by the uncertainty factor of 100.

[3] NOEL is significant for factoring acute dietary risk and short-term occupational or residential exposure (1 to 7 days).

b. Subchronic Toxicity

In a 21 day dermal study (MRID# 42893001, revision of MRID# 42003401), Sprague-Dawley rats received repeated dermal applications of Bolero® 8EC (85.2% a.i.) at doses of 0, 40, 160, or 500 mg/kg, 5 days per week, over a 22-day period. Thirty-six animals of each sex were used, 6 animals/sex/dose for the 0, 40, 160 and 500 mg/kg dose plus an extra 6/sex/dose for the 0 and 500 mg/kg doses at recovery. There was a dose related increase in the incidence of skin irritation in treated versus control rats of both sexes. Six additional animals dosed with 0 and 500 mg/kg were held for 2 weeks following dosing as a recovery group. Reduced food intake with an associated reduction in body weight gain was observed in the mid- and high-dose groups. The reduction in body weight gain persisted in high-dose males in the recovery group. Statistically significant decreases in food efficiency were observed in mid-and high-dose males. For dermal toxicity, a NOEL was not observed and the LOEL was less than 40 mg/kg/day based on the skin irritation observed. For systemic toxicity, the NOEL was 40 mg/kg/day and the LOEL was 160 mg/kg/day based on decreases in body weight gain and food consumption in males and females, and statistically significant decreases in food efficiency in males.

Subchronic toxicity studies are classified as supplementary data, not adequate to satisfy Subdivision F guidelines. Therefore, the data requirements for subchronic studies in rats and dogs are satisfied by the chronic feeding studies in the rat and dog (see chronic toxicity and carcinogenicity section).

c. Chronic Toxicity

In a combined chronic toxicity/carcinogenicity feeding study (MRID# 00154506), Fischer 344 rats received 0, 20, 100 or 500 ppm (approximately 0, 1, 5, and 25 mg/kg/day by standard conversion methods) technical Bolero® (95.3% a.i.) in the diet for 2 years. Systemic toxicity was noted at 100 ppm and higher as decreased body weight gain, food consumption and food efficiency. There was also an increase in blood urea nitrogen. However, no evidence of carcinogenicity at the dose levels tested was observed. For chronic toxicity, the NOEL was 1 mg/kg/day and the LOEL was 5 mg/kg/day based on decreased body weight gains, food consumption, food efficiency and increased blood urea nitrogen.

In a chronic oral toxicity study (MRID# 00144742), Beagle dogs received 0, 1, 8, or 64 mg/kg/day of thiobencarb technical (Lot# SX-1381; Purity 96.3% a.i.) by capsule for 52 weeks. Systemic toxicity was noted in the high dose males as decreased body weight gains and increased absolute and relative kidney and liver weights in high dose males and females. There were decreases in serum albumin and protein in high dose males and females (a slight effect was noted in mid dose males). In addition, there were decreased erythrocyte counts and hemoglobin levels with a reduction in hematocrit in high dose males and females along with decreases in alanine aminotransferase and cholesterol

levels in the high dose group. For systemic toxicity, the NOEL was 8 mg/kg/day and the LOEL was 64 mg/kg/day based on increased liver and kidney weights, and decreased hematological and clinical chemistry parameters. Based on biologically significant depression in cholinesterase activity, for plasma cholinesterase, the NOEL was 1 mg/kg/day and the LOEL was 8 mg/kg/day. For erythrocyte cholinesterase, the NOEL was 8 mg/kg/day and the LOEL was 64 mg/kg/day. For brain cholinesterase, the NOEL was equal to or greater than 64 mg/kg/day and the LOEL was greater than 64 mg/kg/day.

d. Carcinogenicity

In a carcinogenicity study (MRID# 00086004), B6C3F1 mice received 0, 25, 100, 400, or 1600 ppm (0, 3, 14, 56, and 235 mg/kg/day for males and 0, 5, 19, 75, and 302 mg/kg/day for females, respectively) technical Bolero® (93.7% a.i.) for 121 weeks. Systemic toxicity was noted at 14 mg/kg/day for males and 19 mg/kg/day for females and higher as histopathological changes in the liver. These observations included an increased incidence of hepatocytic (glycogen) pallor; the high dose animals also had increased incidence of fatty vacuolization (moderate or marked mid-zonar). High dose males had marked fine fatty periacinar, vacuolization, and increased relative heart and liver weights. At 14 mg/kg/day and above, males had decreased absolute and relative kidney weights, while high dose females had increased relative kidney weights. Upon gross examination, there was an increased incidence of pale foci of the lungs in high dose animals, and pale livers in the high dose males (external examination showed abdominal swelling). There was also an increased incidence of focal epithelialization of the alveolar walls of the lungs with associated macrophages. In addition, high dose females had reduced body weight gains. There was no evidence of carcinogenicity in either sex at the dose levels tested. For chronic toxicity, the NOEL was 3 mg/kg/day for males and 5 mg/kg/day for females and the LOEL was 14 mg/kg/day for males and 19 mg/kg/day for females based on histopathological changes in the liver.

e. Developmental Toxicity

In a developmental toxicity study (MRID# 00115248), albino rats of the Sim: (SD) FBR (Sprague Dawley derived) strain received by oral gavage either 0, 5, 25, or 150 mg/kg/day thiobencarb technical (97% a.i.) in Deionized Water/CMC/Tween 80 on days 6 through 19 of gestation. Maternal toxicity was observed as a treatment related decrease in body weight gains in the high dose group. There was no effect on food consumption; however, the high dose had lower food efficiency than the control group, an indicator of systemic toxicity. For maternal toxicity, the NOEL was 25 mg/kg/day and the LOEL was 150 mg/kg/day based on decreased body weight gains and decreased food efficiency. Developmental toxicity was noted as a slight increase in skeletal anomaly observations at the high dose mostly related to reduced ossification and an increase in runts in the high dose group. For developmental toxicity, the NOEL was 25 mg/kg/day and the LOEL was 150 mg/kg/day based on increased skeletal anomaly observations and an increase in the number of runts.

In another developmental toxicity study (MRID# 00164313), New Zealand white rabbits received 0, 20, 100, or 200 mg/kg/day technical thiobencarb (96.0% a.i,) by oral gavage from days 6 through 18 of gestation. Maternal toxicity was observed at 200 mg/kg/day as statistically significant increase in absolute and relative liver weights. For maternal toxicity, the NOEL was 100 mg/kg/day and the LOEL was 200 mg/kg/day based on increased liver weights. No developmental toxicity was observed at dose levels tested. For developmental toxicity, the NOEL was equal to or greater than 200 mg/kg/day and the LOEL was greater than 200 mg/kg/day.

Based on the results of these studies, thiobencarb is not considered to be a developmental toxicant in rats or rabbits.

f. Reproductive Toxicity

In a multigeneration reproduction study (MRID# 40446201), Charles River CD rats received either 0, 2, 20, or 100 mg/kg/day Technical Bolero® (96.7% a.i.) by daily oral gavage in 0.5% CMC aqueous solution. Systemic toxicity was noted at 20 mg/kg/day and higher based on enlargement of centrolobular hepatocytes (both generations), and hepatocyte single cell necrosis observed in both sexes of both generations including renal atrophic tubule consisting of regenerated epithelium. There were increased liver weights (absolute and relative) and increased kidney weights (absolute and relative) in the high dose group. There were also significant changes in body weights at 100 mg/kg/day and male kidney weights were increased in the high dose group. There were no effects on reproductive parameters. For parental/systemic toxicity, the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on histopathological changes of the liver and kidney. For reproductive toxicity, the NOEL was equal to or greater than 100 mg/kg/day and the LOEL was greater than 100 mg/kg/day.

g. Mutagenicity

Thiobencarb was evaluated in an Ames assay (MRID#s 00041174, 00084131 and 00135285), and was negative in tester strains TA100, TA98 and TA1537 at levels up to 50μg/plate, both with and without metabolic activation.

Thiobencarb was negative in a dominant lethal assay in mice (MRID# 00084133 and 00135282), administered at a single oral dose of 600 mg/kg, and at an oral dose of 300 mg/kg for 5 days.

In a clastogenicity test using human lymphocytes (MRID# 40352401), thiobencarb (96.0% a.i.) was tested at dose levels of 0, 5, 10, and 20 μg/ml without S9 activation and at dose levels of 0, 10, 20, and 40μg/ml with S9 activation. No mutagenic activity was noted.

In a micronucleus test in mice (MRID# 40352402), thiobencarb (96.0% a.i.) was tested at dose levels of 0, 270, 540, and 1080 mg/kg in males and at dose levels of 0, 405,

810, and 1620 mg/kg in females, as a single oral dose. A dose related increase in micronuclei was noted, and was statistically significant in high dose males and in the two highest doses in females. Four consecutive daily doses of 540 mg/kg caused statistically significant increases in the incidence of micronuclei in both sexes. This was considered as a positive mutagenic response.

Thus, thiobencarb was shown to lack mutagenicity in three of the four mutagenicity tests conducted. No further testing is required at this time.

h. Metabolism

In a general metabolism study (MRID# 42340302), the disposition and metabolism of [Phenyl-U-^{14}C]-thiobencarb was investigated in male and female Sprague-Dawley rats at a single low oral dose (30 mg/kg), repeated low oral doses (30 mg/kg x 14 days), and a single high dose (300 mg/kg). Thiobencarb was rapidly absorbed after oral administration as judged by the rate of excretion. No significant sex-related or dose group differences in absorption were noted. Excretion was relatively rapid at all doses tested, with a majority of radioactivity eliminated in the urine and feces by 48 hours. The extent of excretion was completed by 72 hours at the 300 mg/kg dose, but the mechanism responsible for this delay was not identified. No significant sex- or dose-related differences in urinary or fecal excretion of thiobencarb derived radioactivity were noted. Repeated low oral dosing did not affect elimination of thiobencarb in either male or female rats.

Fecal elimination of [Phenyl-U-^{14}C]-thiobencarb derived radioactivity was a minor route of excretion, and for urine, no significant sex- or dose-related differences in amount of radioactivity excreted by this route were observed. Residual levels of thiobencarb derived radioactivity were also minor (less than 0.5% of an administered dose).

Urinary and fecal metabolites of [Phenyl-U-^{14}C]-Thiobencarb were isolated and identified by HPLC, TLC, and mass spectral analysis. The major metabolite detected was the glycine conjugate 4-chlorohippuric acid, comprising between 74-81% of an administered dose in urine. Other metabolites detected included 4-chlorobenzyl methyl sulfoxide and -sulfone, des-ethyl thiobencarb, and 4-chlorobenzoic acid, each representing less than 10% of an administered dose of thiobencarb. A single high or repeated low oral dose did not significantly affect the urinary or fecal metabolite profile for thiobencarb in male or female rats.

i. Neurotoxicity

Acute Neurotoxicity

In an acute neurotoxicity study (MRID# 42987001, 43148202), male and female Sprague-Dawley rats received a single oral administration of thiobencarb (96.9%) at doses

of 0, 100, 500 or 1000 mg/kg. Neurobehavioral evaluations, consisting of Functional Observational Battery (FOB) and motor activity, were conducted at pre-study, day 0, at time of peak effect (4 hrs post-dosing), day 7 and day 14. At day 15, animals were euthanized and neuropathological examination performed on control and high-dose animals (5/dose/sex). With the exception of one high-dose female, which died on day 3 of the study, all other animals survived until terminal sacrifice. An increased incidence of clinical signs, consisting of red deposits around the noses and mouths of high-dose animals, were noted. Gait abnormalities (rocking, lurching and swaying) were observed in some high-dose females. No significant differences were noted in either the mean body weight or body weight gain of any of the treated animals. Neurobehavioral evaluation revealed treatment-related FOB and motor activity findings at the mid- and high-dose levels. The effects were, in general, transient and observed only at the peak time of effect (4 hrs post-dosing). Although the incidences of FOB findings were not significantly different from control values, when taken together, a consistent, treatment-related pattern of neurobehavioral effects becomes clear. These findings included gait abnormalities (lurching, swaying and rocking), impaired mobility, and decreased sensory responses (approach, touch, startle, tail pinch and pupil responses). In high-dose males, the startle response achieved statistical significance when measured at the time of peak effect. Hindlimb resistance was reduced in high-dose animals. Mean body temperature was significantly decreased in all treated males and mid- and high dose females. Total and ambulatory motor activity, measured at the peak time of effect on day 0, showed significant treatment-related decreases in all mid- and high-dose animals. No treatment-related gross or neuropathological findings were present. Brain weights and measurements of the treated animals were comparable to control values. Thus, for systemic toxicity, the NOEL was 100 mg/kg/day and the LOEL was 500 mg/kg based on increased clinical signs and gait abnormalities. For neurobehavioral toxicity, the NOEL was 100 mg/kg/day and the LOEL was 500 mg/kg based on gait abnormalities, decreased sensory responses, decreased body temperature, and decreased motor activity.

Subchronic neurotoxicity

In a subchronic neurotoxicity study (MRID# 43001001), male and female Sprague-Dawley rats (10/sex/group) received oral administration of Bolero® 8EC (89 percent purity) at 0, 2, 20 or 100 mg/kg/day for 13 weeks. All animals survived until terminal sacrifice. Clinical signs were evident only within the first 4-hours post-dosing. During this time, there was an increased incidence of dried red material around the noses of all treated animals and dried tan or red material around the mouths of mid- and high-dose animals. Mean body weights and body weight gains of high-dose females were lower than controls. Food consumption was not affected by treatment. The absolute-and relative (to terminal body weight and brain weight) liver and kidney weights of high-dose males and females was statistically significantly increased. The relative (to the terminal body weight) liver weights of mid-dose males and the kidney weights of mid-dose females were statistically significantly increased. No clinical pathology was conducted. In addition, no treatment-related gross or neuropathological findings were present. Thus, for systemic

toxicity, the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on increased clinical signs, decreased body weights, increased liver and kidney weights. For neurotoxicity, the NOEL was greater than 100 mg/kg/day (HDT) and a LOEL was not established.

j. Endocrine Disruptor Effects

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

k. Epidemiological Information

No cases of poisoning were located from any of the available databases on incidents related to the use of thiobencarb. EPA believes that this may be due partly to the relatively limited use of this chemical.

2. Toxicological Endpoints for Risk Assessment

a. Reference Dose (RfD)

The RfD/Peer Review Committee met on February 8, 1996, to discuss and evaluate the existing and/or recently submitted toxicology data in support of the thiobencarb reregistration and to reassess the RfD for this chemical.

The Committee recommended that the existing RfD for thiobencarb remain unchanged. The RfD for this chemical was based on the two year rat feeding study (MRID# 00154506) with a NOEL of 20 ppm (1 mg/kg/day). At the next higher dose level of 100 ppm (5mg/kg/day), decreased body weights and increased blood urea nitrogen levels were observed. An uncertainty factor of 100 was applied to account for both inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated by the Committee to be 0.01 mg/kg/day.

b. Carcinogenic Classification

The carcinogenic potential of thiobencarb was evaluated by the RfD/Peer Review Committee on February 8, 1996. The Committee considered the carcinogenicity phases of the combined chronic toxicity/carcinogenicity studies in rats (MRID# 00154506) and the carcinogenicity study in mice (MRID# 00086004) for carcinogenic classification.

The highest dose level tested in rats (500 ppm, or 25 mg/kg/day) was considered to be adequate for carcinogenicity testing based on depression of cholinesterase activity and reduced body weight gain. The highest dose level tested in mice (1600 ppm, or 235 mg/kg/day in males and 302 mg/kg/day in females) was considered to be adequate based on body weight gain depression.

In rats, there was no treatment-related increase in tumors of any kind at any dose level. The Committee, therefore, concluded that the treatment did not alter the spontaneous tumor profile in this strain of rat.

In mice, adenomas and carcinomas of the harderian glands appeared to be increased in treated females (1, 2, 6, 5 and 7 tumors for the 0, 25, 10, 400 and 1600 ppm groups, respectively). However, the Committee noted several limitations with the study. First, the concurrent control incidence was lower than expected for females of this strain. This decreased incidence in the control group could possibly be due to chance and could not be precluded. Second, if a greater number of control mice had lived until completion of the study, more spontaneous tumors may have occurred, thus resulting in similar tumor incidence between treatment and control groups. Third, the study was carried out for 121 weeks, a significantly longer period than guideline requirements. Thus, the increased study length may have contributed to the appearance of tumors in treated females. Fourth, the Committee concluded that historical control incidence data from studies conducted for a significantly shorter duration should not be considered. The Committee reasoned that these shorter duration studies may not accurately depict tumor incidences because the tumor incidence would most likely be lower than what was observed in the studies used for carcinogenic classification. Thus, no historical control data were acceptable for review by the Committee.

On this basis, the Committee recommended that thiobencarb be classified as Group D chemical (not classifiable as to human carcinogenicity).

c. Other Toxicological Endpoints

On April 30, 1996, the Agency's Office of Pesticide Program Health Effects Division Toxicity Endpoint Selection Committee (i.e. the TES Committee), met to discuss the toxicological endpoints to be used in various risk assessments for thiobencarb. A summary of the endpoints selected is provided in Table 3.

Dermal Absorption. In addition to the toxicological endpoints listed in Table 2, the TES Committee discussed the dermal absorption of thiobencarb.

Table 3. Summary of Toxicological Endpoints for Thiobencarb

Type of Exposure	NOEL	Endpoint
Acute Dietary (one day)	NOEL = 25 mg/kg/day established in a rat developmental toxicity study (MRID 00086873, 00093691 and 00115248)	Increases in incidence of reduced ossification and an increase in fetal runts.
Short-Term Occupational or Residential Exposure (one to seven days)	NOEL = 25 mg/kg/day established in a rat developmental toxicity study (MRID 00086873, 00093691 and 00115248).	Increases in the incidence of reduced ossification and an increase in fetal runts.
Intermediate-Term Occupational or Residential Exposure (one week to several months)	NOEL = 2 mg/kg/day for systemic toxicity established in a rat subchronic neurotoxicity study (MRID 43001001). This NOEL of 2 mg/kg/day is supported by a similar NOEL (2 mg/kg/day) established in the multigeneration reproduction study (MRID 40446201 and 409085701).	Histopathological changes in the liver and kidney.

In a dermal absorption study (MRID# 41215311), Sprague-Dawley® Crl:CD® (SD)BR male rats were dermally treated with either 0, 0.05, 0.5 or 5.0 mg/rat of ^{14}C-Thiobencarb (Radiochemical purity: 98.8%, Specific Activity: 359,092 dpm/μg) for exposure durations of 1, 2, 4, 10, or 24 hours (4 rats per dose per duration). The unlabeled compound used was Bolero® 8EC (Thiobencarb, Purity: 89% a.i.). This study may represent a worst-case scenario since the skin was washed approximately 1 hour prior to dosing rather than the recommended 24 hours (which would allow normal replacement of skin oils). Thus, this might tend to over-estimate absorption. Based on the results of the study, the Committee determined that thiobencarb is rapidly and continuously absorbed at doses of 5.0, 46.8 and 498 μg/cm^2 for exposure times up to 24 hours. Absorption at 10 hours was 60.2, 52.6, and 17.1% for the 5.0, 46.8 and 498 μg/cm^2 dose groups, respectively. Maximum absorption at 24 hours was 71.5, 72.6, and 41.75 for the 5.0, 46.8 and 498 μg/cm^2 dose groups, respectively. Urine was the primary route of excretion.

On this basis, the committee recommended that a dermal absorption factor of 60.2%, observed at 10 hours in a dermal absorption study (MRID# 41215311), be used for risk assessment purposes, even though the Committee recognizes that this value is likely to over-estimate absorption. A new dermal absorption study is requested for confirmatory purposes.

Summary of Science Findings

i. Directions for Use

A tabular summary of the residue chemistry science assessments for reregistration of thiobencarb is presented in Appendix 3. The conclusions listed in Appendix 3 regarding the reregistration eligibility of thiobencarb are based on the use patterns registered by the basic producer. All end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) must be amended such that they are consistent with the basic producer labels.

Table 4. Chemical structures of thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moiety

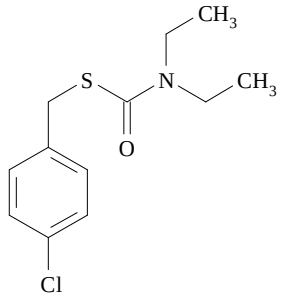
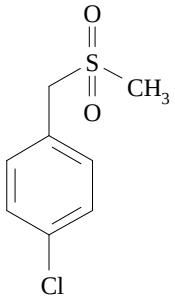
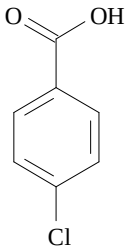
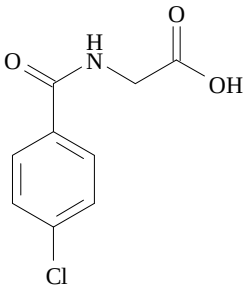
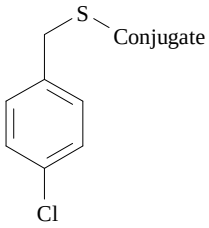
Compound: thiobencarb	**Compound**: Thiobencarb
 Thiobencarb S-((4-Chlorophenyl)methyl)diethylcarbamothioate	 4-Chlorobenzylmethylsulfone
 4-Chlorobenzoic acid	 N-(4-Chlorobenzoyl)glycine
 4-Chlorobenzylthio conjugates	

Table 5. Thiobencarb end-use products (EPs) with food/feed uses.

Registrant	EPA Reg. No.	Acceptance Date	Formulation	Product Name
Valent U.S.A. Corporation	59639-79 [1]	4/20/94	8 lb/gal EC	Bolero® 8EC (Herbicide)
	59639-80 [2]	11/29/93	10% G	Bolero® 10 G (Herbicide)
K-I Chemical U.S.A Inc.	63588-5	2/94	10% G	Bolero® 10 G
	63588-6	2/94	8 lb/gal EC	Bolero® 8EC

[1] EPA Reg. No 59639-79 is the parent label for the following Section 24© registrations: AR940002, AR940003, AR950004, CA930003, FL910003, FL930010, LA950005, MO930007, MO940005, MO950002, MS930009, MS930010, MS950007, TX930023, and LA960004.

[2] EPA Reg. No. 59639-80 is the parent label for the following Section 24© registrations: AR940001, MS930011, and TX930024.

ii. Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on an acceptable study depicting the metabolism of thiobencarb in rice. On May 13, 1993, the Agency's Metabolism Committee determined that the current tolerance expression for residues of thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moieties is appropriate.

iii. Animal Metabolism

For the purposes of reregistration and risk assessment, the qualitative nature of the residue in animals is adequately understood based on acceptable studies conducted on ruminants and in poultry. The residue of concern in eggs, milk, and poultry and livestock tissues include the parent thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moieties. The current tolerance expression for animal commodities, as defined in 40 CFR §180.401(a), is adequate.

iv. Residue Analytical Methods - Plants and Animals

The requirements for residue analytical methods are fulfilled for the purposes of reregistration. Adequate methods are available for enforcement and data collection purposes for both plant and animal commodities. Successful radiovalidation of the enforcement methods, using samples from the metabolism studies, has also been conducted. The 1994 FDA PESTDATA database indicates that residues of thiobencarb are completely recovered (> 80%) using multiresidue method Section 302 (Luke method; Protocol D), and variably recovered using method Section 304 (Mills, Onley, Gaither method; fatty food). The registrant has conducted multiresidue method trials with thiobencarb metabolites 4-chlorobenzylmethylsulfone and 4-chlorobenzylmethylsulfoxide using Protocol E and with 4-chlorobenzoic acid using Protocol B. The Agency has forwarded the results of these multiresidue trials to FDA for evaluation and inclusion in Pesticide Analytical Method (PAM) Vol. I, Appendix I.

v. Storage Stability

Adequate storage stability data are available to support the established tolerances. Acceptable storage stability studies have been submitted for representative plant and animal commodities. The available plant and animal metabolism studies are also validated by adequate storage stability data.

vi. Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in/on plants are fulfilled for the following commodities: celery, endive, lettuce, rice grain and straw. No additional data are required. Adequate field trial data, following treatments according to the maximum registered use patterns, have been submitted for the commodities listed above. The available data were submitted in conjunction with tolerance petitions for celery, endive, and lettuce (PP#5F3158), and rice grain and straw (PP#0F2322, 5G1582, 6F1763, and 2G1231), and are adequate to support reregistration requirements including tolerance reassessment.

vii. Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed food/feed commodities of rice are fulfilled. An acceptable study depicting the potential for thiobencarb residues of concern to concentrate in rice processed fractions has been submitted and evaluated. The data indicate that the combined residues of thiobencarb and 4-chlorobenzylmethylsulfone did not concentrate in polished rice and bran processed from rice samples that received postemergence application of the registered 10% G formulation at an exaggerated rate (5x). However, the combined residues concentrated 2x in hulls. Although residue concentration was observed in hulls, the observed combined residues of thiobencarb and its metabolite (< 0.06 ppm) in/on hulls following exaggerated rate treatment were below the established tolerance of 0.2 ppm for rice grain.

viii. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The reregistration requirements for magnitude of the residue in milk and livestock tissues as well as in eggs and poultry tissues are fulfilled. There are no registered direct animal treatments of thiobencarb on cattle, goats, hogs, horses, poultry, or sheep.

The available dairy cattle and poultry feeding studies indicates that the combined residues of thiobencarb and its metabolites [4-chlorobenzoic acid, 4-chlorobenzyl-methylsulfone, and 4-chlorobenzylmethylsulfoxide] will not exceed the established tolerances.

ix. Magnitude of the Residue in Potable Water

The reregistration requirements for magnitude of the residue in water will be considered fulfilled when revisions are made to Valent's end-use product labels (EPA Reg. Nos. 59639-79 and 59639-80) to prohibit use of treated water for livestock watering or for drinking or irrigation for a specified time period after treatment. Based on the results of an acceptable magnitude of residue in potable water study (MRIDs 43404003, 43404004, and 43404005), thiobencarb and thiobencarbsulfoxide residues in runoff and receiving waters associated with rice fields did not fall to acceptable levels until 14 days after treatment. Thus, the Agency has determined that a 14-day water holding interval should be imposed following thiobencarb applications to rice fields. If the registrant does not wish to institute this label restriction, then a irrigated crop field trial and a drinking water treatment intake study will be required.

The use of the thiobencarb granular formulation (Bolero® 10G, EPA Reg. No. 59639-80) in California is regulated under the Basin Plan for the Sacramento River Basin established by the California Regional Water Quality Control Board, Central Valley Region. A performance goal of 1.5 ppb is strictly monitored, and growers must adhere to a program of approved management practices, including a 30-day water holding restriction.

x. Nature and Magnitude of the Residue in Fish

The reregistration requirements for nature and magnitude of the residue in fish will be fulfilled when label revisions are made on Valent's end-use products (EPA Reg. Nos. 59639-79 and 59639-80) to specify the following use restrictions: "Do not use on rice paddies where commercial catfish or crayfish farming is practiced. Do not use adjacent to catfish or crayfish ponds."

xi. Magnitude of the Residue in Irrigated Crops

Data depicting the magnitude of the residue in irrigated crops are not required for reregistration purposes since the Agency is imposing a 14-day water holding interval.

xii. Magnitude of the Residue in Food-Handling Establishments

Thiobencarb is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

xiii. Confined/Field Rotational Crops

Valent's thiobencarb end-use labels specify a 6-month plantback interval following rice and all other crops, except celery, endive and lettuce for which rotational crop plant-

back intervals are 4-months. These currently specified plant-back intervals are appropriate.

xiv. Residue Information (for dietary risk assessment)

Tolerances for thiobencarb are published in 40 CFR 180.401(a) and (b). Tolerances have been established for rice grain at 0.2 ppm; meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm; eggs at 0.2 ppm; and milk at 0.5 ppm. Tolerances with regional registrations are established for celery, endive, and lettuce at 0.2 ppm each. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. Anticipated residue information was not used for this analysis.

d. Dietary Exposure from Drinking Water

Thiobencarb is not currently regulated under the Safe Drinking Water Act. Public water supply systems are not required to sample and analyze for thiobencarb. Thus, no Maximum Contaminant Level (MCL) is established for thiobencarb in drinking water systems. An MCL is an action level as established by the EPA Office of Water to ensure the safety of drinking water. In addition, a lifetime Health Advisory (HA) for thiobencarb has not been established.

Ground Water

Limited groundwater monitoring information is available for thiobencarb. The "Pesticide in Ground Water Database" (Hoheisel et al., 1992) reported sampling for thiobencarb in 270 wells in California and 65 wells in Missouri. Two detections of thiobencarb in ground water were reported in Missouri and at very low concentrations (0.2 - 0.3 ppb). However, no limit of detection (LOD) or limit of quantification (LOQ) was provided to normalize the data for non-detectable residues. This is an important consideration since thiobencarb was not detected in almost all wells sampled. Therefore, the groundwater sampling data are not usable for drinking water risk assessment purposes.

Surface Water

Thiobencarb has the potential to contaminate surface water from releases of rice paddy water following thiobencarb applications or from spray drift associated with aerial or ground spray application to other registered sites.

The Agency provided estimates of thiobencarb residues in surface water by utilizing the Generic Estimated Environmental Concentration program (GENEEC), EPA's Office of Water's STORET database and data from a California thiobencarb surface water monitoring study. However, the GENEEC and STORET data were not applicable to access thiobencarb in drinking water. First, GENEEC does not model for

rice scenarios. Since almost 95% of all thiobencarb use is on rice, GENEEC exposure estimates are not applicable to most thiobencarb uses. Second, the STORET data were not normalized for non-detectable residues. Approximately 99% of samples collected to measure for thiobencarb indicated non-detectable residues. Therefore, due to limitations with the GENEEC and STORET data, the California surface water modeling study was the only applicable data to measure thiobencarb in surface water. The results of the California thiobencarb surface water monitoring data are provided below.

California Surface Water Monitoring study

Monitoring for residues of specific rice pesticides in surface water of California's Sacramento River basin was performed by the California Environmental Protection Agency (CAL EPA), sometimes in conjunction with the California Rice Industry Association, from 1993 to 1996. The Agency estimates that the City of Sacramento is the only locality in the US rice growing region relying on surface water as its source of drinking water (i.e. the city utilizes the Sacramento River as its source of drinking water).

In 1993, 17 samples were collected just before the intake to the Sacramento River drinking water treatment facility (the only year of the four year study that samples from this location were collected). No detections above a limit of detection of 0.1μg/L were reported. However in 1993, due to substantial flow in the Sacramento River, water was diverted south of the sampling location via the Yolo Bypass. Thus, diverting water from the Sacramento River drinking water treatment facility may have contributed to thiobencarb levels below the limit of detection. Therefore, The Agency concludes that even though thiobencarb residues at the Sacramento River were below the limit of detection (0.1 μg/L), thiobencarb residues may be higher if water was not diverted via the Yolo Bypass.

e. Occupational Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

In the case of thiobencarb, EPA has determined that there is a toxicological concern and there is potential exposure to mixers, loaders, applicators, or other handlers during activities that would occur under the usual thiobencarb use scenarios. Also, there is potential exposure to persons reentering sites that have been treated with thiobencarb. Therefore, the Agency has assessed application and post-application exposure to thiobencarb.

At this time, products containing thiobencarb are intended primarily for occupational uses only and not for homeowner uses. Thus, this exposure assessment is

limited to occupational uses only. Further, EPA expects that, based on the use patterns, exposure to thiobencarb will occur for a short to intermediate duration; chronic exposure is not expected. Finally, the Agency expects exposure to occur via the dermal and inhalation routes.

i. Handler Exposure

EPA has identified eight major exposure scenarios from the use patterns of thiobencarb for its occupational exposure assessment: (1a) mixing/loading liquids for aerial application; (1b) mixing/loading liquids for groundboom application; (2a) loading granulars for fixed-wing aircraft; (2b) loading granulars for tractor-drawn spreader application; (3) applying sprays with a fixed-wing aircraft; (4) applying granulars with a fixed-wing aircraft; (5) applying sprays with a helicopter; (6) applying granulars with a tractor-drawn spreader; (7) applying sprays with groundboom equipment; and, (8) flagging aerial spray applications.

Potential dermal and inhalation baseline unit exposure (which are derived from PHED V. 1.1), along with corresponding calculated daily exposures, are presented in Table 6. No chemical-specific data were submitted. Baseline unit exposure is the PHED exposure estimate with baseline attire (long-sleeve shirts, long pants, shoes, and socks). Dermal exposure is several orders of magnitude greater than inhalation exposure.

Potential daily exposure is calculated using the following formula:

Daily exposure (mg ai /day) = Unit exp. (mg ai/lb ai) x Max. App. Rate (lb ai/ac) x Max. Area Trt. (ac/day)

Table 6. Thiobencarb Baseline Unit Exposures and Daily Exposures (Short and Intermediate-Term).

Exposure Scenario (Number)	Crop	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated	Daily Absorbed Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader Exposure							
Mixing/Loading Liquids for Aerial Application (1a)	Rice	2.9	1.2	4	350	2444.1	1.68
Mixing/Loading Liquids for Groundboom Application (1b)	Rice			4	80	558.7	0.38
	Endive/Lettuce			6		838.0	0.58
	Celery			8		1,117.3	0.77
Loading Granulars for Fixed-wing Aircraft Application (2a)	Rice	0.0076	1.7	4	350	6.6	2.3
Loading Granulars for Tractor-drawn Spreader Application (2b)	Rice				80	1.5	0.54
Applicator Exposure							
Applying Sprays with a Fixed-wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	4	350	See Eng. Controls	See Eng. Controls
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice			4	350		
Applying Sprays with a Helicopter (Enclosed Cockpit) (5)	Rice			4	350		
Applying Granulars with a Tractor-Drawn Spreader (Enclosed Cab) (6)	Rice	0.01	1.24	4	80	19	0.40
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.015	0.7	4	80	2.9	0.22
	Endive/Lettuce			6		4.3	0.34
	Celery			8		5.8	0.45
Flagger Exposure							
Flagging Spray Applications (8)	Rice	0.01	0.28	4	350	8.4	0.39

[a] Baseline dermal unit exposure represents long pants, long sleeve shirt, no gloves, open mixing/loading, and open cab tractor. Baseline data are not available for aerial application and granular applications with a tractor-drawn spreader.

[b] Baseline inhalation exposure represents no respirator.

[c] Application rates are the maximum found in the thiobencarb labels [EPA Reg. Nos. 59639-79 and 59639-80].

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

[e] Daily absorbed dermal exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated * Dermal Absorption Rate (60.2%)

[f] Daily inhalation exposure (mg/day) = Exposure (ug/lb ai) * (1mg/1000 ug)conversion * Appl. Rate (lb ai/A) * Acres Treated

ii. Post-Application Exposure

Based on the use patterns of thiobencarb, EPA has determined that there is potential exposure for persons entering treated sites after application is complete. Workers may be entering treated areas to perform such tasks as scouting, thinning, or hoeing. However, there are no chemical-specific data available upon which to assess the risks from post-application exposures. Since no dislodgeable foliar residue studies or concurrent dermal samples were submitted to the EPA for this RED to measure post-application reentry, a rough surrogate post-application assessment was performed as a default. The surrogate assessment is based on the range of application rates (4-6 pounds active ingredient per acre), the assumption that 20% of the initial application is available as dislodgeable residue after sprays have dried or granules have settled (approximately 12 hours after application is complete), and a residue dissipation rate of approximately 10% per day. The short-term endpoint (25 mg/kg/day) was used for the risk assessment, since EPA does not anticipate that intermediate-term exposures (i.e., 7 days or more of exposure) are likely to occur for post-application workers. EPA also assumed in this surrogate assessment that dermal absorption would be significantly lower that the 60.2 percent used in the handler assessment, since dermal exposure would be to dry residues. Thiobencarb is applied early season, therefore late season tasks, such as harvesting, are not a concern. The tasks of concerns, including scouting, thinning, and hoeing, are not likely to be of long duration. Therefore the Agency chose a transfer coefficient that reflects the relatively low dermal transfer.

f. Aggregate Exposure

In examining aggregate exposure, FQPA requires that EPA take into account available information concerning exposure from the pesticide residue in food and all other exposure for which there is reliable information. These other sources of exposure of the general population (including infants and children) to pesticides include residues in drinking water and non-occupational exposures, e.g. to pesticides used in and around the home and to sources not directly related to use of the pesticide such as Superfund sites or TRI emissions. Only food source and drinking water exposure were evaluated since no non-occupational use is expected.

3. Risk Assessment

EPA expects both dietary and occupational exposure from the use of thiobencarb (there are no residential uses). Dietary exposure occurs via the oral route while occupational exposure occurs via the dermal and inhalation routes. Since an acute inhalation study placed thiobencarb in Toxicity Category IV, an inhalation risk assessment was not initiated.

Dietary exposure (food and drinking water sources) is expected to occur over an acute through chronic period. To assess the acute dietary risk, EPA calculates a margin of exposure (MOE), which is the ratio of the NOEL to exposure. To assess chronic risk, EPA calculated the percent of the reference dose [RfD] (i.e. % RfD) occupied.

a. Dietary Risk

i. Acute Dietary (Food Source) Risk

The Dietary Risk Evaluation System (DRES) acute analysis estimates the distribution of single-day exposure for the overall U.S. population and certain subgroups. It includes all published uses of thiobencarb, even those commodities that are being recommended for revocation. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-1978 Nationwide Food Consumption Survey and accumulates exposure to the chemical for each commodity.

The MOE is calculated by dividing the acute dietary NOEL (i.e. mg/kg/day) by the high-end exposure (see Table 2 of Appendix 5 for the exposure estimates). High-end exposure represents exposure of the pesticide to 99.5% of the targeted population. Because the endpoint of concern for acute dietary risk assessment is a developmental toxicity effect, the only subgroup of concern is females (13+ years). Generally, acute aggregated MOEs greater than 100 tend to cause no dietary concern when the data are compared to a toxicological endpoint from an animal study (such is the case for thiobencarb). Since the only subgroup of concern is females (13+) and represents an MOE = 8928,the Agency is not concerned with acute dietary risks from exposure to thiobencarb residues in food.

ii. Acute Dietary (Drinking Water) Risk

Due to limitations with available groundwater sampling data, no groundwater data are applicable for risk assessment purposes. Even though there is an absence of applicable groundwater data, based on the environmental fate of thiobencarb and the soil profile of rice fields, the Agency does not believe that thiobencarb would be a concern to groundwater. First, thiobencarb is slightly persistent in water, generally not very mobile, tends to bind to soil organic matter, and doesn't desorb. Second, rice fields are usually underlain by a clay layer to restrict water movement through the soil and help contain the water in the flooded field. This clay layer will significantly limit the amount of leaching that occurs in rice fields.

As noted above, approximately 95% of thiobencarb applications are made to rice. In addition, the Agency estimates that the City of Sacramento is the only locality in the US rice growing region utilizing surface water as its drinking water. Data from the California surface water monitoring study indicated thiobencarb residues were not above a limit of

detection of 0.1 μg/L (0.1 ppb). Thus, drinking water exposure was calculated using the following formula:

Exposure (mg/kg/day) = (ppb thiobencarb in the water consumed)(10^{-6})(33.3)

Thus, drinking water exposure = 3.33 x 10^{-6} mg/kg/day and a resulting MOE > 10,000. Therefore, the Agency is not concerned with acute drinking water risks from exposure to thiobencarb residues in drinking water.

Water consumption is defined as all water obtained from the household tap that is consumed either directly as a beverage or is used to prepare foods (mixing water with a can of soup) and beverages (diluting frozen juice concentrate). Since a developmental endpoint was selected for acute dietary exposure, the subpopulation of concern are females (13+ years). This subpopulation are assumed to weigh 60 kg and consume 2.0 liters of water per day (33.3 g/kg-body wt/day), the value used in the above equation.

iii. Total Acute Dietary (Food Sources and Drinking Water)

To assess total acute dietary exposure and MOEs, the following formulas were utilized:

Total acute dietary exposure = acute food source exp. (high end exp.) [mg/kg/day]
+ drinking water exp. (high end exp.) [mg/kg/day]

$$\text{Total acute dietary MOE} = \frac{\text{NOEL (mg/kg/day)}}{\text{total acute dietary exposure (mg/kg/day)}}$$

Food source exposure (high end exposure) was 0.0028 mg/kg/day based on the high end exposure for females (13+ years). Drinking water exposure (high end exposure) was 3.33 x 10^{-6} mg/kg/day based on surface water exposure as discussed previously. Thus, the total acute dietary MOE is 8920. Therefore, The Agency is not concerned with total acute dietary risks from exposure to thiobencarb.

iii. Chronic Dietary (Food Source) Risk

A DRES chronic exposure analysis was performed using tolerance level residues and a 100 percent crop treated assumption to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. A summary of the TMRCs and the % RfD values for the U.S. general population, non-nursing infants (< 1 year old) children (1-6 years) and females (13+ years) are provided in Table 2 of Appendix 5. The chronic analysis for thiobencarb is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with thiobencarb.

As shown in Table 7, much less than 100% of the RfD is occupied by the dietary uses recommended through reregistration. Existing tolerances result in a TMRC which represents 12.8% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (< 1 year old), occupies 42.9% of the RfD. In addition, numerous conservative assumptions have been considered into this assessment. Thus, the actual % RfD is considered $\leq$ 42.9%. Therefore, The Agency is not concerned with chronic dietary risks from exposure to thiobencarb residues in food.

Table 7. Chronic Dietary (Food Source) Risk Evaluation (based on TMRC).

Population Subgroup	Exposure (mg/kg/day)	%RfD (Chronic - noncancer)
General U.S. Population	0.001280	12.8
Non-nursing infants (< 1 year)	0.004294	42.9
Children (1-6 years)	0.002945	29.5
Females (13 + years)	0.001103	11.03

iv. Chronic Drinking Water Risk

As noted previously, due to limitations with available groundwater sampling data, no groundwater data are applicable for risk assessment purposes. However, even though there is an absence of applicable groundwater data, based on the environmental fate of thiobencarb and the soil profile of rice fields. The Agency does not believe that thiobencarb would be a concern to groundwater.

The Agency utilized data from the California surface water monitoring study to access chronic drinking water exposure. A drinking water exposure estimate of 0.1 μg/L (i.e. 2.86 x 10^{-6} mg/kg/day) was used to assess chronic exposure (as was performed for acute drinking water exposure) since this is the only data available. As was noted previously in the acute drinking water exposure assessment, data from the California surface water monitoring study indicated thiobencarb residues were not above the a limit of detection of 0.1μg/L. Thus, high end drinking water exposure was utilized for the chronic drinking water risk assessment and corresponds to a %RfD = 0.29. Therefore, The Agency is not concerned with chronic drinking water risks from exposure to thiobencarb in drinking water.

v. Total Chronic Dietary (Food Sources and Water) Risk

To assess total chronic dietary exposure and MOEs, the following formulas were utilized:

Total chronic dietary exposure = food source chronic exp. (average exp.) [mg/kg/day]
(mg/kg/day) + drinking water exp.high end exp. *) [mg/kg/day]

$$\% \text{ RfD} = \frac{\text{total chronic dietary exposure (mg/kg/day)}}{\text{RfD (mg/kg/day)}}$$

* High end exposure was used due to a lack of average exposure data.

Thus, this represents a percent RfD = 43.2%. Therefore, EPA is not concerned with total chronic dietary risks from exposure to thiobencarb.

vi. Dietary (food source and water) Carcinogenic Risk

Since thiobencarb is a Group D carcinogen (not classifiable as to human carcinogenicity), a dietary carcinogenic risk assessment is not required.

b. Occupational Risk

i. Handlers

The short-term and intermediate-term MOEs for thiobencarb calculated from Baseline, additional personal protective equipment, and engineering controls risk Mitigation unit exposures are provided in Tables 8 and 9. The unit exposure values are from PHED. An inhalation assessment was not undertaken, since no inhalation endpoint of concern has been identified. Appendix 4 provides the assumptions used for exposure calculations.

The daily dermal dose is calculated using a 60 kg body weight (average female bodyweight) for short-term exposure, since this endpoint is based on a developmental toxicity concern. A 70 kg body weight (average person bodyweight) is used for intermediate-term exposure. The following formula was used to calculate the daily dermal dose:

Daily Dermal Dose (mg ai/kg/day) = Daily Dermal Exp. (mg ai/day) x 1/Body weight (kg) x 60.2% dermal absorption

These calculations of daily dermal dose of thiobencarb received by handlers are used to assess the dermal risk to those handlers. The short-term dermal MOEs were calculated using a dermal absorption rate of 60.2 percent and a NOEL of 25 mg/kg/day. The intermediate-term dermal MOEs were calculated using a dermal absorption rate of 60.2 percent and a NOEL of 2 mg/kg/day. The following formula was used for MOE calculations:

MOE = NOEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day)

Short-term

In general, for an endpoint, EPA generally considers an MOE of 100 to be protective of human health. The calculations of short-term risk estimates indicate that the

MOEs are greater than 100 at **baseline** (single-layer of clothing, chemical-resistant gloves, no engineering controls) for the following scenarios:

- (2a) loading granulars for fixed-wing aircraft application;
- (2b) loading granulars for tractor drawn spreader application;
- (2b) applying granulars with a tractor drawn spreader;
- (7) applying sprays with a groundboom sprayer (all rates); and,
- (8) flagging liquid aerial application.

The calculations of short-term risk estimates indicate that the MOEs are greater than 100 with **additional PPE** for (1b) mixing/loading liquids for groundboom sprayer application.

The calculations of short-term risk estimates indicate that the MOEs are greater than 100 with **engineering controls** for the following scenarios:

- (1a) mixing/loading liquids for aerial application;
- (3) applying liquid spray with a fixed-wing aircraft;
- (4) applying granulars with a fixed-wing aircraft;
- (5) applying liquid sprayer with a helicopter; and,

Please note that at this time, the Agency has insufficient data upon which to assess the exposures and risks to applicators in open cockpits.

Table 8. Short-Term Dermal Risk Estimates for Thiobencarb (Baseline and Risk Mitigation MOEs)

Exposure Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	MOE Calculation Considering Risk Mitigation Measures					
				Additional PPE			Engineering Controls		
				Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial Application (1a)	Rice	40.7	0.61	0.025	0.35	71	0.009	0.13	192
Mixing/Loading Liquids for Groundboom Application (1b)	Rice	9.3	3	0.043	0.14	179	NA	NA	NA
	Endive/Lettuce	14.0	2	0.043	0.21	119			
	Celery	18.6	1	0.025	0.16	156			
Loading Granulars for Fixed-wing Application (2a)	Rice	0.11	227	NA	NA	NA	NA	NA	NA
Loading Granulars for Tractor-drawn Spreader Application (2b)	Rice	0.025	1,000	NA	NA	NA	NA	NA	NA
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.07	357
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice						0.0016	0.022	1136
Applying Sprays with a Helicopter (Enclosed Cab) (5)	Rice						NA	NA	NA
Applying Granulars with a Tractor-Drawn Spreader	Rice	0.03	833	NA	NA	NA	0.002	0.006	4,167
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.048	521	NA	NA	NA	NA	NA	NA
	Endive/Lettuce	0.072	347						
	Celery	0.097	258						
Flagger Risk									
Flagging Spray Applications (8)	Rice	0.14	179	NA	NA	NA	NA	NA	NA

NA = Not applicable since the previous MOE exceeded 100.

[a] Absorbed Dermal Dose (mg/kg/day) = (daily absorbed dermal exposure (mg/day) / 60 kg).

[b] Dermal Absorbed MOE = NOEL (25 mg/kg/day) / daily dermal absorbed dose (mg/kg/day).

Additional PPE:

1a Double layer of clothing with chemical resistant gloves.

1b Single layer of clothing with chemical resistant gloves for rice (4lbs ai/acre) and endive/lettuce (6 lbs ai/acre).

1b Double layer of clothing with chemical resistant gloves for celery (8lbs ai/acre).

Engineering Controls:

1a Closed mixing system, single layer of clothing with chemical resistant gloves.

3 Enclosed cockpit, single layer clothing, no gloves.

4 Enclosed cockpit, single layer clothing, no gloves.

5 Enclosed cockpit, single layer clothing, no gloves.

Table 9. Intermediate-Term Dermal Risk Estimates for Thiobencarb

Exposure Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	Risk Mitigation Measures					
				Additional PPE			Engineering Controls		
				Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial Application (1a)	Rice	34.9	0.06	0.025	0.3	7	0.009	0.11	18
Mixing/Loading Liquids for Groundboom Application (1b)	Rice	8.0	0.25		0.07	29		0.02	100
	Endive/Lettuce	12.0	0.17		0.1	20		0.04	50
	Celery	16.0	0.13		0.14	14		0.05	40
Loading Granulars for Fixed-wing Aircraft Application (2a)	Rice	0.05	40	0.0031	0.037	54	None	None	None
Loading Granulars for Tractor-drawn Spreader Application (2b)	Rice	0.02	100	NA	NA	NA	NA	NA	NA
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.06	33
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice						0.0016	0.019	105
Applying Sprays with a Helicopter (Enclosed Cockpit) (5)	Rice						0.0021	0.03	67
Applying Granulars with a Tractor-Drawn Spreader	Rice	0.03	67	0.007	0.02	100	NA	NA	NA
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.041	49	0.01	0.028	71	0.0067	0.018	111
	Endive/Lettuce	0.061	33		0.041	49		0.028	71
	Celery	0.083	24		0.055	36		0.037	54
Flagger Risk									
Flagging Spray Applications (8)	Rice	0.12	17	0.007	0.084	24	0.0002	0.0024	833

NA: Not applicable since the previous MOE exceeded 100.

None: No Engineering Controls exist for this scenario.

[a] Absorbed Dermal Dose (mg/kg/day) = (daily absorbed dermal exposure (mg/day) / 70 kg.

[b] Dermal Absorbed MOE = NOEL (2 mg/kg/day) / daily dermal absorbed dose (mg/kg/day).

Additional PPE:

1a Double layer of clothing with chemical resistant gloves.
1b Double layer of clothing with chemical resistant gloves.
2a Double layer of clothing with chemical resistant gloves.
6 Singel layer of clothing with chemical resistant gloves.
7 Double layer of clothing with chemical resistant gloves.
8 Double layer of clothing with out chemical resistant gloves.

Engineering Controls:

1a Closed mixing system, single layer of clothing with chemical resistant gloves.
1b Closed mixing system, single layer of clothing with chemical resistant gloves.
3 Enclosed cockpit, single layer clothing, no gloves.
4 Enclosed cockpit, single layer clothing, no gloves.
5 Enclosed cockpit, single layer clothing, no gloves.
7 Enclosed cab, single layer clothing, no gloves.
8 Enclosed cab, single layer clothing, no gloves.

i. Intermediate-term

The risks calculated from intermediate-term exposures to thiobencarb indicate that risks from exposures to granular formulations (loading and applying) are lower than those from exposures to the liquid formulation/spray applications. For the granular formulations, the MOEs exceed 100 for all scenarios (except loading to support aerial application) with the addition of personal protective equipment. For many of the liquid formulation/spray application scenarios, the MOEs do not reach 100, even with engineering controls.

Granular Formulations: The Agency believes the risks resulting from intermediate-term exposures to the granular formulation are overestimated due to the use of the 60.2 percent dermal absorption value for the granular scenarios. In general, dermal absorption of granular formulations has been found to be significantly lower than for liquid formulations. Therefore, the Agency has determined that risks to handlers of granular formulations will be adequately mitigated with the addition of personal protective equipment.

Liquid Formulations: The Agency believes that risks resulting from intermediate-term exposures to persons handling liquid formulations are overestimated due to limitations with the hazard identification and the dose-response assessment for the intermediate-term endpoint, particularly in light of the absence of serious effects to these target organs in either the subchronic neurotoxicity or rat chronic feeding study, which suggest the lack of a deleterious response to thiobencarb by the kidney and/or liver. The Agency believes that risks to handlers using liquid formulations will be adequately mitigated with the used of engineering controls and personal protective equipment.

ii. Post-Application Workers

Since no dislodgeable foliar residue studies or concurrent dermal samples were submitted to the EPA for this RED to measure post-application reentry, a rough surrogate post-application assessment was performed as a default. Only the short-term endpoint (25 mg/kg/day) was used for the risk assessment, since EPA does not anticipate that intermediate-term exposures (i.e., 7 days or more of exposure) are likely to occur for post-application workers for these crops in early-stage development. EPA assumed in the surrogate assessment that dermal absorption would be significantly lower that the 60.2 percent used in the handler assessment, since dermal exposure would be to dry residues. The surrogate post-application risk assessment indicated that at all application rates (i.e., 4-8 pounds active ingredient per acre), risks would be acceptable to post-application workers entering treated areas to perform tasks, such as scouting, thinning, or hoeing, provided entry is postponed for 24 hours following application.

c. Short-Term Residential Risk

Thiobencarb is not available for use in a residential setting. Thus, no non-occupational exposure to thiobencarb is expected.

d. Cumulative Risk Assessments

Thiobencarb is structurally similar to thiocarbamate pesticides. Further, other pesticides may have common toxicity endpoints with thiobencarb. However, the Agency has not made a determination whether thiobencarb and any other pesticides have a common mode of toxicity and require a cumulative risk assessment. For the purpose of this Reregistration Eligibility Decision, the Agency has considered only risks from thiobencarb. If required, cumulative exposure and risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

4. Risk Characterization

Short-term and intermediate-term handler MOE determinations were based on exposure estimates from surrogate chemical field studies submitted to the Pesticide Handlers Exposure Database (PHED) and from hazard identification for those exposure scenarios based on the weight-of-the-evidence of the toxicology database for thiobencarb.

a. Hazard Identification and Dose-Response

In terms of short-term exposure, the TESC selected the NOEL of 25 mg/kg/day established in a developmental toxicity study in rats. The LOEL of 150 mg/kg/day was based on increases in reduced ossification and runts in the fetuses of dams given oral administration of thiobencarb. This dose and endpoint was selected based on the assumption that the fetal effects can occur following short-term exposure (i.e., 1-7 days). In addition, the oral NOEL of 25 mg/kg/day is supported by the dermal NOEL of 40 mg/kg/day established in the 21-day dermal study when the 60% dermal absorption factor is utilized, as was demonstrated in this species. Thus, the comparable dermal dose is approximately 40 mg/kg/day [i.e. oral NOEL (25 mg/kg/day)/(0.6% dermal absorption) = 42 mg/kg/day]. In spite of the availability of a 21-day dermal toxicity study, the TESC did not use this study because: (I) the concern for the developmental effects seen in the oral rat study, (ii) developmental endpoints were not evaluated in the dermal rat study, and (iii) the high dermal absorption demonstrated in this species as well. The confidence in the toxicity studies for short-term exposure is high because all three studies were conducted in one species (rat) via different routes (oral and dermal) yielding comparable NOELs.

For intermediate-term exposure, the TESC selected the NOEL of 2 mg/kg/day established in the 2-generation reproduction study in rats. The LOEL of 20 mg/kg/day

was based on the parental/systemic toxicity characterized as enlargement of the centrilobular heptocytes in both generations, hepatocyte single cell necrosis observed in both sexes of both generations, and renal atrophic tubule consisting of regenerated epithelium. This NOEL is supported by the identical NOEL/LOEL established in the 90-day neurotoxicity study in rats; the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on systemic toxicity manifested as statistically significant increases in relative liver weights of male and kidney weights of female rats.

For dermal absorption, the TESC determined the thiobencarb dermal absorption factor was 60.2% at 10 hours based on a rat dermal absorption study. This represents an upper bound estimate of absorption since the skin was washed approximately 1 hour prior to dosing rather than the recommended 24 hours. However, if the study was repeated with the skin washed 24 hours before treatment, the Agency anticipates a lower dermal absorption factor for both thiobencarb formulations (i.e. emulsifiable concentration and granular).

Alternations in liver and kidney weights seen in the subchronic neurotoxicity study were corroborated with histopathological lesions in these organs in the multi-generation reproduction study indicating the liver and kidney to be target organs following intermediate exposure (i.e. up to several months) to thiobencarb-inducted toxicity at 20 mg/kg/day. However, the histopathological effects observed to the liver and kidney are not considered severe. Instead, these effects can be considered a detoxification effect to thiobencarb following an intermediate-term exposure. The lack of renal or liver lesions in the rat chronic feeding study provides support that the target organs have a detoxification reaction to thiobencarb.

b. Occupational Exposure

In terms of occupational exposure, the unit exposure for mixing/loading liquids for aerial application with a closed system (MOE = 18) is derived from four registrant submitted studies in PHED. There are 31 replicates for hand, 16 to 22 replicates for other dermal exposure, and 27 replicates for inhalation. From the 31 replicates in the PHED, only 138 samples (approximately 4%) had non-detectable residues. Dermal and inhalation exposure data are rated as high confidence based on the number of replicates and analytical grading criteria. The Agency's confidence in the unit exposure values are high because exposures are based on detectable residues from high confidence studies. Since detectable residues were observed, normalizing residue estimates to half the level of quantification or half the level of detection to account for non-detectable residues is not necessary. This provides additional support for the Agency's exposure estimates. In addition, most of the dermal data are from studies involving whole body dosimeters, which are generally a more accurate monitoring method than patch dosimetry. The assumption of 350 and 80 acres treated for aerial and groundboom applications, respectively, are acceptable based on agricultural practices.

Even though MOEs are less than 100 for several intermediate-term handler exposure scenarios, the Agency believes that these risks are over-estimated due to limitations with the hazard identification and dose-response assessment. The resulting histopathological lesions to the kidney and liver in the multi-generation study, and the absence of serious effects to these target organs in either the subchronic neurotoxicity or rat chronic feeding study, suggest the lack of a deleterious response of thiobencarb to the kidney and/or liver. This effect, in addition to the overestimate of dermal absorption, indicates a conservative estimate of intermediate-term handler risk. Therefore, the Agency concludes the intermediate-term handler MOEs are under-estimated and are not at a risk of concern.

C. Environmental Assessment

The environmental assessment consists of four sections: Ecological Toxicity Data; Environmental Fate and Transport; Ecological Exposure and Risk Assessment; and Environmental Risk Characterization. The first section reports ecological toxicity data from laboratory studies. The second section describes the environmental fate and transport data from field and laboratory studies, assesses the impact to water resources, and details the environmental fate assessment. The third section estimates ecological exposure and assesses the effects to non-target terrestrial and aquatic organisms. The fourth section, the Environmental Risk Characterization Section, integrates the exposure and effects assessment to determine the extent and potential for risk to the environment.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An oral (LD_{50}) study (preferably mallard or bobwhite quail) and two subacute dietary (LC_{50}) studies (one species of waterfowl, preferably the mallard duck and one species of upland game bird, preferably bobwhite quail) are required to establish the toxicity of a pesticide to birds. Results of these tests are tabulated below.

Table 10. Avian Acute Oral Toxicity Findings (LD_{50}).

Species	% A.I.	LD_{50} (mg a.i./kg)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Northern bobwhite	96.9	> 1938[a]	MRID 42600201 S.M. Campbell and M. Jaber. 1992.	Practically nontoxic	Yes
Northern bobwhite	Technical IMC 3950	--	Acc. No. 095106	--	No, invalid[b]
Mallard duck	Technical IMC 3950	--	Acc. No. 095106	--	No, invalid[b]

[a] There were no mortalities in birds receiving a dose of 1938 mg ai/kg thiobencarb.

[b] This study was performed by Industrial Bio-Test Laboratories, Inc. Data from all studies performed by this laboratory are considered invalid and cannot provide any information for ecological risk assessments.

Table 11. Avian Subacute Dietary Toxicity Findings (LC_{50}).

Species	% A.I.	LC_{50} (ppm ai)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Northern bobwhite	"Technical"	> 5620[a]	Acc. No. 241483. 1979.	Practically nontoxic	No, supplemental
Northern bobwhite	"Technical"	--	MRID 00057224 Acc. No. 095086	--	No, invalid[b]
Mallard duck	"Technical"	--	MRID 00057225 Acc. No. 095106	--	No, invalid[b]

[a] In this range-finding test for reproductive effects, there were no treatment-related mortalities in eight birds that were fed a diet containing 5620 ppm for eight weeks.

[b] This study was performed by Industrial Bio-Test Laboratories, Inc. Data from all studies performed by this laboratory are considered invalid and cannot provide any information for ecological risk assessments.

These results indicate that thiobencarb is practically nontoxic to avian species on an acute oral basis. A supplemental study (Acc. No. 241483), which was designed to be a range-finding study for determining dose levels for a reproductive study, suggests that thiobencarb is probably also practically nontoxic to the bobwhite on a subacute dietary basis. This conclusion is uncertain, though, since the study was not designed to test subacute dietary toxicity and because only eight birds were used in the control and each test level rather than the recommended ten. The guideline requirements for the acute oral testing [GLN 71-1(a)] are fulfilled. The guideline requirements for subacute dietary testing [GLN 71-2(a and b)] are not fulfilled. The Agency requires that additional data be submitted on the subacute dietary toxicity to a waterfowl species, preferable the mallard duck [GLN 71-2(b)]. The Agency is not requesting additional testing with an upland game species [GLN 71-2(a)]. (MRID 42600601)

(2) Birds, Chronic

Avian reproduction studies using the technical grade of the active ingredient (TGIA) are required when birds may be exposed to a pesticide repeatedly or continuously through its persistence, bioaccumulation, or from multiple applications, or if mammalian reproduction tests indicate possible adverse reproductive effects. The preferred test species are the mallard duck and bobwhite quail. Avian reproduction studies are required for thiobencarb because it is persistent in the terrestrial environment and may bioaccumulate. Results of these tests are tabulated below.

Table 12. Avian Reproduction Findings.

Species	% A.I.	NOEC (ppm ai)	LOEC (ppm ai)	Endpoints Affected	MRID No. Author/Year	Fulfills Guideline Requirement?
Northern bobwhite	97.5	267	930	Hatchling weight, number of hatchlings per live embryos	MRID 43075401 J. Beavers, K. Chafey, L. Mitchell, and M. Jarber. 1993.	Yes
Northern bobwhite	Technical	--	--	--	MRIDs 00025776, 00025774, 00025775	No, invalid
Mallard duck	95.5	100	300	Number of eggs laid, number of normal hatchlings	Acc. No. 241483	No, supplemental
Mallard duck	--	--	--	--	Acc. No. 095106	No, invalid[a]
Japanese Quail	50.0 (Saturn EC)	750	350	fertility and hachability	Acc. No. 095106	No, supplemental

[a] This study was performed by Industrial Bio-Test Laboratories, Inc. Data from all studies performed by this laboratory are considered invalid and cannot provide any information for ecological risk assessments.

The results indicate that dietary concentrations of 300 ppm can impair reproduction in birds. The guideline requirement for testing with an upland gamebird species [71-2(a)] is fulfilled , but the guideline requirement for testing with a waterfowl species [71-2(b)] is not fulfilled. Additional avian reproduction testing with the mallard is requested. (MRID 43544902)

(3) Mammals

Wild mammal testing may be required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern and pertinent environmental fate characteristics. This testing has not been required for thiobencarb. Acute oral LD_{50} data for laboratory rats submitted to the Agency for evaluation of human toxicity were used to assess the mammalian acute toxicity of thiobencarb. The LD_{50} for male and female rats are 1033 and 1130 mg ai/kg, respectively (MRID 42130701). The risk assessment for wild mammals is based on the geometric mean of these values, 1080 mg ai/kg. These results classify thiobencarb as slightly toxic to mammals on an acute basis.

Smith (1993) reports that the LD_{50} of technical grade thiobencarb is 920-1903 mg/kg in the rat, which supports the definitive findings reported above. Smith (1993) also reports the LD_{50} of technical grade thiobencarb for the mouse to be 2745 mg/kg, indicating that the mouse is less sensitive than the rat.

In a chronic feeding study, rats receiving thiobencarb at a dietary concentration of 100 ppm (5 mg/kg/d) had decreased body weight gains, food consumption, food efficiency, and increased blood urea nitrogen (MRID 00154506). The NOEL for this

study was 20 ppm (1 mg/kg/d). In a reproductive study, parental rats receiving a dietary concentration of 40 ppm (2 mg/kg/d) had histopathological effects on the liver (MRIDs 40446201, 40985701). As this was the lowest concentration tested, the NOEL was < 40 ppm. Changes in body weights and increased kidney weights were observed at 2000 ppm (100 mg/kg/d). No reproductive effects were observed at any test concentration, yielding a NOEL of > 2000 ppm. Based on these results, 20 ppm is considered to be a conservative NOEL for effects of thiobencarb on wild mammals. (MRIDs 42130701, 00154506, 40446201, 40985701)

(4) Insects

A honey bee acute contact LD_{50} study using the technical grade of the active ingredient is required when the proposed use will result in honey bee exposure. A honey bee acute contact study is not required for this pesticide because its use sites are not expected to result in significant exposure to bees.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

Two freshwater fish toxicity studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to freshwater fish. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). Results of these tests are given below.

Table 13. Freshwater Fish Acute Toxicity Findings.

Species	% A.I.	LC_{50} (mg ai/L)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Bluegill sunfish	10[a]	0.56	MRID 00050665, 1980	Highly toxic	Yes, for TEP only
Rainbow trout	10[a]	1.5	MRID 00050664, 1980	Moderately toxic	Yes, for TEP only
Rainbow trout	95.5	1.2	U.S.D.I., Acc. No. 095106, 1973.	Moderately toxic	No, supplemental
Bluegill sunfish	95.5	2.5	U.S.D.I., Acc. No. 095106, 1973.	Moderately toxic	No, supplemental
Channel catfish	95.5	2.3	U.S.D.I., Acc. No. 095106, 1973.	Moderately toxic	No, supplemental
Bluegill sunfish	Technical	2.6	Acc. No. 095106, 1974	Moderately toxic	No, supplemental
Carp	Technical	2.8	Acc. No. 095106, 1974	Moderately toxic	No, supplemental
Bluegill sunfish	84.0[b]	1.7	U.S.D.I., Acc. No. 095106, 1973.	Moderately toxic	No, supplemental
Rainbow trout	84.0[b]	1.1	U.S.D.I., Access. No. 095106, 1973.	Moderately toxic	No, supplemental
Channel catfish	84.0[b]	2.3	U.S.D.I., Access. No. 095106, 1973.	Moderately toxic	No, supplemental

[a] Bolero 10 G
[b] Bolero 8 EC

The majority of the results indicate that thiobencarb is moderately toxic to fish on an acute basis. The sole exception was an acute test of bluegill sunfish exposed to Bolero 10 G (10% ai) that determined the LC_{50} to be 0.56 ppm ai. This result is inconsistent with the results of two other acute tests which both determined that the LC_{50} for the bluegill sunfish was greater, in the range of 2.5 to 2.6 ppm ai. Results of tests with rainbow trout found that LC_{50}'s for this species are slightly greater than 1, putting it in the moderately toxic range (> 1-10 ppm) but close to the highly toxic range (0.1-1 ppm). The Agency therefore concludes that thiobencarb is moderately to highly toxic to freshwater fish.

The only fully acceptable studies on the acute toxicity of thiobencarb to fish were conducted with Bolero 10 G. These studies fulfill only the guideline requirements for testing with a TEP [GLN 72-1(b) and 72-1(d)]. The guideline requirements for testing with the technical grade [GLN 72-1(a) and 72-1(c)] are not fulfilled by any particular studies, but the group of ten acute freshwater fish studies, when considered in its entirety, is sufficient for fulfilling these guidelines. (MRID 00050664 and 00050665, Acc. No. 095106).

(2) Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for thiobencarb because the end-use product may be applied directly to water or expected to be transported to water from the intended use site (rice) and because the following conditions are met: (1) some aquatic acute LC_{50} and EC_{50} are less than 1 mg/l, (2) EECs in water (based on measured concentrations) were greater than 1% of acute LC_{50} and EC_{50} values, and (3) the half-life in water is greater than 4 days. No study with a freshwater fish species has been submitted. A study with a marine/estuarine species (sheepshead minnow) was submitted (MRID 00079112), but this study does not fulfill the guideline because it failed to determine the NOEC. The guideline for an early life-stage toxicity study with a fish species [GLN 72-4(a)] has not been fulfilled. However, the Agency does not request that the registrant submit a study for this guideline. Instead, the Agency requests that the registrant submit a core study that tests the effects of technical thiobencarb over the life-cycle of a fish (GLN 72-5). The Agency is justified in requiring a fish life-cycle test for thiobencarb because the end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site (rice), and because the EEC is greater than one-tenth of the NOEC in the invertebrate life-cycle test. This test should be conducted with a freshwater fish, preferably the fathead minnow or rainbow trout.

(3) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to assess the toxicity of a pesticide to freshwater invertebrates. The preferred test organism is *Daphnia magna*, but early instar amphipods, stoneflies, mayflies, or midges may also be used. Results of this test are tabulated below.

Table 14. Freshwater Invertebrate Acute Toxicity Findings.

Species	% A.I.	LC_{50} or EC_{50} (ppm ai)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Daphnid *Daphnia magna*	94.4	EC_{50} = 0.10	MRID 00025788 Acc. No. 25788, 1978.	Highly toxic	Yes
Daphnid *Daphnia magna*	82.25[a]	EC_{50} = 0.17	MRID 00079118 1980.	Highly toxic	Yes, for TEP
Daphnid *Daphnia magna*	10[b]	EC_{50} = 0.46[c] LC_{50} = 1.2	MRID 00050666 1980.	Highly toxic	No, supplemental
Scud *Gammarus pseudolimimaeus*	95.5	LC_{50} = 0.72	U.S.D.I., Acc. 095106, 1973.	Highly toxic	No, supplemental
Scud *Gammarus pseudolimimaeus*	85[a]	LC_{50} = 1.0	U.S.D.I., Acc. 095106, 1973.	Moderately toxic	No, supplemental
Crayfish *Procambarus clarkii*	95.5	LC_{50} = 2.0	Acc. No. 095106	Moderately toxic	No, supplemental
Apple snail *Pomacea aludosa*	85[a]	LC_{50} = 1.85	MRID 40031001	Moderately toxic	No, supplemental

[a]Bolero 8 EC
[b]Bolero 10G
[c]The effect used to determine the EC_{50} was clumping of organisms.

The results indicate that thiobencarb is highly toxic to aquatic invertebrates on an acute basis. The guideline requirements for testing the TGAI [72-2(a)] and the TEP [72-2(b)] are fulfilled. (Acc. No. 25788 and MRID 00079118).

(4) Freshwater Invertebrate, Chronic

An aquatic invertebrate life-cycle test using *Daphnia magna* using the TGAI is required for thiobencarb because the end-use product may be applied directly to water or expected to be transported to water from the primary use site (rice) and because the following conditions are met: (1) some aquatic acute LC_{50}'s and EC_{50}'s are less than 1 mg/l, (2) EECs in water (based on measured concentrations) were greater than 1% of acute LC_{50} and EC_{50} values, and (3) the half-life in water is greater than 4 days. *Daphnia magna* is the preferred test species.

Table 15. Freshwater Invertebrate Chronic Toxicity Findings.

Species	% A.I.	NOEC (ppb)	LOEC (ppb)	MATC (ppb)	MRID No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement?
Daphnid *Daphnia magna*	95.2 - 95.9	1.0	3.0	1.7	Acc. No. 241483	Reduced number of young, adult mortality	Yes
Daphnid *Daphnia magna*	96.9	48	90	66	42680401 Putt, 1993	Reduced number of young	No, Supplemental[1]

[1] This study is supplemental because measure concentrations were highly variable, the solvent was changed during the test, the solvent in the solvent control was changed at a different time than in the test solutions, and chemical analysis of the test material was not performed immediately after the solvents were changed.

The core life-cycle toxicity study measuring the toxicity of thiobencarb to the daphnid (Acc. No. 241483) indicates that thiobencarb concentrations as low as 3.0 μg/L can inhibit the reproduction in freshwater invertebrates. The MATC of derived from this study was 1.7 μg/L. This toxicity value was used for conducting the risk assessment because it is the only core (i.e., fully acceptable) data available and it yielded the lowest toxicity estimate. A second life-cycle study with daphnid (MRID 42680401), which was classified supplemental due to procedural deficiencies, yielded a greater toxicity estimate (MATC = 66 μg/L).

(5) Estuarine and Marine Animals, Acute

Acute toxicity testing with estuarine and marine organisms (fish, shrimp, and oysters) using the technical grade of the active ingredient is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The preferred test organisms are the sheepshead minnow, mysid shrimp and eastern oyster. Estuarine/marine acute toxicity testing is required for this pesticide because its use on rice is expected to result in significant exposure to marine and estuarine environments. Application of thiobencarb on rice fields will contaminate tailwater (i.e., water discharged from the water management system) which may flow into estuaries. The tables below show the results of these tests for fish and aquatic invertebrates.

Table 16. Acute Toxicity Findings for Marine/Estuarine Fish.

Species	% A.I.	LC_{50} (ppm)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Sheepshead minnow	95.1	0.66	MRID 00079112, 1979.	Highly toxic	Yes
Sheepshead minnow	95.1	0.9	MRID 00079110, 1979.	Highly toxic	Yes
Sheepshead minnow	85.5[a]	1.4	MRID 00079111, 1979.	Moderately toxic	Yes, for TEP only
Sheepshead minnow	90	> 0.9	Borthwick and Walsh, 1981.	Not more than "highly toxic"	Open literature, supplemental
California grunion *Leuresthes tenuis* (Static tests)	90	0.31 (0 d old) 0.48 (7 d old) 0.59 (14 d old) 0.50 (28 d old)	Borthwick et al., 1985.	Highly toxic	Open literature, supplemental
California grunion *Leuresthes tenuis* (Flow-through tests)	90	0.27 (0 d old) 0.24 (7 d old) 0.38 (14 d old) 0.33 (28 d old)		Highly toxic	
Atlantic silverside *Menidia menidia* (Static tests)	90	0.46 (0 d old) 0.45 (7 d old) 0.63 (14 d old) 0.75 (28 d old)		Highly toxic	
Atlantic silverside *Menidia menidia* (Flow-through tests)	90	0.39 (0 d old) 0.20 (7 d old) 0.41 (14 d old) 0.68 (28 d old)		Highly toxic	
Tidewater silverside *Media peninsulae* (Static tests)	90	0.53 (0 d old) 0.40 (7 d old) 0.51 (14 d old) 1.2 (28 d old)		Moderately to highly toxic	
Tidewater silverside *Media peninsulae* (Flow-through)	90	0.30 (0 d old) 0.46 (7 d old) 0.39 (14 d old) 0.82 (28 d old)		Highly toxic	

[a]Bolero 8 EC

The results indicate that thiobencarb is highly toxic to marine/estuarine fish on an acute basis. The guideline requirements for fish are fulfilled for the TGAI [GLN 72-3(a)] and for a TEP, Bolero 8 EC [GLN 72-3(d), MRID]. (MRID 00079110, 00079111,and 00079112).

Table 17. Acute Toxicity Findings for Marine/Estuarine Invertebrates.

Species	% A.I.	EC_{50} (ppm)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Eastern oyster (embryo-larvae)	95.1	0.56	MRID 00079114, 1979.	Highly toxic	Yes
Eastern oyster (embryo-larvae)	85.5[a]	0.32	MRID 00079115, 1979.	Highly toxic	Yes, for TEP
Eastern oyster (embryo-larvae)	90	0.9 - 9.0	EPA-600/4-81-076, Office of Research and Development, 1981.	Moderately to highly toxic	Open literature, supplemental
Mysid shrimp (< 1 day old)	94.6	0.15	MRID 00050667, 1980	Highly toxic	Yes
Mysid shrimp (6-8 days old)	95.1	0.29	MRID 00079117, 1979.	Highly toxic	No, supplemental
Mysid shrimp (< 1 day old)	90	0.33	Borthwick and Walsh, 1981.	Highly toxic	Open literature, supplemental
Grass shrimp *Palaemonetes pugio*	85.5[a]	1.0 (adults), 0.38-0.57 (juveniles)	Acc. No. 095106, 1975	Highly toxic	No, supplemental
Pink Shrimp *Penaeus duorarum*		0.57		Highly toxic	
White Shrimp *Penaeus setiferus*		0.31		Highly toxic	
Brown shrimp *Penaeus azetecus*		0.47		Highly toxic	
Ghost shrimp		1.1		Moderately toxic	
Fiddler crab	85.5[a]	4.4	MRID 00079113	Moderately toxic	No, supplemental
Shore crab	"Tech. "	3.6	Acc. No. 095106	Moderately toxic	No, supplemental

[a]Bolero 8 EC

The results indicate that thiobencarb is highly toxic to marine/estuarine mollusks on an acute basis. The guideline requirements for mollusks are fulfilled for the TGAI [GLN 72-3(b)] and for a TEP, Bolero 8 EC [GLN 72-3(e)]. The results indicate that thiobencarb is also highly toxic for marine/estuarine shrimp. The guideline requirements for shrimp are fulfilled for the TGAI [GLN 72-3(c)]. (MRID 00079114, 00079115, and 00050667).

(6) Estuarine and Marine Animals, Chronic

Data from estuarine/marine fish early life-stage and aquatic invertebrate life-cycle toxicity tests are required if the product is applied directly to the estuarine/marine

environment or expected to be transported to this environment from the intended use site, and when any one of the following conditions exist: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; (2) any acute LC_{50} or EC_{50} is less than 1 mg/L; (3) the EEC in water is equal to or greater than 1% of any acute EC_{50} or LC_{50} value; or (4) the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value *and* any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected, physicochemical properties indicate cumulative effects, or the pesticide has a half-life in water greater than 4 days. The preferred test organisms are the sheepshead minnow and mysid shrimp.

Chronic testing with thiobencarb is required because it has a primary use (rice) for which it is applied directly to water or is applied to land which is subsequently flooded with water. In addition, concentrations of thiobencarb measured in aquatic field studies are as great as 0.085 ppm, which is greater than 0.01 of the LC_{50} for marine/estuarine fish and aquatic invertebrates. Results of this test are given below.

Table 18. Estuarine/Marine Chronic Toxicity Findings

Species	% A.I.	NOEC (ppb)	LOEC (ppb)	MATC (ppb)	MRID No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement?
Mysid	95.1	ND, EC_{05} = 9.8[b]	ND	ND	MRID 00079117	Reproduction, survival of offspring	No, supplemental
Grass shrimp	84.7	< 21[c]	21[c]	< 21[c]	Acc. No. 241484, 1977.	Adult mortality	No, supplemental
Opossum Shrimp	"Technical"	3.2	6.2	4.5	MRID 43976801 Bailey, 1993	Survival of offspring	No, supplemental
Mysid	Not reported	22	35	28	McKenney, 1985	Number of young produced	Open literature, supplemental
Sheepshead Minnow	95.1	ND	150	< 150	MRID 00079112, 1979.	Wet weight	No, supplemental

[a] ND designates that the value was not determined.
[b] The NOEC could not determined because the control had no replication. A nonlinear regression analysis (Bruce and Versteeg, 1992) was used to calculate the EC_{05} which can be used in lieu of the NOEC.
[c] Levels are highly uncertain because measured concentrations were highly variable.

The results indicate that a concentration of 150 ppb can adversely affect the growth of juvenile fish. Concentrations less than 150 ppb may also have had adverse effects if they had been tested. Because the study failed to determine NOECs, the guideline requirement for a fish early life-stage study [72-4(a)] has not been fulfilled. (MRID 00079112)

The Agency does not request that the registrant repeat the fish early life-stage study [GLN 72-4(a)]. Instead, the registrant is required to submit a core study that tests the effects of technical thiobencarb on the life-cycle of a fish (GLN 72-5). The Agency is justified in requiring a fish life-cycle test because the end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site (rice), and because the EEC is greater than one-tenth of the NOEC in the invertebrate life-cycle test. This test should be conducted with a freshwater fish, preferable the fathead minnow or rainbow trout. The Agency reserves the right to require a second fish life-cycle study using a saltwater species at a later time.

Chronic toxicity of thiobencarb to crustaceans is uncertain because none of the studies submitted to the Agency was conducted in accordance to the guidelines for this study. Based on supplemental data, the MATCs for crustaceans range from 4.5 to 35 ppb. Although no single study provided core data, the combination of supplemental data from four separate studies is sufficient to characterize the toxicity of thiobencarb to marine/estuarine crustaceans. The guideline requirement for life-cycle testing with a shrimp or mysid [GLN 72-4(b)] is thus fulfilled. (MRID 00079117 and 43976801, Acc. No. 241484, McKenney, 1985)

(7) Aquatic Field Studies

The conclusion of high risk to aquatic organisms, based on results from laboratory toxicity tests, triggered the requirement for aquatic field testing with thiobencarb (GLN 72-7). The following aquatic field studies have been conducted on the use of thiobencarb on rice.

Table 19. Aquatic field studies on thiobencarb on rice.

Title	Location and Date	Reference	Performed By	Sponsor	Fulfills Guideline Requirements?
Studies in Halls Bayou to Test the Effects of a Pre-Emergent Herbicide, Bolero, on Aquatic Organisms	Halls Bayou/ Chocolate Bay, Brazonia County, Texas 1979	Acc. No. 241484	Harper Environmental Consulting Company	Chevron Chemical Company	No, supplemental
Impact of Bolero Runoff on a Brackish Water Ecosystem	Matagorda, Texas 1982 - 1984	MRIDs 92182086, 92182089	Biospheric, Inc.	Chevron Chemical Company	Yes[1]
Thiobencarb: Studies on Residue Level and Behavior in Selected Irrigation Creeks in Agricultural Areas in Saga Prefecture, Southwestern Japan	Saga Prefecture, Kyushu, Japan 1975	Acc. No. 241476	Life Science Research Institute	Unknown	No, supplemental

[1] Following the review of this study, an additional aquatic field study was requested to monitor aquatic residues in other localities where rice is grown. This additional study, however, was waived in December 1993. No further field studies are requested for thiobencarb at this time.

Hall's Bayou Study: The first field study conducted in the U.S, was in rice fields bordering Halls Bayou, a tidally influenced, narrow stream that empties into West Bay near Galveston, Texas. This study is also referred to as the Chocolate Bay study. This estuarine area is a complex and highly important ecosystem that supports many commercial species. . Contaminated water was released into the bayou when rice fields were irrigated with a small amount of water (i.e. flushed) to moisten the soil. Also, heavy rainfall occurring during the experiment resulted in two additional releases of contaminated water. Sampling sites were established 500 ft downstream and 500 ft upstream of the point of discharge from the rice fields. Water samples collected at the field outlets and in Halls Bayou were analyzed for residues of thiobencarb. Fish, nektonic macroinvertebrates, benthic organisms, and phytoplankton were also sampled in these areas before, during, and after discharge from the rice fields. Fish and macroinvertebrates were also held in cages in Halls Bayou to monitor their response to the discharge of thiobencarb.

Due to poor experimental design and experimental conditions that caused excessive stress to the caged organisms, the Agency concluded that the results of the caged tests with fish and shrimp were invalid. They thus yield no information which can be used for risk assessment. Other parts of the field study provided some information and were thus classified as supplemental

The highest concentrations of thiobencarb were measured on a day when heavy rainfall (3.23 inches) occurred on the same day that thiobencarb was applied, resulting in an unscheduled flush overflow. Peak thiobencarb concentrations were 8.9 ppm (8900 ppb) where the tailwater exited the rice field and 690 ppb at the point where the drainage water entered Halls Bayou. The highest concentrations measured in the Halls Bayou on days that were not associated with heavy rainfall were 83 ppb at the upstream station (E) and 64 ppb at the downstream station (F). The abundance of fish, invertebrates, and plankton sampled at the downstream station were similar to or greater than those sampled at the upstream station. Gillnet catches declined in only one of the two areas sampled after discharges from the rice fields. Seine and trawl sampling indicated a decline in abundance of fish and invertebrates occurred near the end of the study. All declines were observed at both the upstream and downstream stations. Some differences in species composition of fish and invertebrates were observed between the upstream and downstream stations, and some changes in the species composition of benthic organisms were observed over time. None of these differences, however, could be conclusively linked to the discharge of thiobencarb.

The biological findings of the Halls Bayou study were inconclusive since there were no significant differences in species abundance or clear trends in the changes in species composition between stations upstream and downstream of the point of discharge. The upstream stations, being only 500 feet upstream of the site of discharge, were likely close enough to be affected by contamination moving upstream as the result of tidal mixing. Also, the abundance and composition of species were probably influenced by

other factors, including tidal cycles, salinity changes, and release of other pesticides from neighboring areas. Small samples sizes further limited the usefulness of this study. This study does not provide much useful information on the effects of thiobencarb on the estuarine environment.

Matagorda Study: A larger aquatic field study was conducted in 1982-1984 near Matagorda, Texas. The site consisted of a rice field that drained through a ditch into the tidal waters of the lower Colorado River of eastern Texas. As with Hall's Bayou, this estuarine area is a complex and highly important ecosystem that supports many commercial species. No thiobencarb applications were made in 1982; this year provided baseline data for the site. Baseline thiobencarb concentrations were as high as 9 ppb. In 1983 and 1984, approximately 500 acres of the field were treated with thiobencarb at a rate of 4 lbs ai per acre. Fields were flushed with water within 3 to 12 days after application. Data collected from 1982 through 1984 included (1) residues of thiobencarb in water, sediment, fish and shrimp; (2) catch per unit effort measurements of fish and aquatic invertebrates; and (3) percentages of grass shrimp (*Palaemonetes pugio*) that were gravid. While samples were collected during all three years of the study, the sampling effort on the third year was very poor.

A control station was also planned on the Colorado River upstream of the confluence with the drainage ditch. However, during the course of the study, the Agency and the registrants agreed that this station could not serve as a control for the field study because it contained preexisting residues of thiobencarb. It was therefore only possible to compare residues and biological samples collected during 1983 and 1984 to those collected during 1982, before the initial treatment. This represents a shortcoming of this study since the results could have been influenced by yearly fluctuations in environmental conditions that are unrelated to the applications of thiobencarb. Another shortcoming is that other pesticides (ordram, basagran, machette, and propanil) were applied to fields that drain into the test ditch during the period of this study. The toxicity of these pesticides could have contributed to the observed effects.

The results of the study were:

1. Residues of thiobencarb were transported into the estuary via runoff and drift. Residues in water exceeded the aquatic invertebrate MATC (1.7 ppb). Maximum residues measured in water, sediment, fish, and shrimp were 25.1 ppb, 50 ppb, 2400 ppb, and 970 ppb, respectively.

2. Although the overall population of fish was apparently not affected, marked declines were observed during the treatment years in three species, *Gambusia affinis*, *Dormitator maculatus*, and *Poecilia latipenna*.

3. Several taxa of aquatic invertebrates showed substantial decline in numbers caught per unit effort. Species richness and diversity also declined significantly during treatment years.

4. The percentage of gravid shrimp decreased significantly in 1983 compared to 1982. The decline was about 50% at stations 1 and 2, and averaged 23% for all four stations. (Sampling was inadequate to assess the effect on the percentage of gravid shrimp in 1984.)

5. A kill of the fish menhaden (*Brevoortia patronus*) was observed in the area where the field runoff entered the drainage ditch. It occurred at the point of discharge from the drainage canal, one to two days after a post-application flush of the rice fields. Although other pesticides that were applied that year (ordram, basagran, and propanil) may have been present in the tailwater, this kill was attributed to thiobencarb contamination because the dead fish contained high residues of thiobencarb (mean of 3.56 ppm).

6. Field BCF for thiobencarb were estimated to be 109X for fish and 44X for shrimp.

Declines in fish, aquatic invertebrates, and gravid shrimp cannot conclusively be attributed to the use of thiobencarb. Nevertheless, the findings in the field were consistent with effects demonstrated in laboratory studies. They suggest that the application of thiobencarb to rice fields may result in significant environmental damage to the adjacent estuarine habitat. Possible effects include chronic effects to sensitive fish, acute and chronic effects to ecologically important aquatic invertebrates, chronic effects to grass shrimp and possibly to commercial shrimp, and indirect detrimental effects to organisms at higher trophic levels that depend on these organisms for food.

Japan Study: The Agency reviewed a study that measured residues of thiobencarb in creek water after application to rice paddies in Japan. Thiobencarb was applied in the form of 7% granules at a rate of 30 kg/ha, which is equivalent to 1.9 lb ai/A. Water samples were taken from ten stations along creeks that flow through the rice fields and drain into the Hayatsue River. Water sampling was conducted from March through November, with thiobencarb treatments being made from June 28 through July 2. The creeks served as storage for irrigation water until May, when the water is pumped onto the fields. The creeks resembled large ponds during the storage period.

Very low thiobencarb concentrations (0.2 ppb or less) were reported at all stations in March and April before applications were made. Concentrations peaked at the sampling period of July 1, when concentrations at most stations were between 20 and 40 ppb. The greatest concentration was measured was 40.5 ppb. Concentrations declined fairly rapidly thereafter; the half-life of thiobencarb in creek water was estimated to be 8.8 days. This rate of decline represents dilution as well as biological and physical degradation processes. The Agency cannot interpret the significance of these results or extrapolate conclusions

to other areas because of the lack of important information on the test conditions, such as flow rates within the creeks and rainfall during the study.

A difficulty with all three of the field studies was that water flow measurements were not made, making it impossible to discern effects of dissipation versus dilution. While water residues were generally short-lived, it is not clear whether thiobencarb residues were broken down by chemical or biological forces, or they were swept away and diluted by tidal flow. Because it is possible that dilution was the primary mode of dissipation in all three studies, the rate at which thiobencarb degrades by chemical or biological means in estuaries remains unknown. Thiobencarb residues thus may persist longer in other areas where dilution is of less importance in the dissipation of residues.

The three biological field studies demonstrate that application of thiobencarb on rice can cause significant contamination to water, sediments, and aquatic organisms in off-site aquatic habitats. Harm to estuarine and freshwater ecosystems is possible when thiobencarb is used in southeastern United States. Although shortcomings of these studies make it impossible to identify thiobencarb as the sole cause of observed adverse effects, the studies fail to refute the Agency's presumption that the use of thiobencarb on rice results in severe effects on aquatic ecosystems.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial non-residential outdoor use patterns and which may move off the application site through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$ mm Hg at 25°C) or drift (aerial or irrigation), and/or which may have endangered or threatened plant species associated with the application site. Terrestrial plant testing is required for thiobencarb because it is an herbicide with a terrestrial nonresidential use pattern (rice) and because aerial applications may result in drift.

For the seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and another of which is a root crop, and (2) four species of at least two monocotyledonous families, one species of which is corn (*Zea mays*).

Results of Tier II seedling emergence toxicity testing on technical thiobencarb are given below.

Table 20. Nontarget Terrestrial Plant Seedling Emergence Toxicity Findings (Tier II).

Species	% AI	Parameter Affected	EC_{25} (lb ai/A)	NOEC (lb ai/A)	MRID No. Author/Year	Fulfills Guideline Requirement?
Monocot--Corn	96.6	Shoot length	> 1.7	1.7	MRID 41690902 Hoberg, J.R. 1990	Yes
Monocot--Oat		Shoot length	0.086	0.055		Yes
Monocot--Onion		Shoot length	2.0	0.94		Yes
Monocot--Ryegrass		Mortality	0.019	0.0051[1]		Yes[2]
Dicot/Root Crop--Carrot		Shoot length	> 3.1	2.1		Yes
Dicot--Cabbage		Shoot length	0.082	0.071		Yes
Dicot-Cucumber		Shoot length	> 1.7	0.16		Yes
Dicot--Lettuce		Mortality	0.27	--		No, supplemental
Dicot--Soybean		Shoot length	> 1.7	0.94		Yes
Dicot--Tomato		Shoot length	1.1	0.94		Yes

1 This NOEL is based on 17% mortality of plants occurring at the next higher test level, 0.011 lb ai/A.
2 Seedling emergence data for ryegrass is upgraded from supplemental to core.

In the tier II seedling emergence test, mortality of test plants occurred in the tests with ryegrass, cabbage, and lettuce. Mortality was the most sensitive toxic endpoint for these species (plants tended to die shortly after emerging). Grasses appear to be exceptionally sensitive to thiobencarb. The most sensitive species was ryegrass, a monocot, for which the EC_{25} based on mortality (i.e. LC_{25}) was 0.019 lb ai/A. The most sensitive dicot was lettuce. The lettuce EC_{25} based on mortality was estimated to be 0.27 lb ai/A, but this is not a definitive result since it was calculated from supplemental data.

The guideline requirement for seedling emergence testing [123-1(a)] is only partially fulfilled. Core seedling emergence data is outstanding for lettuce. Lower dosages may need to be tested to determine the NOEC for this species. (MRID 41690902)

Results of Tier II seedling vegetative vigor toxicity testing on the technical thiobencarb are given below.

Table 21. Nontarget Terrestrial Plant Vegetative Vigor Toxicity Findings (Tier II)

Species	% A.I.	Parameter Affected	EC_{25} (lb ai/A)	NOEC (lb ai/A)	MRID No. Author/Year	Fulfills Guideline Requirement?
Monocot- Corn	96.6	Shoot length, shoot weight, and root weight	> 2.2	2.2	MRID 41690902 Hoberg, J.R. 1990	Yes
Monocot--Oat		Shoot weight	0.17	0.12		Yes
Monocot--Onion		Shoot length	1.2	0.80		Yes
Monocot--Ryegrass		Shoot length	0.073	0.020		Yes
Dicot/ Root Crop--Carrot		Shoot length, shoot weight, and root weight	> 2.2	2.2		Yes
Dicot--Cabbage		Root weight	1.2	1.4		Yes
Dicot--Cucumber		Shoot weight and root weight	--[a]	< 0.12		Yes
Dicot--Lettuce		Root weight	1.3	0.80		Yes
Dicot--Soybean		Shoot weight	1.2	0.80		Yes
Dicot--Tomato		Root weight	1.8	2.2		Yes

[a]Greater than a 25% reduction was recorded at some or all exposure levels, but the EC_{25} could not be determined because no dose-response relationship was apparent.

In the Tier II vegetative vigor tests, soybean was the most sensitive dicot and ryegrass was the most sensitive monocot. The guideline requirement for vegetative testing [123-1(b)] is fulfilled. (MRID 41690902)

(2) Aquatic

Aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses in which it may move off-site by runoff (solubility > 10 ppm in water), by drift (aerial or irrigation), or which is applied directly to aquatic use sites (except residential). The following species should be tested: *Kirchneria subcapitata*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. Aquatic plant testing is required for thiobencarb because it may be applied directly to water, it may be applied aerially, and it is applied to rice paddies where it is expected to contaminate the tailwater that leaves the field.

Results of Tier II toxicity testing on technical thiobencarb are given below.

Table 22. Nontarget Aquatic Plant Toxicity Findings (Tier II).

Species	% A.I.	EC_{50} (ppb)	NOEC (ppb)	MRID No. Author/Year	Fulfills Guideline Requirement?
Freshwater diatom *Navicula pelliculosa*	96.6	380	65	MRID 41690901 Giddings, J.M. 1990.	Yes
Duckweed *Lemna gibba*		770	140		Yes
Green algae *Selenastrum capricornutum*		17	13		Yes
Marine diatom *Skeletonema costatum*		73	18		Yes
Blue-green algae *Anabaena flos-aquae*		> 3100	3100		Yes
Marine diatom *Skeletonema costatum*	95.5	327-459[a]	--	EPA-600/4-81-076, Office of Research and Development, 1981.	Open literature, supplemental

[a]96-hour EC_{50}

The Tier II results indicate that green algae is the most sensitive aquatic plant species. A thiobencarb concentration of 17 ppb ai is predicted to cause a 50% reduction in the growth and reproduction of this species. The guideline requirement (123-2) is fulfilled (MRID 41690901).

2. Environmental Fate

a. Environmental Fate Assessment

Thiobencarb is generally nonpersistent in the water column but moderately persistent in soils and sediments. Thiobencarb dissipates in the environment by binding

to soil, by aerobic soil metabolism at the soil/H_2O interface, and by aqueous photolysis in the presence of photosensitizers. Ground water contamination is not likely from use on the primary crop, rice, and surface water is not likely to receive significant amounts of thiobencarb unless there is excess rainfall soon after application, leading to uncontrolled runoff. When used on the rice, thiobencarb is more likely to be found in the soil than in the paddy water. Furthermore, greater quantities of thiobencarb are associated with soil when applied preflood to soil rather than in standing water. The parition of thiobencarb associated with soil was approximately 10 times more when applied preflood to soil than when applied to standing water, primarily since thiobencarb has time to bind to soil prior to flooding. As a result, sensitized aqueous photolysis is expected to be more significant as a dissipation route when thiobencarb is applied to water than when it is applied to dry soil, due to a greater amount of thiobencarb remaining in paddy water containing natural photosensitizers.

Thiobencarb has a water solubility of 27.5 ppm, a vapor pressure of 2.2×10^{-5} Torr, and a Henry's Law Constant of 2.71×10^{-7} atm m^3/mol. It is stable to hydrolysis, non-sensitized aqueous photolysis, soil photolysis, anaerobic aquatic metabolism, and aerobic aquatic metabolism. In an aqueous photolysis study with and without the use of photosensitizers, the half-lives were 12 and 190 days, respectively. Since photolysis humic substances in natural waters have been shown to act as photosensitizers (Chou and Eto, 1980; Zepp et al, 1985; Mudambi and Hassett, 1988, attached), the 12-day half-life was used in the risk assessment. Thiobencarb also degraded moderately slowly under aerobic conditions with calculated half-lives of 27-58 days in soils that typically support rice production (58 days was used for risk assessment).

Thiobencarb slowly mineralizes in soil without forming significant quantities of non-volatile degradates. The major degradate during aqueous photolysis and soil metabolism studies was a 4-chlorobenzoic acid (56 and 5 % respectively). CO_2 and bound residues are the primary products from soil metabolism studies, occurring in proportions of 42-77 and 23-42 %, respectively. Aqueous residues did not exceed 4.5 % in soil metabolism studies.

Parent thiobencarb was moderately mobile to essentially immobile in the tested soils with Freundlich K_{ads} values of 5.42-20. The K_{oc} values ranged from 384-6750. 4-Chlorobenzoic acid, a degradate of thiobencarb, was very mobile to moderately mobile in the tested soils with Freundlich K_{ads} values of 0.74-3.26. The corresponding K_{oc} values ranged from 84-416. Mobility generally decreased with increasing clay content, increasing organic matter content, and increasing cation exchange capacity.

Results from an aquatic field dissipation study in Louisiana, where thiobencarb was applied as a spray directly to soil and flooded 7 days later, show half-lives of 5.8 days in flood water and 36 days in hydrosol. Residues of thiobencarb were 64 times higher in the standing water than in the hydrosoil.

In two field studies in California where granules were applied into standing water, the half-lives in flood water were 8.7 days (guideline study) and 4.5 days (literature review, Ross and Sava, 1986). The half-lives in hydrosol were 153 and 56 days, respectively. The median ratios of soil:water thiobencarb residues were 5.6:1 and 6.6:1.

Thiobencarb moderately accumulated in bluegill sunfish with maximum bioconcentration factors of 128x, 639x, and 411x for edible (muscle) tissue, nonedible tissue, and whole fish, respectively. Depuration is rapid, with 93-95% of the accumulated [^{14}C]residues being eliminated from the tissues in three days. The degradates 4-chlorobenzylmethylsulfoxide, thiobencarb sulfoxide, desethylthiobencarb, and 2-hydroxythiobencarb were identified in edible and nonedible tissue. Based on results of crop accumulation studies, thiobencarb does not appear to accumulate in plants.

b. Environmental Fate and Transport

(1) Degradation

(a) Hydrolysis

Thiobencarb is stable to degradation by hydrolysis. Thiobencarb did not degrade in sterile aqueous buffer solutions (pH 5, 7, and 9) that were incubated in darkness at 25 ^{o}C for 30 days. The guideline requirement (GLN 161-1) is fulfilled. (MRID 41609012)

(b) Photodegradation

In Water

Thiobencarb photodegraded with a calculated half-life of 190 days in a nonsensitized sterile pH 7 aqueous buffer solution at 25 ^{o}C. Photodegradation was more rapid in a solution photosensitized with acetone with a half-life of 12 days. Thiobencarb did not degrade in the dark control (non-sensitized). The photoproducts identified in the nonsensitized and sensitized irradiated solutions were 4-chlorobenzoic acid, 4-chlorobenzaldehyde, 4-chlorobenzyl alcohol, and N,N-diethyl-4-(chlorobenzylthio)carbamate S-oxide (thiobencarb sulfoxide). In the non-sensitized, irradiated solution, no photoproduct exceeded 3.9 % of the applied. The major photoproducts in the sensitized solutions were 4-chlorobenzoic acid and 4-chlorobenzaldehyde, reaching maximum amounts of 56 and 29.4 % of applied, respectively. 4-Chlorobenzyl alcohol reached 6.1-6.7 % of applied by 14-30 days and thiobencarb sulfoxide reached a maximum amount of 5 % by 14 days, and declined to 1.1 % by 30 days. One additional degradate, O-[(4-chlorophenyl)methyl]diethyl carbamate (bencarb), was isolated in the irradiated sensitized solution and reached 17.7 % by 21 days, and declined to 12.4 % by 30 days. The guideline requirement (GLN 161-2) is fulfilled. (MRID 42257801)

On Soil

Based on 30-day studies, thiobencarb slowly photodegraded on sandy loam soil irradiated under natural sunlight at Richmond, California with an extrapolated half-life of 168 days, and degraded in the dark controls with a calculated half-life of 280 days. In the study, no volatile or non-volatile degradates exceeded 1.3 % of applied. Non-extractable residues did not exceed 8.7 % in the irradiated samples and 5.7 % in the dark control samples by 26 days. The guideline requirement (161-3) is fulfilled. (MRID 41215312)

Photodegradation in Air

No data were reviewed. This study was waived (4/29/91) because volatility is not a significant dissipation route in the environment for thiobencarb.

(c) Aerobic Soil Metabolism

Thiobencarb is moderately persistent in soils in California and Louisiana that support rice production. The calculated half-lives in three soils were 27-58 days in two acceptable studies (MRID's 43300401, 00040925). One supplemental study (MRID 43121201) provided additional information that supported the results of the two acceptable studies.

Thiobencarb appeared to degrade in a biphasic pattern with half-lives of 58 days for 0-56 days after treatment and 137 days for 56-366 days in a Stockton Clay Adobe soil from California (24 % sand, 30 % silt, 46 % clay, 2.2 % OC, pH 6.1). The biphasic pattern may be a result from thiobencarb binding to soils. After the 56-day sampling interval, the rate of degradation was significantly slower. There were six non-volatile degradates detected in the study, but none of the degradates exceeded 5.4 % of the applied dose (3.1 ppm). The primary degradates were CO_2, reaching 42.5 % of the applied by the end of the study (366 days), and nonextractable residues, reaching 23.2 % by the end of the study.

The reviewer-calculated half-lives in a clay soil from Biggs, California and a silty clay loam from Crowley, Louisiana were 37 and 27 days, respectively. The clay soil (18 % sand, 26 % silt, 56 % clay, 1.13 % OC, pH 4.6, CEC 32.5 meq/100g) and the silty clay loam from Crowley, LA (3 % sand, 69 % silt, 28 % clay, 0.79 % OC, pH 5.8, CEC 14.5 meq/100g) were representative soils from major rice growing regions of the U.S. Evolved CO_2 increased to 54-77 % by 1 year. The extractable, non-volatile degradates did not exceed 5 % of applied, and bound residues increased to a maximum of 42 % of applied by 1 year. (GLN 162-1, MRID 00040925)

In a supplemental guideline study using a California soil, CO_2 increased to 8.6 % of applied by 132 days, and bound residues increased to 23.3 % of applied. The soil was a Stockton Clay Adobe (18 % sand, 27 % silt, 55 % clay, 2.0 % OC, pH 6.0). This was

intended to be an aged soil mobility study, but determination of meaningful Freundlich coefficients was not possible due to the stability of thiobencarb. Thiobencarb decreased from 87.1 % at time zero to 57.2 % by 132 days of incubation. The calculated half-life was 250 days. Thiobencarb slowly mineralized in soil without forming significant quantities of non-volatile degradates. (GLN 163-1, MRID 43121201)

(d) Anaerobic Soil Metabolism

Anaerobic soil metabolism studies were not required because the registrant submitted an anaerobic aquatic metabolism (GLN 162-3, MRID 00040925) instead. (GLN 162-2, waived)

(e) Anaerobic Aquatic Metabolism

Thiobencarb is stable under anaerobic aquatic conditions. The registrant-calculated half-life in sediment was 1962 days (5.4 years) (MRID 43252001). In supplemental guideline studies, the registrant-calculated half-lives were 243 days in a sediment from Louisiana and > 181 days in a sediment from California (Walker et al., 1988). Supplemental information from open literature reported half-lives of 9-517 days in sediment, and 31 and 82 days in non-sterile and sterile water, respectively. The 9-day half-life in sterile sediment reported in the literature study is not consistent with the other data that show thiobencarb to be more persistent in sterile test conditions than in non-sterile conditions. The guideline (GLN 162-3) is fulfilled. (MRID 43252001)

Anaerobic metabolism of thiobencarb was measured in clay sediment from the Sacramento Valley (Stockton Clay Adobe, 16 % sand, 32 % silt, 52 % clay, 2.0 % OC, pH 6.1) and water from the Sacramento River (pH 7.1, 44 mg/L alkalinity, total hardness of 50.4 mg/L $CaCO_3$). The extrapolated half-life was 5.4 years (1962 days). The percentages of total thiobencarb residues in the sediment were 66.2 % at time zero, 76.6-86.8 % from 7-272 days, and 65 % by 363 days. Residues in water decreased from 20 % at time zero to 3.1-7.5 % from 7-272 days, and then increased to 23.3 % by 363 days. Volatile residues did not exceed 0.9 % of applied. The degradate 4-chloro-benzoic acid reached 14.2 % of the radioactivity in water at 70 days, which was only 0.3 % of the applied. It then decreased to 1.3-12.1 % of the radiocarbon in water (< 0.3 % of the applied). No other degradate reached 10 % of the radiocarbon in water. The guideline requirement is fulfilled. (GLN 162-3, MRID 43252001)

In a study that was considered supplemental because of deficient material balance, the registrant-calculated half-lives were > 181 and 243 days in clay soil (Biggs, California, 18 % sand, 26 % silt, 56 % clay, 1.13 % OC, pH 4.6, CEC 32.5 meq/100g) and silty clay loam (Crowley, Louisiana, 3 % sand, 69 % silt, 28 % clay, 0.79 % OC, pH 5.8, CEC 14.5 meq/100g)/water systems, respectively. Non-volatile degradates and CO_2 did not exceed 3.8 %, indicating thiobencarb partitioned primarily into the sediment.

Unextracted residues increased to 42.8 % in the clay soil and 27.8 % in the silty clay loam by 364 days. (GLN 162-3, MRID 00040925)

Walker et al. (1988) determined the first order biotic and abiotic degradation rate constants for 14 pesticides (including thiobencarb) in estuarine water and sediment/water slurry systems (sterile and non-sterile) . The half-lives in non-sterile and sterile sediment ranged from 9-517 days. The half-lives in sterile water and non-sterile water were 31.5 and 82 days, respectively. (Walker et al., 1988)

Chen et al. (1982) created a model aquatic ecosystem and applied ^{14}C-thiobencarb to determine its partitioning in the laboratory environment. It was not possible to calculate a half-life because of limited sampling. By the end of the experiment (23 days), thiobencarb partitioned mostly into sand (23.2 % of applied) and to a lesser extent into water and biota (2.7 and 0.31 % of applied, respectively) . The authors attributed the low recovery of radioactivity to volatility, photodecomposition, and microbial decomposition. (Chen et al., 1982)

(f) Aerobic Aquatic Metabolism

Thiobencarb was stable to aerobic aquatic metabolism in a clay soil/water system from the rice-growing area of California. The guideline requirement (162-4) is fulfilled. (MRID 42015301)

(2) Mobility

Unaged Mobility (Batch Equilibrium)

Thiobencarb was moderately mobile to immobile in five soils. Freundlich K_{ads} values ranged from 5.4 to 20.1 in the tested soils, and Koc's ranged from 384 to 1435 (see below Table). The unaged portion of the guideline requirement (GLN 163-1) is fulfilled. (MRID 41215313)

Table 23. Results of aged mobility studies with thiobencarb.

Soil Texture (% OC)	Freundlich K_{ads}	Freundlich Koc_{ads}	Freundlich K_{des}	Freundlich Koc_{des}	N (slope values) for adsorption and desorption
Sandy Loam (0.5)	5.4	1084	14.3	2860	0.8, 1.0
Loam (1.9)	7.3	384	21.7	1142	1.1, 1.1
Silty Clay (1.5)	9.3	618	28.8	1920	1.1, 1.1
Clay Loam (1.1)	11.3	1027	46.7	4245	1.2, 1.2
Silt Loam (1.4)	20.1	1435	94.5	6750	1.0, 1.1

Aged Mobility

Based on batch equilibrium experiments, the degradate 4-chlorobenzoic acid was very mobile to moderately mobile in the tested soils with Freundlich K_{ads} of 0.7-3.3 (See below Table).

Mobility generally decreased with increasing clay content, increasing organic matter content, and increasing cation exchange capacity. The aged portion of the guideline requirement (GLN 163-1) is fulfilled. (MRID 43150601)

Table 24. Results of aged mobility studies with thiobencarb

Soil Texture (% OC)	Freundlich K_{ads}	Freundlich Koc_{ads}	Freundlich K_{des}	Freundlich Koc_{des}	N (slope values) for adsorption and desorption
Sandy Loam (0.88)	0.74	84	2.2	250	1.6, 1.6
Loam (0.76)	1.0	130	1.9	250	1.6, 1.5
Silt Loam (0.88)	1.2	140	2.4	280	1.6, 1.6
Clay (2.0)	3.3	160	8.3	420	1.3, 1.2

Laboratory and Field Volatility

Volatility testing was waived (4/29/91) since volatility is not a significant means of dissipation of thiobencarb. (GLNs 163-2 and 163-3, waived, see also GLN 161-4)

(3) Accumulation

Accumulation in Irrigated Crops

Thiobencarb was detected (detection limit of 0.07 ppm) in the tops of table beets grown in plots of clay soil in California that were sprinkler-irrigated five times at 8- to 13-day intervals with water containing thiobencarb (Bolero 8 EC, 85% emulsifiable concentrate) at approximately 200 ppb. Thiobencarb was not detected (detection limit of 0.01 ppm) in either the beet root or in tomato fruits grown under similar conditions. In addition, the potential degradate 4-chlorobenzylmethyl sulfone was not detected in beet tops or roots, or in tomato fruits. In the 0- to 6-inch depth of the treated soil, parent thiobencarb and the degradate thiobencarb sulfoxide were 0.04-0.13 and < 0.02 ppm, respectively, at all sampling intervals. There was no apparent pattern of accumulation or decline of either parent thiobencarb or the degradate. (GLN 165-3, MRID 43148201)

Bioaccumulation in fish

Thiobencarb residues accumulated in juvenile bluegill sunfish exposed to [^{14}C]thiobencarb at 0.05 mg/L, with maximum bioconcentration factors of 128x, 639x, and 411x for edible (muscle) tissue, nonedible tissue, and whole fish, respectively. The degradates 4-chlorobenzylmethylsulfoxide, thiobencarb sulfoxide, desethylthiobencarb, and 2-hydroxythiobencarb were identified in edible and nonedible tissue. By day 3 of the depuration period, 93-95% of the accumulated [^{14}C]residues were eliminated from the tissues. The guideline requirement (GLN 165-4) is fulfilled. (MRID 42460401)

c. Field Dissipation

(a) Terrestrial Field Dissipation

The registrant has submitted sufficient information on terrestrial field dissipation (164-1) to do an environmental fate assessment for the 40,000 acres of vegetables in Florida. Considering the small acreage of this use, the aquatic field dissipation study for rice in Louisiana provided adequate information on the fate of thiobencarb under terrestrial conditions, in addition to aquatic conditions. Therefore, terrestrial field dissipation data are reserved for any future terrestrial uses of thiobencarb.

(b) Aquatic Field Dissipation

In two field studies in California where granules were applied into standing water, the half-lives in water were 8.7 days in the guideline study (MRID 43404005) and 4.5 days in the literature study (Ross and Sava, 1986). The soil half-lives determined in the two studies were 153 and 56 days, respectively. The median amounts of thiobencarb in soil were 5.6 and 6.6 times higher than in water, respectively. No leaching was observed below 6 inches of depth. GLN. 164-1, MRID 42003404. The guideline is only partially satisfied since the registrant did not provide storage stability of samples and since the movement of water in the CA guideline study (MRID 43404005) was not described in detail.

Thiobencarb dissipated with an observed half-life of approximately 6 days in silty clay loam soil in Louisiana that had been planted to rice. The plot was flooded at 7 days posttreatment; thiobencarb dissipated from the floodwater with a registrant-calculated half-life of 5.8 days. Thiobencarb was not detected in the soil below 10 centimeters. The degradates 1-(((4-chlorophenyl)methyl)sulfonyl)-N,N-diethylformamide (thiobencarb sulfoxide) and 4-chlorobenzyl-methylsulfone were detected primarily in the upper 5 cm of the soil and in the floodwater. (MRID 42003404)

Thiobencarb (10 G) was applied in one application by air at 4 lbs ai/A to flooded plots of Anita clay loam (28 % sand, 26 % silt, 46 % clay, 2.47 % OC, pH 6.1, CEC of 46). Soil cores were taken to 30 cm (1 foot) of depth throughout the study at 0-551 days after treatment. There was one 8-foot core taken at 153 days, which was divided into segments ranging from 5 cm at the surface to 30 cm at lower depths. Water samples were taken at 0-92 days after treatment. Water samples were also collected from the fallow field replicates from days 15-21 and day 27.

The half-life in soil was 20 days for the 0-92 day (flooded) sampling periods, and was 153 days when all sampling intervals (0-551 days) were considered. The half-life in water was 4.8 days when the 0-33 day sampling intervals were considered. (MRID 43404005)

Ross and Sava (1986) studied two commercial rice fields in the Sacramento Valley of CA. Thiobencarb was applied at 4 lbs ai/A using fixed-wing aircraft into standing water when rice plants had not yet emerged (1-3 leaf growth stage). Water was held at 10.4 inches of depth for 6 days with no inflow or outflow (stagnant water). After 6 days, the field was rapidly drained to 6.8 inches of depth with intermittent inflow and outflow. Water temperatures averaged 28 °C (82 °F) for 30 days. Water, soil, and vegetation samples were collected from four pads within each rice field. The pads were located at the field inlet and outlet and two randomly-chosen points in between. Samples were taken at -1, 0, 2, 4, 8, 16, and 32 days after application near the pads and where the water flow was slower. The dynamics of herbicide dissipation were examined using a split plot analysis or variance (ANOVA). Air, water, soil, and vegetation were analyzed using GC.

Thiobencarb was predominantly distributed between water (34.5 %) and soil (43 %), with less than 1% associated with air and vegetation. Thiobencarb water concentrations at 0, 2, 4, 6, 8, 16, and 32 days after treatment were 79. 567, 576, 515, 367, 56, and 8 mg/L, respectively. Soil concentrations of thiobencarb were 3250, 2880, 3350, 3860, 2020, 2260, and 2330 μg/kg (ppb), respectively. Thiobencarb air concentrations at 0, 1, 2, and 3 days after treatment were 1.4, 0.9, 0.8 and 0.43 mg/m^3, respectively. The calculated half-life in air was 2.2 days. The evaporative flux rates were 37, 8, 16, and 6 ng/cm^2 h^{-1} at 0, 1, 2, and 3 days after treatment, respectively. Thiobencarb vegetative concentrations were 78, 691, 1750, 1360, 1280, 796 and 169 mg/kg (ppb), respectively, leading to a calculated half-life of 8.5 days using natural logarithm data. Concentrations in water, soil, and vegetation were significantly higher in the holding period than in the postholding period. Water and vegetation concentrations were stable in the holding period and only declined with time during the postholding period. In contrast, soil concentrations did not change during either period. The mass balance (including air, water, soil, and vegetation) increased from 41 % at 0 days after treatment to 67-70 % by 2-6 days after treatment and then decreased to 26-27 % by 16-32 days after treatment.

The guideline requirement (GLN 164-2) is only partially fulfilled. This guideline can fulfilled if the field dissipation study conducted in Louisiana (MRID 42003404) is upgraded by the submittal of more detailed information on the water management used at the study site and the storage stability of the test samples. (GLN 164-2, MRID 41722504, 42003404, 43404005).

(1) Spray Drift (Droplet Size Spectrum/Drift Field Evaluation)

No thiobencarb specific studies were reviewed. Droplet size spectrum (GLN 201-1) and drift field evaluation (GLN 202-1) studies are required for thiobencarb, since the different formulations may be applied by aircraft and it is estimated that there will be detrimental effects to non-target terrestrial and semi-aquatic plants due to drift. However, to satisfy these requirements the registrant, in conjunction with other registrants of other

pesticide active ingredients, formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1996 the Agency plans to evaluate these studies. In the interim, and for this assessment of thiobencarb, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The estimated drift rates at 100 feet downwind of the treated sites are 1% at the applied spray volume from ground applications and 5% from aerial applications. After review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks of the application of thiobencarb products.

d. Water Resources

(1) Ground Water

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

Persistence, mobility, and detections in ground water are also used to evaluate a chemical to determine whether its use should be restricted for ground water concerns. A pesticide may be recommended as a candidate for restriction if it exceeds one or more criteria for *each* of the three factors (persistence, mobility, and detections).

(a) Persistence and Mobility

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

Table 24. Mobility and Persistence of Thiobencarb Relative to Restricted Use Criteria.

Factor		Characteristic	Restricted Use Criteria	Reported Values[a]
Persistence	1	Field dissipation half-life	> 3 weeks	8, 21.9 weeks (56, 153 days)[b]
	2	Lab-derived aerobic soil metabolism half-life	> 3 weeks	3.9 - 8.3 weeks (27 - 58 days)
	3	Hydrolysis half-life	< 10% in 30 days	Stable
	4	Photolysis half-life (Soil)	< 10% in 30 days	50% in 168 days (calculated)
Mobility	5	Soil adsorption: K_d	< or = 5 ml/g	5.4 - 20.1 ml/g
	6	Soil adsorption: K_{oc}	< or = 500 ml/g	384, 618, 1024 - 1435 ml/g
	7	Depth of leaching in field dissipation study	75 cm	15 cm[b]

[a] Shaded area indicates that parameter exceeds trigger.

[b] Because thiobencarb is used almost exclusively on rice, no terrestrial field dissipation studies were submitted by the registrant. Aquatic field dissipation studies were conducted to address this use. The half-lives reported are aquatic field dissipation for soil. Refer to Section C.2.b. of the Agency RED chapter for additional data.

(b) Degradates and Binding

The aerobic metabolism studies found that, after one year, the degradation to carbon dioxide and binding of residues to soil were significant pathways for dissipation of thiobencarb (see Section C.2.b.). Carbon dioxide accounted for 42-77% of the applied and bound residues accounted for 23-42% of the applied. Literature data reported that the thiobencarb in the soil slowly mineralized without forming significant quantities of non-volatile degradates. This will significantly reduce the amount of thiobencarb available to leach through the soil profile.

(c) Ground Water Detections

The Agency has limited monitoring information for thiobencarb in ground water in the United States. The "Pesticides in Ground Water Database" (Hoheisel et al., 1992) reports sampling for thiobencarb in 270 wells in California and 65 wells in Missouri. Two detections of thiobencarb in ground water were reported in Missouri, these were very low (0.2 - 0.3 ppb). A summary of this is presented below.

Table 25. Mobility and Persistence of Thiobencarb Relative to Restricted Use Criteria.

Criterion	Characteristic	Restricted Use Criteria	Reported Detections
Detections	Number of wells per state with detections	25 wells in 4 or more states or	2 wells in 1 state
Detections	Number of counties with detections > 10% of reference point	3 counties at > 10% of MCL or HAL	No MCL or HA Established

(d) Restricted Use

Thiobencarb met the persistence and mobility triggers for classification as a restricted use chemical for ground-water concerns, but not the detections triggers. The Agency believes that ground water concerns do not warrant use restrictions.

(e) Ground Water Reference Points

There is no MCL established for thiobencarb residues in drinking water. The lifetime Health Advisory for thiobencarb also has not yet been established, but an estimated Health Advisory can be calculated from the Reference Dose. The Agency has established the RfD of thiobencarb at 0.01 mg/kg/day.

The Agency estimated the lifetime HA for thiobencarb to be 70 ppb. This was calculated from the Reference Dose as follows:

Assumed: Adult with body weight of 70 kg consuming 2 L water/day
RfD for thiobencarb = 0.01 mg/kg/day
RSC = Relative source contribution, assumed to be 20%

$$\text{DWEL} = \frac{(\text{RfD})\ (70\ \text{kg})}{(2\ \text{L/d})} = \frac{(0.01\ \text{mg/kg/day}) \times 70\ \text{kg}}{(2\ \text{L/d})} = 0.35\ \text{mg/L}$$

Lifetime HA = DWEL x RSC = 0.35 mg/L x 0.20 = 0.07 mg/L = 70 μg/L (ppb)

(f) Ground Water Concerns

Thiobencarb is slightly persistent in water, generally not very mobile, tends to bind to soil organic matter, and doesn't desorb. The Agency has estimated the Lifetime Health Advisory for thiobencarb residues in drinking water to be 70 ppb. Thiobencarb also has low acute mammalian toxicity. Based on the limited data available and very low concentrations found in ground water, there is no indication that thiobencarb concentrations in ground water would exceed the estimated HA of 70 ppb.

The principle use of thiobencarb is rice in the lower Mississippi Valley and the Central Valley of California. Rice fields are usually underlain by a clay layer to restrict water movement through the soil and help contain the water in the flooded field. This clay layer will significantly limit the amount of leaching that occurs in the rice fields.

Although thiobencarb does exceed several of the criteria for restricted use, the Agency does *not* consider thiobencarb to be a candidate for restricted use due to ground water concerns. The Agency does not consider thiobencarb to be a concern in ground water, nor a human health concern from residues in drinking water that are derived from ground water.

(2) Surface Water

Environmental fate information indicates thiobencarb is non-persistent[4] in the water column (aquatic field dissipation half-lives ranging from approximately 6 to 9 days). It is stable to degradation from abiotic hydrolysis; however, degradation via aqueous photolysis with photosensitizes was shown in the laboratory studies. The vapor pressure and Henry's Law constant indicate thiobencarb will not volatilize readily from surface water environments. Based on the Freundlich adsorption coefficients (K_{ads} range: 5.42-20 ml/g), thiobencarb adsorbs to soil and sediment particles and may be transported on entrained sediment in surface runoff. Partitioning of thiobencarb onto soil or sediment was demonstrated in three aquatic field dissipation studies where thiobencarb concentrations on soil were approximately 5 to 64 times greater than water concentrations. However, the results of field monitoring studies indicate thiobencarb can be transported primarily via dissolution in runoff water if sufficient rainfall occurs immediately following field application. In surface waters, thiobencarb dissipates principally by binding to sediment, and degrading by sensitized aqueous photolysis. Mineralization is also known to occur at the soil-water interface in rice fields. This is aerobic degradation. Thiobencarb has the potential to contaminate surface water from releases of rice paddy water which closely follow field application, or from spray drift associated with aerial or ground spray application.

Thiobencarb is not currently regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) is not established. It is classified as category III for oral acute toxicity. The estimated lifetime Health Advisory level (HA) is 70 mg/L using the Reference Dose of 0.01 mg/kg/day. Public water supply systems are not required to sample and analyze for thiobencarb.

In the EPA Office of Water's STORET database, thiobencarb detections in surface waters were reported for filtered water samples only (detections limits varied from 0.002-0.008 mg/L). Detections of thiobencarb were listed for 8 states: California, Georgia, Maryland, North Carolina, Oregon, Oklahoma, Texas, and Washington.[5] Thirty-nine positive detections were reported for 3,130 samples (approximately 1%) with a maximum concentration of 0.24 mg/L (7/22/92 and 8/26/92; Klamath Falls, OR) and a mean concentration of 0.10 mg/L. Whole (i.e., unfiltered) water samples did not find detectable levels of thiobencarb. Surface water concentrations for the field monitoring studies are several orders of magnitude greater (approximately 100 to 3000 times larger) [6]than the detections reported in the STORET database. The sources of this variation are not known;

[4] Based on the criteria established by McEwen and Stephenson (1979*).*

[5] The Agency does not know why thiobencarb was detected in these states since, with the exception of California, registered uses of thiobencarb should not occur within these states.

however, the filtered sample results (0.7 mm filters) in the STORET data suggest very low concentrations of thiobencarb in the aqueous phase of surface water samples. This finding is consistent with the partitioning of thiobencarb onto sediment which would lower the concentrations in the aqueous phase. It is not clear whether the results from the field monitoring studies were determined from filtered or unfiltered water samples. Additional surface water monitoring data are described in Section 3a(2)(b).

Aquatic EEC modeling for rice uses was not conducted because the Agency currently does not have a computer simulation model which will estimate these concentrations. For the lettuce, endive and celery uses, the GENEEC model was used to complete a Tier 1 exposure assessment (Table I). The range of aquatic EECs was 140 mg/L for the 6 lb a.i. application rate and 180 mg/L for the 8 lb a.i. application rate. The initial (peak) EEC varied by a factor of 23 mg/L for each pound increase in thiobencarb. Comparison of the initial EECs with the 21-day and 56-day EECs indicates thiobencarb dissipates in the pond water at an approximate rate of 0.4-0.6 mg/L/day.

Increased transport time to the water intakes will allow greater binding of thiobencarb to suspended solids and/or sediments. Any thiobencarb that may reach surface water will be predominantly bound with suspended solids and sediments. Standard coagulation and flocculation processes used in these plants should remove most of the suspended solids and sediments from the water, thereby removing most of the potential risk of thiobencarb in drinking water.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

(1) Background Information

Risk Quotients and the Levels of Concern

Levels of Concern (LOCs) are criteria used to indicate potential risk to nontarget organisms. Exceeding the criteria indicate that a pesticide, when used as directed, has the potential to cause undesirable effects to nontarget organisms. Two general categories of LOC (acute and chronic) exist for each of the four nontarget faunal groups, and one category (acute) exists for each of two nontarget floral groups. To determine if an LOC has been exceeded, a risk quotient is derived and compared to the LOC. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by the appropriate toxicity test effect level. The acute effect levels are:

-- EC_{25} (terrestrial plants)
-- EC_{50} (aquatic plants and invertebrates)
-- LC_{50} (fish and birds)

-- LD_{50} (birds and mammals)
-- EC_{05} or NOEC (endangered plants)

The chronic effect levels are the:

-- NOEC (avian and mammal reproduction studies)
-- NOEC or MATC for aquatic species.

When the RQ exceeds the LOC for a particular category, risk is presumed. Risk presumptions, along with the corresponding LOCs, are tabulated below.

Table 26. Risk Quotients and LOCs for Animals

Endpoint	Risk Quotient (RQ)	LOC
Birds		
Acute High Risk	EEC/LC_{50} or LD_{50}/sq. ft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sq. ft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD50/sq. ft LD_{50}/day	0.1
Chronic High Risk	EEC/NOEC	1
Chronic Endangered Species	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC_{50} or LD50/sq. ft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sq. ft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD50/sq. ft or LD_{50}/day	0.1
Aquatic Animals		
Acute High Risk	EEC/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic High Risk	EEC/MATC or NOEC	1
Chronic Endangered Species	EEC/MATC or NOEC	1

Table 27. Risk Quotients and LOCs for Plants

Endpoint	Risk Quotient (RQ)	LOC
Terrestrial and Semi-Aquatic Plants		
Acute Plants	EEC/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1
Aquatic Plants		
Acute Plants	EEC/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

At this time, The Agency has no procedures for assessing chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

Thiobencarb Use Patterns Addressed in Risk Assessment

The majority of thiobencarb use (95%) is to control terrestrial and aquatic weeds in rice production. The maximum label use rate on rice is 4 lb ai/A, and the average rate is approximately 3 lb ai/A. Application may be by aircraft or ground equipment. For rice grown in the Gulf Coast and Mississippi River Valley, thiobencarb is usually applied as a liquid (EC formulation) to nonflooded fields. "Dry-seeded" rice is frequently grown in this area, in which seeds are sowed and grown in dry seed beds for several weeks before flooding. If there is no rainfall, fields are irrigated with a small volume of water (i.e. flushed) to promote seed germination. Some rice in this area is "water-seeded", meaning that seeds are applied to water in flooded fields. In this part of the country, thiobencarb is usually applied to fields before they are flooded. Fields are then flooded for seeding with rice. These floods are normally dropped temporarily after seeding to allow rice seedlings to grow, resulting in a discharge of water. In California, the majority of rice grown is water-seeded with a continuous flood. Unlike the southern region, thiobencarb in California is almost always applied as a granule to water in flooded fields. A small percentage of rice farmers in California use "pin-point flood" culture, in which case thiobencarb may be applied as a liquid to dry-ground before fields are flooded. California state regulations prevent rice farmers from discharging tailwater from rice fields for 4 to 30 days after application.

Additionally, a relatively small amount of thiobencarb is used on lettuce, endive, and celery. Registrations for these uses are restricted to Florida. The maximum label rate is 6 lb ai/A for lettuce and endive and 8 lb ai/A for celery. Application is by boom sprayers.

(2) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Liquid Applications- Acute and Chronic Risk

For thiobencarb products applied as a liquid to soil, risk is assessed by comparing LC_{50} values to estimated residues (i.e. EECs) on dietary food items immediately following application. The table below gives the predicted 0-day maximum and mean residues of thiobencarb that are expected to occur on selected avian or mammalian dietary food items.

Table 28. Maximum EECs on Avian and Mammalian Food Items for Uses of Thiobencarb.

Use Site	Maximum Application Rate (lbs a.i./A)	Maximum EEC (ppm)			
		Short grass	Long grass	Broadleaf plants and insects	Fruit
Rice	4	960	440	540	60
Lettuce and Endive	6	1440	660	810	90
Celery	8	1920	880	1080	120

In an avian dietary LC_{50} test with the northern bobwhite (Acc. No. 241483), no mortality occurred at the maximum test level, 5620 ppm. Environmental concentrations are predicted to be much less than 5620 ppb. The acute risk to birds from all uses of thiobencarb is minimal. No acute effects to threatened and endangered species are expected.

The chronic risk quotients for liquid applications are given below.

Table 29. Avian Chronic Risk Quotients (RQs) for Liquid Applications Based on a Mallard Duck NOEC and Maximum EECs.

Crop	Maximum Application Rate (lbs a.i./A)	Food Items	Maximum EEC (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)	Number of Days EEC > NOEC
Rice	4	Short grass	960	100	9.6	29
		Long grass	440	100	4.4	19
		Broadleaf plants and insects	540	100	5.40	21
		Fruit	60	100	0.6	0
Lettuce and Endive	6	Short grass	1440	100	14.4	34
		Long grass	660	100	6.6	24
		Broadleaf plants and insects	810	100	8.10	26
		Fruit	90	100	0.9	0
Celery	8	Short grass	1920	100	19.2	37
		Long grass	880	100	8.8	27
		Broadleaf plants and insects	1,080	100	10.80	30
		Fruit	120	100	1.2	3

In addition to the magnitude of the RQs, chronic risk can be assessed by estimating the duration when EECs are expected to be high enough to possibly cause effects in birds. This duration is based on the magnitude of the initial EEC and the rate of dissipation. The dissipation of thiobencarb from foliage was estimated from data collected in a biological field study conducted at Halls Bayou, Texas (Acc. No. 241484). Thiobencarb residues were measured from broadleaf weeds and sedges collected 12 m downwind of the edge of the field on 0, 7, 14, and 21 days after application. The calculated foliage half-lives for broadleaf weeds and sedges were 5.4 and 8.6 days, respectively. These values are

consistent with those estimated for other pesticides (Willis and McDowell, 1987). The more protective value of 8.6 days was used in the risk assessment. Assuming a first-order rate of dissipation, EECs are predicted to exceed the mallard NOEC for up to 37 days, depending on the use rate and type of plant.

Most of the chronic risk quotients exceed the LOC of 1 for use on rice, lettuce, endive, and celery. The use rate would have to be reduced to 0.4 lb/A, one-tenth the current maximum label rate for rice, to reduce all of the chronic RQs to below the LOC. Furthermore, the maximum EECs for all food types except fruit exceed the mallard NOEC for relatively long durations, generally three weeks or more. These results indicate that all uses of thiobencarb pose a risk of causing chronic effects to birds and may cause chronic adverse effects to threatened and endangered bird species.

Granular Applications--Acute Risk

A granular formulation is used only when thiobencarb is applied to flooded rice fields. Most of the granules will fall onto the water surface and sink to the bottom. These granules would not be accessible to many birds, although they possibly could be ingested by waterfowl and sandpipers which feed off the bottoms of the flooded fields. A small portion of the granules may fall on levees built around and within rice fields or get caught in emerging rice plants. These granules could be available for birds to consume. Some exposure of granular pesticides to birds is therefore expected, but the overall degree of exposure is probably less than when thiobencarb is applied on dry fields.

Thiobencarb has very low acute toxicity to birds. In an acute single-dose test with the northern bobwhite, a dose of 1938 mg ai/kg Bwt resulted in no mortality or overt signs of toxicity (MRID 42600201). The Agency expects that the risk of acute effects to birds from exposure to granular thiobencarb is minimal.

Granular Applications--Chronic Risks

The Agency currently does not have a procedure for assessing the chronic risk posed by granular applications.

(b) Mammals

Acute hazard to small mammals was addressed using the acute oral LD_{50} value for the rat converted to an estimated LC_{50} value for dietary exposure. The estimated LC_{50} was derived using the following formula:

$LC_{50} = LD_{50}$ x body weight (g) / food consumed per day (g)

Acute risk to mammals was assessed by calculating RQs for three representative species: the meadow vole, the field mouse, and the least shrew. Estimated mammalian LC_{50} values for these three species of small mammals are presented below:

Table 30. Estimated Small Mammal Dietary Exposure (Based on an LD_{50} = 1080 mg/kg).

Small Mammal	Body Weight (g)	Percent of Weight Eaten Per Day	Food Consumed Per Day (g)	Estimated LC_{50} (ppm)
Meadow vole	46	61 %	28.1	1770
Adult field mouse	13	16 %	2.1	6690
Least shrew	5	110 %	5.5	982

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

The risk quotients are calculated by dividing the EECs (i.e. residues) by the estimated LC_{50}'s. The table below shows the risk quotients for peak exposures of thiobencarb.

Table 31. Mammalian Acute Risk Quotients.

Species and Diet	Use Site	Application Rate (lb ai/A)	Maxium EEC[1] in Food Item (ppm)	Risk Quotient
Meadow vole consuming short grasses	Rice	4	960	0.54
	Lettuce and Endive	6	1440	0.64
	Celery	8	1920	1.09
Adult field mouse consuming seeds	Rice	4	60	< 0.1
	Lettuce and Endive	6	90	< 0.1
	Celery	8	120	0.02
Least shrew consuming insects	Rice	4	540	0.55
	Lettuce and Endive	6	810	0.82
	Celery	8	1080	1.10

[1]Based on Hoeger and Kenaga (1972) with modifications by Fletcher et al. (1994).

For all use sites, RQs for the meadow vole and the least shrew are greater than 0.5, the LOC for presumption of risk. This indicates that use of thiobencarb in a liquid formulation on rice, lettuce, endive, and celery poses an acute risk to mammals.

Liquid Applications--Chronic Risk

RQs were calculated for chronic effects of thiobencarb to mammals. The number of days that the EEC will exceed the chronic mammalian NOEC was also estimated using the method described earlier for chronic effects to birds.

Table 32. Mammalian Chronic Risk Quotients (RQs) for Liquid Applications Based on a Rat NOEC and Maximum EECs.

Crop	Maximum Application Rate (lbs a.i./A)	Food Items	Maximum EEC (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)	Number of Days EEC > NOEC
Rice	4	Short grass	960	20	48	48
		Long grass	440	20	22	38
		Broadleaf plants and insects	540	20	27	41
		Fruit	60	20	3	14
Lettuce and Endive	6	Short grass	1440	20	72	53
		Long grass	660	20	33	43
		Broadleaf plants and insects	810	20	41	46
		Fruit	90	20	5	19
Celery	8	Short grass	1920	20	96	57
		Long grass	880	20	44	47
		Broadleaf plants and insects	1080	20	54	50
		Fruit	120	20	6	22

All of the chronic RQ for mammals exceed the LOC of 1 for use on rice, lettuce, endive, and celery. Except for exposure on fruit, all RQs are very high (22 or greater). Also, EECs on wildlife foods are expected to persist at levels greater than the mammalian NOEC for many days. These results indicate that all uses of thiobencarb pose a risk of causing chronic effects to mammals and may cause chronic adverse effects to threatened and endangered species of mammals.

The specific responses of the tested organisms in the study yielding the 20 ppm NOEL were reduced weight gain and food consumption, food efficiency, and increased blood urea nitrogen at 100 ppm, the next highest test level above 20 ppm. In another study, no reproductive effects were observed at dietary concentrations as high as 2000 ppm. Thus the chronic risk to mammals relate to growth and physiology. Available data do not suggest high risk of reproductive impairment to mammals at any application level.

Granular--Acute Risks

A granular formulation is used only when thiobencarb is applied to flooded rice fields. Most of the granules will fall onto the water surface and sink to the bottom. These granules probably would not be accessible to most mammals. The active ingredient of these granules would disperse into the water, and mammals could then be exposed by drinking this water. But, considering the large degree of dilution that would take place and the low mammalian toxicity of thiobencarb, this would pose minimal risk to mammals. The primary route of exposure to mammals from granular thiobencarb probably would be from ingestion of granules that fall on the levees within and around the

edges of rice fields. Mammals do not intentionally ingest grit, but may inadvertently ingest granules that adhere to food items.

Thiobencarb has low acute toxicity to mammals. In an acute single-dose test with the rat, the LD_{50} was 1080 mg ai/kg BWt (MRID 42130701). The Agency expects that the risk of acute effects to mammals from exposure to granular thiobencarb is minimal.

Granular Applications--Chronic

The Agency currently does not have a procedure for assessing the chronic risk posed by granular applications.

(c) Insects

Use of thiobencarb on rice, lettuce, endive, and celery is not expected to cause significant exposure to honey bees. The risk to honey bees is therefore minimal.

(3) Exposure and Risk to Nontarget Aquatic Animals

(a) Expected Aquatic Concentrations

The Agency calculated EEC's using the Generic Expected Environmental Concentration Program (GENEEC) to estimate exposure for use of thiobencarb on celery, lettuce, and endive. The resultant EEC's, termed GEEC's, were used for assessing acute and chronic risks to aquatic organisms. Acute risk assessments were performed using 0-day GEEC values for a single application. Chronic risk assessments were performed using the 21-day average GEECs for invertebrates and 56-day average GEECs for fish.

The GENEEC program uses a few basic chemical parameters and pesticide label application information to provide a rough estimate of the expected environmental concentrations. The model calculates the concentration of pesticide in a hypothetical 1-ha, 2-m deep pond taking into account adsorption to soil and sediment, soil incorporation, degradation in soil before runoff to a water body, and degradation within the water body. The model also accounts for direct deposition of spray drift into the water body. The rate of spray drift deposition is assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively. The following values were selected for input into the GEEC Program:

Soil Organic Carbon Partitioning Coefficient:	384
Soil Aerobic Metabolic Half-life:	58 days
Aquatic Aerobic Metabolic Half-life:	stable
Hydrolysis Half-life:	stable
Photolysis Half-life (at pH 7):	12 days
Water Solubility	27.5 ppm

To be protective, the values were selected to maximize calculated exposure estimates.

GEECs based on runoff from a single application on a 10-hectare field to a 1-hectare x 2-meter deep water body are given below.

Table 33. Generic Estimated Environmental Concentrations (GEECs) for Aquatic Exposure.

Use Site	Application Method	Maximum Application Rate (lbs a.i./A)	Number of Applications	Initial (Peak) EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Celery (FL)	Ground, unincorporated	8	1	186	173	157
Lettuce and Endive (FL)	Ground, unincorporated	6	1	140	130	118

(b) Measured Aquatic Concentrations

The Agency used aquatic concentrations measured in field studies and monitoring projects to estimate the exposure of aquatic organisms from use of thiobencarb on rice. Measured water concentrations were available from two biological field studies performed in Texas (MRID 92182086 and 92182089, Acc. No. 241484), two environmental fate field studies performed in Louisiana and California (MRID 42003404 and 43404005), monitoring data from California (MacCoy et al., 1995, MRID 43359700), and studies reported in the open literature (Ross and Sava, 1986; Watanabe et al., 1982). While data from all of these sources were reviewed, the risk assessment for dry-seeded rice in the Southeast was based primarily on data from the two biological field studies and the risk assessment for water-seeded rice in California was based on data from the monitoring programs. These sources were most relevant because they provided measured concentrations of thiobencarb residues in off-site bodies of water, rather than in the rice fields themselves.

Dry-Seeded Rice in the Southeast

The two biological field studies provide examples of residues that can result in slow-moving bodies of water that receive drainage from surrounding dry-seeded rice fields where thiobencarb is applied. The Agency considers both Halls Bayou and the canal studied near Matagorda, Texas to be representative of small brackish waterways that occur in the rice-growing region of the Gulf Coast. These field studies will also be used in the risk assessment to represent freshwater habitats of the Mississippi Valley since no study specific to this region is available. The 1978 Stream Evaluation Map for the state of Texas categorizes the section of Hall's Bayou where the field study was located as Category I, a "highest-valued fishery resource". The drainage ditch in the Matagorda study was a 120-130 ft wide permanently flooded canal that is also considered to be a biologically significant habitat. Biological sampling in both studies found these waterways are abundant and diverse in fish and invertebrate life.

The greatest exposure from dry-seeded rice culture probably results from the first flush or heavy rainfall that occurs after thiobencarb has been applied. Pesticide residues

in the soil are dissolved in this water as it passes over the field and then discharged into an aquatic habitat. As demonstrated in the Hall's Bayou field study, unplanned flushes resulting from rainfall usually result in greater residues in off-site aquatic habitats than do planned flushes. Planned flushes usually occur one to two weeks after application, allowing much of the pesticide to bind to the soil. Furthermore, since rice farmers normally try to use the minimal amount of water required to adequately wet the soil, little water is normally discharged in a planned flush. On the other hand, rainfall may occur soon after the pesticide is applied, and if it is intense, may result in a large volume of water being discharged from the field.

The biological field study that collected water samples from Halls Bayou, Texas [see section C.1.b(7)], provides an example of a near worst-case scenario. Halls Bayou is a long narrow waterway that meanders through rice-growing areas in the Texas coastal plane. During the field study, a very heavy rainfall event (3.23 inches in 24 hours) happened to occurred on the same day that thiobencarb was applied, resulting in unplanned release of water from rice fields. The measured concentrations of thiobencarb in samples taken this day were as great as 8900 ppb in the field outflow and 690 ppb at the point where a ditch draining from the fields discharged into Hall's Bayou. Heavy rainfall of this magnitude is common in the Gulf Coast region, often occurring several times in the same location during the spring. However, the Agency believes that these thiobencarb concentrations represent near the upper bound of concentrations that are likely to occur in aquatic habitats for the following reasons: 1) rainfall occurred on the same day that pesticide is applied; 2) in the area of the field study, Halls Bayou was surrounded by rice fields; and 3) Halls Bayou is a relatively small waterway with little flow or tidal flushing, resulting in little dilution of water draining from rice fields.

The aquatic residues measured at other times during the Halls Bayou study, as well as those measured in a drainage ditch in the biological field study conducted near Matagorda, Texas [see section C.1.b(7)], provide examples of situations that would result in exposures that are moderately high, but more typical. Other than the concentrations measured after the intense rainfall event of the 19th of April, the greatest thiobencarb concentrations were measured in samples taken on 7 April following several planned flushes in the region during the previous week. Samples taken that day at two sites in the Bayou near the point of discharge of water draining from the rice fields were 83 and 64 ppb. Measured residues were 40 and 48 ppb in two samples taken on 6 April, and 33 ppb in a sample taken on 8 April. Residues remained at a concentration of 10 ppb or greater through April 12, when sampling was ceased.

Aquatic residues measured in the study near Matagorda study were less than those measured at Halls Bayou. The greatest measured residues (average of two replicate samples) was 20 ppb in 1983 and 21 ppb in 1984. Residues were commonly between 1 and 15 ppb for a few days following applications of thiobencarb and/or flushing of fields.

Figure 1 provides an example of the change in aquatic residues over time. This data is from the 1983 sampling in the drainage ditch at the Matagorda study site. Thiobencarb was applied at a rate of 4 lb/A to a 100-A field that bordered the ditch. Prior to this application, thiobencarb had not been applied to fields in the region for 33 days. A peak concentration of 20 ppb was recorded on the day of application at station 2. Unfortunately, no water samples were taken 1, 2, and 3 days after treatment (DAT). By 5 DAT, residues at station 2 had dramatically decreased, but peaks in residues were occurring at the downstream stations 3 and 4. Residues at the point of discharge into the Colorado River peaked on the following day. This data shows that the highest residues measured tend to occur in peaks that last for only a day or two at any particular location, after which the high residues move further downstream.

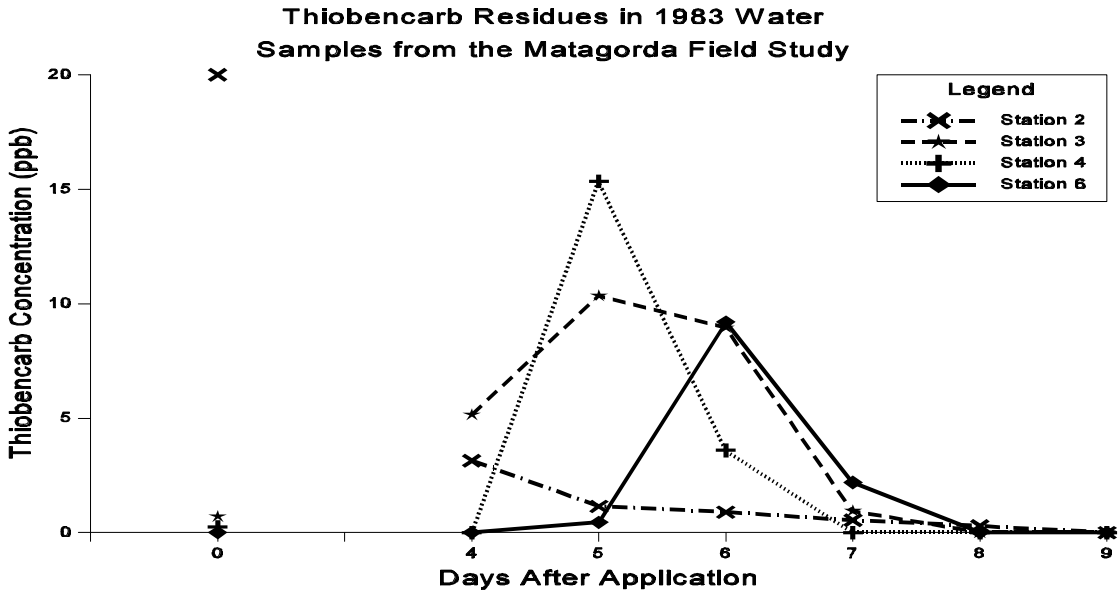


Figure 1. Thiobencarb concentrations in water sampled from a drainage canal (stations 2-4) and in the Colorado River at a point downstream of the confluence with the drainage canal (station 6). Thiobencarb was applied on day 0 at a rate of 4 lb/A on 100 A of a field adjacent to the drainage canal. No residues were reported on 1, 2, and 3 days after treatment.

Water-seeded rice in the Southeast

The monitoring data discussed does not represent aquatic EECs resulting from water-seeded rice grown in the Mississippi Valley and Gulf Coast. Also, no monitoring data were available for aquatic concentrations resulting from water-seeded rice in these

regions. Unlike in California, thiobencarb is primarily applied to water-seeded rice in these regions by applying a liquid to soil before the fields are flooded. This use is similar to dry-seeded rice in terms of expected environmental exposure. Therefore, the concentrations measured for dry-seeded rice in the biological field studies was also used to represent exposures from water-seeded rice in the southeastern regions.

Water-seeded Rice in California

The Agency used surface water monitoring data to approximate the concentration of thiobencarb likely to be found in water in areas of California where water-seeded rice is grown. Two recent sources of data on thiobencarb were available. One was a US Geological Survey Open-file Report on the monitoring of dissolved pesticide concentrations in the San Joaquin River and Sacramento River in 1991 through 1993 (MacCoy et al., 1995). The other source of data was monitoring of thiobencarb concentrations in waterways that drain rice growing areas in the Sacramento River Valley. This data was submitted to the EPA by Valent U.S.A. Corporation under the 6(a)(2) provisions of FIFRA.

Approximately three years of routine water monitoring of the San Joaquin River at Vernalis, California and of the Sacramento River at Sacramento, California (MacCoy et al., 1995) found that thiobencarb concentrations were always low, below 0.05 ppb. For most of the sampling period, thiobencarb residues were not detected or were below 0.025 ppb. The only exception was a 10-12 period during May and June of 1993 when measured residues generally were greater than 0.1 ppb. Peak residues were 0.53 ppb in the San Juaquin River and 0.70 ppb in the Sacramento River.

Monitoring conducted by the California Environmental Protection Agency and submitted by the Valent U.S.A. Company found that levels of thiobencarb in some of the waterways draining into the Sacramento River were occasionally greater than in the river itself. Concentrations were always below 1 ppb in the Butte Slough, but frequently greater than 1 ppb in the Colusa Basin Drain (Table 34). A peak concentration of 37 ppb was recorded in the Colusa Basin Drain.

Table 34. Thiobencarb concentrations measured in waterways flowing into the Sacramento River, California

Date Sampled	Water Sampling Locations			
	CBD1	CBD5	SS1	BS1
5-3-94	--	not detected	--	0.10
5-5-94	--	0.18	--	0.09
5-9-94	--	0.49	--	0.06
5-12-94	--	0.42	--	0.07
5-16-94	0.212	37.4	0.34	0.11

Date Sampled	Water Sampling Locations			
	CBD1	CBD5	SS1	BS1
5-19-94	0.103	0.768	0.40	0.09
5-22-94	3.34	1.04	0.26	0.08
5-26-94	0.8	0.992	0.19	0.11
5-30-94	0.46	0.66	0.12	0.18
6-2-94	0.28	4	nd	0.12
6-6-94	0.58	0.5	0.10	nd
6-9-94	15.8	0.38	0.08	0.10
6-13-94	6.2	0.34	0.08	nd
6-16-94	4.74	0.284	0.10	0.08
6-20-94	--	0.42	--	nd
6-23-94	--	0.11	--	0.53
6-27-94	--	0.51	--	nd
6-30-94	--	0.63	--	nd
7-4-94	--	0.28	--	0.12
7-7-94	--	0.21	--	0.18

(nd = not detected)

Vegetables in Southern Florida

Very limited information is available on thiobencarb concentrations in southern Florida. The National Water Quality Assessment Program (NAWQA), being conducted by the US Geological Survey, is currently collecting water samples in southern Florida and analyzing them for pesticides, including thiobencarb. One sampling station is located in an area that is drained by agricultural land in Palm Beach County where most of the Florida use of thiobencarb is located. This station is on the Hillsborro canal along the southern border of the Loxahatchee National Wildlife Refuge, and thus would provide indication if thiobencarb is entering this important wetland habitat.

To date, testing for thiobencarb has only been completed for approximately 16 samples that were taken in the fall of 1996 into the winter of 1997. Thiobencarb was not detected in these samples. The minimum detection level of thiobencarb is 0.002 μg/L. However, it is premature to draw any conclusions from these data. For one thing, these data do not yet include sampling for the spring, the time when most applications of thiobencarb are made. Interpretation of the NAWQA monitoring data should be postponed until the collection, quality control, and analysis of the data have been completed.

(c) Freshwater Fish

The risk of acute effects to freshwater fish from the use of thiobencarb on rice is uncertain. The maximum residue measured in Halls Bayou when heavy rainfall occurred on the day of application was 690 ppb. This exceeded the lowest LC_{50} determined for freshwater fish, 560 ppb for the bluegill sunfish, indicating a high risk to freshwater fish. This conclusion is supported by a fish killed observed in the Matagorda study which was attributable to thiobencarb exposure. Several other supplemental studies, however, found that the LC_{50} for various freshwater fish is greater, in the range of 1.1 to 2.8 ppm. Based on these supplemental data, the acute risk of thiobencarb would be minimum to low. Furthermore, other aquatic residues measured in the Halls Bayou, as well as all of those measured in the Matagorda study, were well below even the lowest LC_{50} of 560 ppb. Therefore, the acute risk of thiobencarb to fish is uncertain. If there is an acute risk, it apparently would be limited to high exposure situations in which heavy rainfall occurs soon after application discharges contaminated water into a small water body where it would not be greatly diluted.

Measured aquatic residues from monitoring in California were no greater than 37 ppb. As this is well below levels that are expected to cause acute effects, use of thiobencarb on rice in California is expected to pose minimal acute risk to freshwater fish. No acute effects on threatened and endangered species are expected.

For other uses of thiobencarb, acute risk quotients for freshwater fish are given Table 35.

Table35. Risk Quotients (RQs) for Freshwater Fish Based on a Bluegill Sunfish LC_{50}

Use Site	Use Rate (LB/A)	LC_{50} (ppb)	EEC Initial (ppb)	Acute RQ (EEC/LC_{50})
Celery (FL)	8	560	186	0.33
Lettuce and endive (FL)	6	560	140	0.25

These results indicate that use of thiobencarb on vegetables in Florida, at the maximum label rate, does not pose a high acute risk to freshwater fish. They do not exceed the high-risk LOC of 0.5. The risk quotients are greater than 0.1, however, indicating that restricted use may be necessary to mitigate this risk. Also, these uses of thiobencarb may harm endangered species of freshwater fish.

Chronic risk quotients could not be calculated because data is lacking on the chronic toxicity of thiobencarb to freshwater fish. The best approximation of the chronic risk to freshwater fish is given by the chronic risk assessment for marine and estuarine fish [Section 3a(2)(c)].

(d) Freshwater Invertebrates

The maximum residue measured in Halls Bayou after a heavy rainfall was 690 ppb, which was 6.9 times greater than the acute EC_{50} for *Daphnia magna*, 100 ppb. Residues measured in Halls Bayou on another day that was not associated with a heavy rainfall event were 83 and 64 ppb. Risk quotients calculated based on these values are 0.83 and 0.64, respectively, which are greater than the LOC for presumption of high risk, 0.5. Aquatic residues measured in the Matagorda study were less and do not indicate a high risk to acute aquatic invertebrates. These results indicate that the risk to freshwater invertebrates posed by use of thiobencarb on rice in the southeastern regions range from low to high, depending on the weather and local conditions. High risk probably is limited to aquatic habitats near the discharge of tailwater and during times when heavy rainfall occurs soon after thiobencarb is applied.

Measured aquatic residues from monitoring in California were no greater than 37 ppb. An acute risk quotient based on this value is 0.37, which is less than the LOC of 0.5. Therefore, use of thiobencarb on rice in California is expected to pose minimal acute risk to freshwater invertebrates. Although risks are minimal for freshwater invertebrates, in general, there is still a concern for threatened and endangered species.

Based on a chronic toxicity study with the *Daphnia magna*, thiobencarb is predicted to cause chronic effects in freshwater invertebrates when concentrations remain near or above 1 to 2 ppb for an extended period of days. Aquatic residues measured during the two biological field studies indicate that this condition will commonly occur in areas where thiobencarb is applied. For example, of the 24 samples analyzed from Area II of Halls Bayou between 24 March and 30 April, all but two had thiobencarb concentrations greater than 2 ppb. Even in the Matagorda study, where residues were generally lower, measured residues equal or exceeded 1 ppb for 9 consecutive days in 1983 and 7 consecutive days in 1984. During periods of peak exposure, residues were 12 to 406 times greater than the MATC for *Daphnia magna*. These findings indicate that use of thiobencarb on rice in the southeast regions poses a definite high risk of causing chronic effects to freshwater invertebrates. Adverse effects to freshwater invertebrates are expected to occur frequently.

Use of thiobencarb on water-seeded rice in California is predicted to pose less of a chronic risk to aquatic invertebrates than in the southern rice-growing regions. Water sampling from the Sacramento River and San Juaquin River show that thiobencarb concentrations never exceeded 1 ppb, the NOEC for *Daphnia magna*. The majority of readings were less than 0.05 ppb. In contrast, concentrations in smaller waterways occasionally approached or exceeded the NOEC of 1 ppb, as well as the MATC of 1.7 ppb (Table J). The data indicates that the exposure is very pulsed, but several pulses may occur successively to create a chronic exposure. The risk assessment indicates that the use of thiobencarb in California poses a chronic risk to freshwater invertebrates living in the smaller waterways, but minimal risk to those in the larger rivers.

For uses other than rice, acute and chronic risk quotients for freshwater invertebrates are given below.

Table 36. Risk Quotients (RQs) for Freshwater Invertebrates Based on a Daphnid EC_{50} and a Daphnid MATC

Use Site	LC_{50} (ppb)	MATC (ppb)	EEC Initial (ppb)	EEC 21-Day (ppb)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/MATC)
Celery (FL)	100	1.7	186	173	1.86	101.76
Lettuce and endive (FL)	100	1.7	140	130	1.40	76.47

Acute and chronic risk quotients exceed the LOC for high risk. These results indicate that use of thiobencarb on vegetables in Florida, at the maximum label rate, poses a risk to freshwater invertebrates due to both acute and chronic effects. Because the chronic risk quotients are extremely high, chronic effects on invertebrates are expected to be severe.

(e) Estuarine and Marine Animals

Based on aquatic residues measured in the biological field study at Halls Bayou, use of thiobencarb on dry-seeded rice can result in concentrations of thiobencarb of 690 ppb. This represents a near worst-case scenario when heavy rainfall occurs immediately after thiobencarb is applied. Concentrations this great would exceed the acute LC_{50} for the mysid (150 ppb) and eastern oyster (320 ppb), and would be close to the LC_{50} for the sheepshead minnow (660 ppb). They would also approach or exceed the LC_{50} values that Borthwick *et al*. (1985) reported for the Atlantic silverside, tidewater silverside, and California grunion. These findings indicate that the use of thiobencarb on rice in the southeast regions poses a high acute risk to estuarine fish, crustaceans (including shrimp), and mollusks at times of high exposure resulting from heavy rainfall occurring soon after application.

Other than the one measurement of 690 ppb, however, concentrations in Halls Bayou were not greater than 83 ppb. Furthermore, two years of sampling in the biological field study near Matagorda found that residues reached a maximum of 21 ppb. Using the exposure value of 83 ppb, the risk quotients for fish, mollusks, and shrimp are 0.13, 0.26, and 0.55, respectively. This indicates that, under conditions other than those described above, the acute risk is minimal to fish and mollusks. The RQ still exceeds the LOC, however, for high risk for shrimp and other crustaceans.

The measured concentration of 690 ppb, representing a high exposure associated with heavy rainfall, indicates a high chronic risk to fish and crustaceans. In addition, a high chronic risk to crustaceans exists even for exposures measured not associated with heavy rainfall. The MATC from chronic studies with crustaceans found MATCs that ranged from 4.5 to 35 ppb. Water concentrations measured near Matagorda exceed the lower bound of this range, and those measured at Halls Bayou exceed even the upper

bound of this range. The lower end of the range was sometimes exceeded for several consecutive days in both of the biological field studies (for example, 8 days in Area II of Halls Bayou, 4 days at Station 1 on the canal in the Matagorda study in 1984). It is therefore clear that use of thiobencarb on rice in the southeastern regions poses a high chronic risk to shrimp and other aquatic crustaceans.

Chronic risk to fish is less certain. A test concentration of 150 ppb caused reduced growth in the sheepshead minnow. High exposures of thiobencarb, such as the 690 ppb measured at Halls Bayou, will exceed this level, but probably for only short periods of time. Monitoring data show that peaks in aquatic residues usually last for only a day or two (Fig. 1). Under typical conditions, maximum exposures would be considerably less than 150 ppb. For water-seeded rice, thiobencarb concentrations are expected to exceed 150 ppb in the field, but it is not known if they would exceed 150 ppb in off-site aquatic habitats. The available data thus indicate that thiobencarb has the potential to cause chronic effects on estuarine fish in the southern growing region. However, the level of this risk is highly uncertain because a chronic NOEC has not been determined.

In California, the only estuarine habitats that are likely to be exposed to significant residues of thiobencarb are bays near San Francisco that receive water from the Sacramento River and San Juaquin River. All of the rice-growing region in California is drained by these two rivers. Stringent regulation requiring the retainment of floodwater from rice fields have greatly reduced concentrations of thiobencarb occurring in the Sacramento-San Joaquin Delta since 1985 (Bailey, 1993). Monitoring data show that between 1991 and 1993 thiobencarb concentrations in these rivers are always less than 1 ppb, and are usually below 0.1 ppb (MacCoy et al., 1995). This level of exposure would not be expected to cause any significant acute or chronic effects to any estuarine fish or invertebrate. Because concentrations in the bays would be no greater than concentrations in the rivers that feed them, the risk assessment indicates that use of thiobencarb on rice in California poses minimal acute and chronic risk to marine/estuarine fish and invertebrates (including shrimp and mollusks). For uses other than rice, the acute and chronic risk quotients for three estuarine and marine organisms are given below.

Table 37. Risk Quotients (RQs) for Freshwater Fish Based on a Daphnid EC_{50} and a Daphnid MATC

Use Site	Test organism	LC_{50} (ppb)	MATC (ppb)	EEC Initial (ppb)	21- or 56-Day EEG (ppb)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/MATC)
Celery (FL)	Sheepshead minnow	660	< 150	186	157	0.28	> 1.04
	Eastern oyster	320	ND	186	173	0.58	--
	Mysid	150	4.5 - 35	186	173	1.24	4.9 - 38
Lettuce and endive (FL)	Sheepshead minnow	660	< 150	140	118	0.21	> 0.79
	Eastern oyster	320	ND	140	130	0.44	--
	Mysid	150	4.5 - 35	140	130	0.93	3.7 - 29

[1] The 21-day EEC is used for assessing risk to aquatic invertebrates whereas the 56-day EEC is used for assessing risk to fish.

These results indicate that use of thiobencarb on vegetables in Florida, at the maximum label rate, poses a high acute risk to marine/estuarine oysters, shrimp, and other aquatic invertebrates. The RQ for chronic effects to shrimp and other marine/estuarine invertebrates is imprecise because only supplemental data are available. Nevertheless, based on the range of findings from the four available supplemental studies, it is clear that the RQ for these organisms is well above the LOC of 1, signifying a high chronic risk.

The acute RQ for marine estuarine fish in Florida is less than the LOC of 0.5, indicating the acute risk is not high, but it is greater than the LOC of 0.1, indicating that restricted use may be applied. This risk quotient also indicated that threatened and endangered species of fish may be adversely affected.

Definitive chronic RQs could not be determined for marine/estuarine fish because the only available chronic fish study failed to determine an NOEC. However, since adverse effects were observed at a test concentration of 150 ppb, it is certain that both the NOEC and MATC would have been less than this value if lower concentrations were tested. The chronic fish RQ may therefore be expressed as a "greater than" value. At the rate of 8 lb/A, the maximum use rate for celery, the RQ is greater than 1.0, signifying a high chronic risk. At the rate of 6 lb/A, the maximum use rate for lettuce and endive, the RQ is greater than 0.79. Since this value is not much less than the LOC of 1, use at this rate may also pose a high chronic risk to fish. These findings thus indicate that the use of thiobencarb on vegetables in Florida may pose a high chronic risk to fish. An additional fish life-cycle study (GDLN 72-5) is needed to confirm this risk.

(4) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

The Agency does separate risk assessments for two categories of nontarget plants, terrestrial and semi-aquatic. Non-target terrestrial plants inhabit non-aquatic areas which are generally well drained. Non-target semi-aquatic plants inhabit low-lying areas that are usually wet, although they may be dry during certain times of the year. Both the terrestrial and semi-aquatic plants are exposed to pesticides from runoff, drift, and volatilization. They differ, however, in that terrestrial plants are assumed to be subjected to sheet runoff, whereas semi-aquatic plants are assumed to be subjected to channelized runoff.

The Agency assumes that runoff will expose nontarget plants to a fixed percentage of the application rate. This percentage is estimated based on the water solubility of the active ingredient:

Water Solubility	% Runoff Assumed
< 10 ppm	1%
10 - 100 ppm	2%

> 100 ppm 5%

Since the water solubility of thiobencarb at 20°C is 27.5 ppm, the percent runoff is assumed to be 2%. For non-target terrestrial plants, The Agency assumes a scenario in which plants are exposed from sheet runoff. A treated site of 1 acre is assumed to drain into an adjacent area of 1 acre where terrestrial plants may be impacted. In the scenario used for non-target semi-aquatic plants, exposure from runoff is assumed to be from channelized runoff. A treated site of 10 acres is assumed to drain into a distant low-lying area of 1 acre where semi-aquatic plants may be impacted.

Exposure from spray drift was also assumed to be a fixed percentage of the application rate. Spray drift exposure is assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively.

Formulae for Calculating EECs

Terrestrial plants inhabiting areas adjacent to treatment sites

Unincorporated ground application:

Runoff Loading = maximum application rate (lbs ai/acre) x runoff value
Drift Loading = maximum application rate x 0.01
Total Loading = runoff (lb ai/acre) + drift (lb ai/acre)

Aerial applications:

Runoff Loading = maximum application rate (lbs ai/acre) x 0.6 (assumed application efficiency) x runoff value
Drift = maximum application rate (lbs ai/acre) x 0.05
Total Loading = runoff (lb ai/acre) + drift (lb ai/acre)

Semi-aquatic plants inhabiting wet, low-lying areas

Unincorporated ground application:

Runoff Loading = maximum application rate (lbs ai/acre) x runoff value x 10 acres
Drift Loading = maximum application rate x 0.01
Total Loading = runoff (lb ai/acre) + drift (lb ai/acre)

Aerial applications:

Runoff = maximum application rate (lbs ai/acre) x 0.6 (60% application efficiency assumed) x runoff value x 10 acres
Drift = maximum application rate (lbs ai/acre) x 0.05
Total Loading = runoff (lb ai/acre) + drift (lb ai/acre)

Use of thiobencarb on rice is not expected to result in significant exposure to nontarget terrestrial and semiaquatic plants from runoff. Rice fields are always bordered by a dike or temporary berm which would prevent runoff from leaving the field. These structures do have a gate or opening for the release of water from the field, but this water is normally channeled into a stream or river. Outflow from rice fields will therefore not

normally enter dry-land and wetland habitats where terrestrial and semiaquatic plants occur, respectively.

Nontarget plants also may be exposed from spray drift. The Agency calculated risk quotients by dividing the EECs by the vegetative vigor EC_{25} for the most sensitive of the test species. Spray drift, and thus exposure to nontarget plants, will be negligible when thiobencarb is applied as a granule. The Agency assumes that spray drift from liquid (EC) formulations of thiobencarb results in EECs that are 5% and 1% of the application rate for aerial and ground applications, respectively. When applied at the maximum label rate of 4 lb/A, the EECs for nontarget plants are thus 0.2 lb/A for aerial applications and 0.04 lb/A for ground applications. The EC_{25} for vegetative vigor of the most sensitive test species, ryegrass, is 0.073 lb/A. The risk quotients are 2.7 for drift from aerial applications and 0.55 for drift from ground applications. These results indicate that spray drift from aerial liquid application of thiobencarb to rice poses a high risk to nontarget plants. Risk to nontarget plants is minimal from all ground applications and aerial applications of granules to rice.

For uses other than rice, exposure to nontarget terrestrial and semiaquatic plants has a runoff component as well as a spray drift component. Only ground applications are permitted for these uses. Estimated environmental concentrations for terrestrial and semi-aquatic plants are given below.

Table 38. Estimated Environmental Concentrations (EECs) For Terrestrial and Semi-Aquatic Plants

Use Site	Use Rate (lb ai/A)	Runoff Value	Runoff Loading		Spray Drift Loading (lb ai/A)	Total Loading	
			Sheet Runoff (lb ai/A)	Channelized Runoff (lb ai/A)		Adjacent Area (Sheet Runoff + Drift)	Semi-aquatic Area (Channel Run-off + Drift)
Celery (FL)	8	0.02	0.16	1.60	0.08	0.24	1.68
Lettuce and endive (FL)	6	0.02	0.12	1.20	0.06	0.18	1.26

Risk to emerging seedlings was assessed by comparing the EECs listed above with levels in the seedling emergence study that caused 25% mortality most sensitive test species. (The toxicity level for plants is normally referred to as the EC_{25}, but since in this case the effect being considered is mortality, it is also the LC_{25}). The EC_{25} for the most sensitive species, ryegrass, was 0.019 lb ai/A, respectively. RQs for nonrice uses are given below.

Table 39. Exposure and Risk Quotients for Emerging Seedlings of Terrestrial and Semi-aquatic Plants

Use site	Use Rate (Lb/A)	Type of Plants	Exposure Scenario	EEC (lb ai/A)	Risk Quotients
Celery (FL)	8	Terrestrial	Sheet runoff + spray drift (1%)	0.24	13
		Semi-aquatic	Channelized runoff + spray drift (1%)	1.7	88
Lettuce and endive (FL)	6	Terrestrial	Sheet runoff + spray drift (1%)	0.18	9.5
		Semi-aquatic	Channelized runoff + spray drift (1%)	1.3	66

The RQs are between 9.5 and 88. These are very high, especially when considering that the effect being considered is mortality to 25% of the population rather than just a 25% decrease in growth. The use of thiobencarb on celery, lettuce, and endive will likely kill emerging seedlings of sensitive species of terrestrial and semiaquatic plants.

Use of thiobencarb on nonrice crops may also expose mature plants by way of spray drift. The Agency calculated risk quotients by dividing the EECs by the vegetative vigor EC_{25} for the most sensitive of the test species. The vegetative vigor EC_{25} for the most sensitive species, ryegrass, is 0.073 lb ai/A. Only ground application is permitted for these uses, for which the Agency assumes that the EEC for offsite areas is 1% of the application rate. For application on celery at the maximum label rate of 8 lb/A, the EECs is 0.08 lb ai/A and the RQ is 1.1. For application on lettuce and endive at the maximum label rate of 6 lb/A, the EEC is 0.06 lb ai/A and the RQ is 0.82. The RQs for lettuce and endive does not exceed the LOC of 1 for presuming risk. Although the RQ for use on celery slightly exceeds the LOC, the magnitude of the RQ is low compared to those calculated previously for emerging seedlings. The risk assessment indicates that use of thiobencarb on celery, lettuce, and endive in Florida poses a high risk to nontarget terrestrial and semiaquatic plants, primarily through exposure from runoff and drift to emerging seedlings. The risk posed by exposure to vegetation by spray drift is comparatively low.

(b) Aquatic Plants

Exposure to nontarget aquatic plants may occur through runoff and spray drift from adjacent treated sites. A risk assessment for aquatic vascular plants was performed using duckweed (*Lemna gibba*) as a surrogate species. A risk assessment for nonvascular aquatic plants was performed using green algae (*Kirchneria subcapitata*), which was the most sensitive nonvascular test species. Runoff and drift exposure to aquatic plants was based on actual measurements from water samples for rice uses and GEECs estimated by the GENEEC program [see section 3.a(2)] for Florida vegetable uses. For the latter, risk quotients were determined by dividing the day-0 GEEC in water by the plant EC_{50}.

The concentrations of thiobencarb measured in aquatic habitats in the two biological field studies were many times greater than the EC_{50} for green algae (17 ppb). The maximum residue measured in Halls Bayou after a heavy rainfall was 690 ppb, and residues measured in Halls Bayou at other times that were not associated with a heavy rainfall event were as high as 83 ppb. This suggests that the risk quotient for green algae is in the range of 5 to 41. The field study done near Matagorda found thiobencarb concentrations as high as 21 ppb, which yields a risk quotient of 1.2. All of these results lead to the conclusion that use of thiobencarb on rice in the southeast regions poses a high risk of harming algae in aquatic habitats.

Use of thiobencarb on water-seeded rice in California is predicted to pose less of a chronic risk to aquatic plants than in the southern rice-growing regions. Water sampling

from the Sacramento River and San Juaquin River show that thiobencarb concentrations never exceeded 1 ppb. Thiobencarb concentrations in these rivers are not expected to approach levels toxic to algae. In contrast, concentrations measured in smaller waterways that feed into the Sacramento River occasionally approached or exceeded the algae EEC of 17 ppb (Table B). These results indicate that the use of thiobencarb in California poses some risk of affecting algae in the smaller waterways, but minimal risk to algae in the larger rivers.

The EC_{50} for duckweed is 770 ppb. This indicates that the toxicity of thiobencarb to vascular aquatic plants is low relative to the aquatic EECs for rice. However, the Agency believes that the phytotoxicity test with duckweed poorly represents the toxicity of thiobencarb to many aquatic vascular plants. The seedling emergence studies indicate that grasses are highly sensitive to thiobencarb. Duckweed is not a good surrogate for aquatic grasses and sedges. Duckweed is a dicot with primitive vascular structure, whereas aquatic grasses and sedges are monocots with advanced vascular structure. Furthermore, the primary phytotoxic effect of thiobencarb is inhibiting shoot growth of immature plants. The aquatic plant test with duckweed does not address toxicity through this mode of action. The Agency was unable to perform a reliable risk assessment for the effects on emerging vascular aquatic plants. However, since thiobencarb is used to control the growth of aquatic weeds in rice fields, the Agency assumes that thiobencarb residues discharged into aquatic habitats poses a risk of killing emerging seedlings of vascular aquatic plants that are sensitive to thiobencarb. The risk appears to be greatest to aquatic grasses. Risk to mature aquatic vascular plants is predicted to be minimal.

For other uses of thiobencarb, risk quotients for aquatic plants are given below.

Table 40. Risk Quotients (RQs) for Aquatic Plants Based on a the EC_{50} of Green Algae (*Selenastrum capricornutum*).

Use Site	Use Rate (LB/A)	Test Species	EC_{50} (ppb)	EEC (ppb)	RQ (EEC/EC50)
Celery (FL)	8	Green algae	17	186	10.9
Lettuce and endive (FL)	6	Green algae	17	140	8.2

These results indicate that use of thiobencarb on vegetables in Florida at the maximum label rate poses a high risk to nonvascular aquatic plants. As with use on rice, the Agency assumes that thiobencarb residues that may reach aquatic habitats by drift and runoff pose a risk of killing emerging seedlings of vascular aquatic plants that are sensitive to thiobencarb.

(5) Endangered Species

The above risk assessment indicates that use of thiobencarb on rice poses a risk to threatened and endangered species (TES) of birds, mammals, fish, and aquatic invertebrates (including crustaceans and mollusks). The greatest risk is from chronic effects, although some risk of acute effects exists for all of these animals except birds.

Use of thiobencarb on rice also poses a risk to T & E Species of plants. All types of applications may harm aquatic plants, whereas only aerial applications of liquid formulations are expected to harm terrestrial and semiaquatic plants when thiobencarb is used according to label directions.

Use of thiobencarb on lettuce, endive, and celery in Florida may harm all types of threatened or endangered species (birds, mammals, fish, aquatic invertebrates, and all types of plants). In 1985, the USFWS declared jeopardy from use on Florida vegetables to the Snail Kite, but not to the Wood Stork or Bald Eagle; the jeopardy opinion for the Snail Kite was reversed to non-jeopardy in 1987 after additional data were available.

In 1988, the USFWS determined that use of thiobencarb on rice in Arkansas may jeopardize the fat pocket pearly mussel (*Potamilus capax*). The current label for Bolero 8EC contains use prohibitions to protect this species. These use prohibitions apply to the Arkansas counties of Mississippi, Poinsett, Cross, St. Francis and Lee where the Fat Pocketbook Mussel is known to occur. Comparable warnings would be appropriate where use on rice can expose other threatened and endangered mussels. In 1987, the USFWS determined that, because thiobencarb is not as toxic to the apple snail as to other aquatic invertebrates, it is not expected to jeopardize the Everglades kite.

The Endangered Species Protection Program currently includes use limitations to protect mussels associated with certain rice areas. In some cases, (e.g., Arkansas), label requirements exist; in other areas, voluntary use limitations are being expressed in county bulletins being distributed to pesticide users until the program becomes final. California and Florida have state-initiated plans that would be expected to protect any listed species in those states. Additional use limitations for other species and areas are expected, but these have not yet been defined and may be formulation specific. Some use limitations could be developed by the Agency, but additional consultations with the USFWS may be necessary. Registrants will be informed if any label changes are necessary.

4. Risk Characterization

a. Extent of Use

The Biological and Economical Assessment Division estimates that approximately 1,190,000 lb of thiobencarb active ingredient are applied on rice annually. Use on rice is divided into three general areas: the Gulf Coast (Texas and Louisiana), the Mississippi River Valley (Arkansas, Mississippi, Louisiana, and Missouri) and the Sacramento and San Joaquin River Valleys in California. A small amount of rice is also grown in Palm Beach and Hendry Counties, Florida.

A much smaller use of thiobencarb is on celery, lettuce, and endive in Florida. The estimated annual use of thiobencarb on these crops is approximately 30,000 lb ai. The majority of these crops are grown in Palm Beach County.

b. Summary of Risk Assessment

Thiobencarb poses a risk not only to nontarget plants (as do most herbicides) but also potentially significant risk to many aquatic habitats and terrestrial wildlife. The ecological risks of the various uses are summarized below.

- Use of liquid formulations pose some acute risk to mammals. The acute risk to birds is minimal.

- Use of liquid formulations pose a high **chronic** risk to birds and mammals. The chronic risk from granular formulations could not be assessed.

- Use of thiobencarb on rice in the southeast US poses a high risk of chronic effects to freshwater and estuarine aquatic invertebrates, including shrimp and mollusks. There is also likely a high risk of chronic effects to fish, but additional data are needed to confirm this. This use of thiobencarb also poses a high risk of acute effects to fish and aquatic invertebrates in certain high-exposure situations.

- Use of thiobencarb on rice in California poses a risk of causing chronic effects to aquatic organisms in the smaller drains and waterways, but not in the larger rivers. Its use poses minimal risk of acute effects to fish and aquatic invertebrates. Minimal risk of both acute and chronic effects is expected for all estuarine organisms in California.

- Spray drift from aerial application of liquid thiobencarb on rice poses a high risk to nontarget terrestrial and semiaquatic plants. Drift of granular thiobencarb and spraying of liquid thiobencarb applied with ground equipment pose minimal risk to these plants.

- All uses of thiobencarb on rice may pose a risk of killing emerging seedlings of aquatic plants, especially aquatic grasses. Use of thiobencarb on rice may pose a risk to aquatic algae in the southeast US and in smaller drains and waterways in California.

- Use of thiobencarb on celery, lettuce, and endive in Florida poses a high risk of causing chronic effects to fish, freshwater invertebrates, and estuarine invertebrates, including shrimp. Additionally, this use poses a high risk of causing acute effects to freshwater and estuarine invertebrates, including oysters and shrimp.

- Use of thiobencarb on celery, lettuce, and endive in Florida poses a high risk to terrestrial plants, semiaquatic plants, and algae. It may also pose a risk to emerging seedlings of vascular aquatic plants.

c. Impacts to Water Resources

(1) Ground Water

Although thiobencarb does exceed several of the criteria for the proposed ground water restricted use rule, the Agency does not consider thiobencarb to be a candidate for restricted use due to ground water concerns. The Agency does not consider use of thiobencarb to be a concern in ground water, nor a human health concern from residues in drinking water that are derived from ground water.

(2) Surface Water

Detections of thiobencarb in water samples were relatively rare in the STORET database of the Office of Water, EPA. Thirty-nine positive detections were reported for 3,130 samples, with a maximum concentration of 0.24 mg/L and a mean concentration of 0.10 mg/L. Surface water concentrations measured in biological field studies were several orders of magnitude greater than this. The field study measurements were taken in surface water that was immediately adjacent to rice fields and were taken soon after thiobencarb was applied. This suggests that high levels of contamination of thiobencarb in surface water is limited to local areas and for brief time periods.

Unlike the filtered sample results reported in STORET, results reported in the biological field studies may have been from unfiltered samples. As thiobencarb tends to partition more into sediment than water, the presence of suspended sediment in the water samples may have contributed to higher concentrations being reported in the field studies than in the STORET database.

Aquatic EEC modeling for lettuce, endive and celery uses estimated relatively high levels of contamination in surface water. The range of aquatic EECs was 140 mg/L for the 6 lb a.i. application rate and 180 mg/L for the 8 lb a.i. application rate. Thiobencarb is expected to dissipate in pond water at an approximate rate of 0.4-0.6 mg/L/day.

d. Environmental Fate and Risk Characterization

(1) Rice in Southeastern United States

(a) Terrestrial Ecosystems

The main risk from thiobencarb to terrestrial vertebrates (birds, mammals, reptiles, and terrestrial stages of amphibians[7]) is from reproductive and chronic pathological

[7] No data were available for reptiles or amphibians; therefore, risk to these organisms is inferred from the assessment of risk to birds and mammals.

effects. The risk assessment for mammals determined that there is also a risk of acute mortality from all uses of thiobencarb. However, maximum acute RQs for mammals range from less than approximately 0.5 for use on rice to slightly greater than 1 for use on celery. These RQs are much smaller than those for risk of chronic effects to these organisms. In general, the impact to terrestrial ecosystems from acute effects is expected to be of little significance, whereas the impact from chronic effects is considered to be of greater significance.

Use of thiobencarb in the southeast is expected to harm terrestrial vertebrates by causing chronic physiological effects and, in the case of birds, impairing reproduction. The levels that cause chronically toxic effects in both birds and mammals were quite low for a pesticide that is used at high rates (4 to 8 lb ai/A). Furthermore, thiobencarb does not degrade rapidly in the terrestrial environment. The combination of these factors result in EECs remaining at levels that may cause chronic effects for several weeks (Tables B and C). While reproductive and other sublethal effects may result from ***short-term*** exposures (one week or less), there is higher certainty that these longer-term exposures will cause these effects. Also, the longer exposure in the environment allows greater opportunity for more organisms to be exposed.

The Biological and Economic Analysis Division (BEAD) estimates the typical use rate of thiobencarb on rice is 3 lb ai/A. Compared to the maximum label rate, use at this rate would decrease exposure levels, and thus the risk quotients, by 25%. Chronic risk quotients for birds and mammals would still be great enough to indicate a high chronic risk.

The timing of application of thiobencarb on rice in the southeast region is from March through June. This corresponds with the breeding season of birds and mammals. Avian reproduction studies have shown that thiobencarb may decrease the number of eggs laid or chicks hatched at dietary concentrations that are similar to environmental concentrations expected in some wildlife food. It thus appears likely reproduction could be impaired in birds that feed in rice fields that have been sprayed with thiobencarb.

For the reasons stated above, the chronic risk to terrestrial organisms is characterized as "high". It is not characterized as "very high" because thiobencarb is only moderately persistent in terrestrial environments and its bioaccumulation is only moderate. Also, except for flooded fields in Louisiana, the use of rice fields by wildlife is not expected to be great during the spring in the Southeast (Gusey and Maturgo, 1973).

Another threat to terrestrial ecosystems in the southeast region is the potential harm to nontarget plants. In this area, thiobencarb is usually applied in a liquid EC formulation which may be sprayed from either aerial or ground equipment. Spray drift from aerial applications are predicted to pose a high risk to some nontarget terrestrial and semiaquatic plants. This may degrade the quality of habitat close to rice fields. This risk may be minimized by applying thiobencarb with ground equipment.

(b) Aquatic Ecosystems

Acute Risk to Fish and Invertebrates

Rice is grown along the Gulf coasts of Texas, Mississippi, and Alabama, often in areas extending many miles inland, as well as in Palm Beach and Hendry counties in Florida. Data from the U.S. National Climatological Data Center (USNCDC) indicates that rainfall in this area is typically around 60 inches per year and that storms of three inches or more occur about once per month. The rice farmer cannot always retain this volume of water on the paddy[8]. Therefore farmers might apply thiobencarb one day and be forced to release it through the drain gate the next due to unforeseen heavy rains.

Discharges from rice fields following heavy rain events are expected to result in several hundred parts per billion of thiobencarb for short durations in some small estuaries and streams. Monitoring data is available (Section C.1.b.7) showing that these discharges can raise water concentrations in biologically productive estuaries to levels exceeding the LC_{50}'s for fish and aquatic invertebrates. In general, the Agency would expect fish kills and invertebrate kills due to acute exposure to be localized and to be confined to bodies of water near rice fields that have little flow or tidal flushing.[9] During the Matagorda study, there was a fish kill involving menhaden in such an area. The flesh residues of thiobencarb in these fish indicate that thiobencarb may have caused the kill. However, since other pesticides were being used in the area, it is not certain that thiobencarb was the sole cause. The Agency knows of no other fish kills that have been linked to thiobencarb. There is no evidence to suggest that acute risk to fish is a major, widespread problem.

The acute toxicity of thiobencarb to aquatic invertebrates is about the same as that for fish. Some acute mortality of crustaceans[10] and oyster larvae may occur in localized areas near rice fields where high levels of contamination may occur after heavy rainfall. The toxicity to other invertebrates such as corals and jellyfishes (phylum: coelenterata), rotifers (phylum: rotifera; protozoan like organisms which are abundant in freshwater) has not been determined.

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[8] The rice plant is particularly sensitive to flooding when the stem is long and thin soon after germination. At that time the farmer would try to maintain the water level between 4 to 8 inches. (Personal comm., Dr. Steve Linscombe, LSU).

[9] The rate of flushing refers to how quickly the action of tide and freshwater inputs will purify the estuary. In the Gulf Coast, the difference between high and low tides is only about two feet, which is quite small compared to California or the Northeastern Coast.

[10] Subphylum crustacea, which is comprised of such common animals as shrimps, amphipods(scuds), and copepods, is the most numerous of the marine planktonic animals.

Rice is also grown in the Mississippi River Valley. Rainfall data from Little Rock, Arkansas, which is near that state's rice growing area, indicate that the rain may also be heavy in this area; however, the rainfall patterns are somewhat more predictable than in the Gulf area. Because unpredictable spring thunderstorms are less numerous in this region than on the Gulf Coast (Dr. Robert Rohli, personal communications, LSU), acute risk to aquatic life resulting from heavy rainfall events would be less here than in the Gulf Coast area.

Chronic Risk to Fish and Invertebrates

Exposure to thiobencarb poses extremely high chronic risk to aquatic organisms, especially for estuarine and freshwater crustaceans in the Gulf Coast region. As mentioned above, heavy rains may result in thiobencarb concentrations in aquatic habitats which greatly exceed chronic toxicity levels of crustacea. Monitoring data from Halls Bayou found concentrations in water at the point of inflow from ricefield drainage of several hundred ppb. This far exceeds the EC_{05} for chronic effects[11] of around 10 ppb for the mysid, and the chronic MATC for the opossum shrimp of 4.5 ppb. High levels are expected to persist long enough in some areas to cause chronic effects. Clearly, the chronic risk to shrimp and other crustaceans is very high and there is potential for high impact on these populations (See Risk to Economically Important Organisms, below). There are also many other types of invertebrates that are important components of the estuarine ecosystem, such as worms (annelids), jellyfishes, and rotifers. The chronic toxicity of thiobencarb has not been tested in these species, but it quite possible that thiobencarb would negatively affect their reproduction as it does to crustaceans.

Many species of estuarine crustaceans and other invertebrates are potentially vulnerable to the chronic toxicity of thiobencarb. For example, there are over 100 species of shrimp alone in the Gulf. These creatures would presumably be very vulnerable when they are in estuaries and bayous surrounded by rice fields. For reasons not fully explained, young shrimp mass in the estuaries and streams of the Gulf Coast in the Spring. This is the time when thiobencarb is being applied (see below). Also at great risk are many other crustacean species which are year-round residents in estuaries, including mysids, young blue crabs, many grass shrimp (*Palaemonetes* sp), amphipods (scuds), and isopods (saltwater species related to the garden "sow bug"). These invertebrates serve an important ecological role because they form a fundamental component of the food web. They are important forage for young fish which use estuaries as feeding grounds. Fish whose food web would thus be at stake include drums (e.g., redfish and croaker) and flounder.

Thiobencarb may also harm freshwater in the Southeast. A study submitted to fulfill a test requirement of the Health Effects Division (Guideline Number 171-4f, MRID

[11] The EC_{05} for chronic effects is the concentration that, based on effects observed in laboratory tests, is predicted to cause a 5% reduction in the reproductive parameters in mysid. This level was estimated using nonlinear regression.

43404003) provides information that is useful for assessing ecological impacts to these habitats. This study measured residues of thiobencarb in natural freshwater habitats receiving discharges from rice fields in Arkansas and Texas. In both areas, thiobencarb was applied at approximately the maximum label rate of 4 lb ai/A. In the Arkansas, residue levels measured in Bayou Bartholomew remained low, less than 1 ppb. In Texas, however, much greater residues were measured in West Bernard Creek. Residues measured at one sample point (EB1) remained greater than 1 ppb for 30 consecutive days. At another sample point (EB3), residues were at or greater than 4 ppb for 18 consecutive days. The concentration profiles in West Bernard Creek were also characterized by peaks of higher residues levels that were associated a flush and a rainfall event. During these peaks, concentrations of 20 to 42 ppb were measured for one to three consecutive days. As the reproduction of the waterflea, *Daphnia magna*, has been shown to be adversely affected by 21-day exposures as low as 3 ppb, it is clear that the chronic risk to invertebrates in West Bernard Creek would be high. Thus, this study corroborates our conclusion that the use of thiobencarb on rice in the Gulf coast area poses a high risk to freshwater invertebrates and thereby could cause serious harm to freshwater ecosystems.

Risk to Economically Important Organisms

Pink shrimp (*Penaeus duroarum*), brown shrimp (*Penaeus aztecus*), and white shrimp (*Penaeus setiferous*) make up the bulk of the commercial shrimp harvest in the United States. (These and other species in the family Penaeidae are commonly referred to as "penaeids".) The largest harvests are of the brown shrimp. In total, hundreds of millions of tons of shrimp are taken by U.S. ships in the Gulf of Mexico. Overall the shrimp industry is worth billions of dollars to the economy of this country[12].

The natural history of the three commercial shrimp species puts them into a position to receive maximal concentrations of thiobencarb. They breed offshore with each of the females shedding thousands of demersal (sinking) eggs. After hatching, the shrimp larvae and postlarval stages are planktonic. The postlarvae utilize multiple stimuli, including diminished salinity and variations in light, to position themselves in currents so as to be carried into estuaries. In the estuaries they metamorphose to become benthic (bottom dwelling) juvenile shrimp. Some young shrimp are particularly at risk because they migrate for miles up streams that feed the estuaries, even into freshwater[13]. Given that these streams would often be surrounded by rice farms, there is a great hazard to these young shrimp.

Rice growers typically apply thiobencarb beginning in April and ending around June. The young sensitive stages of the commercial shrimp may be exposed to release of

[12] Economic information provided by Mr. Larry Simpson Director of the Gulf States Marine Fisheries Commission, Ocean Springs, MS.

[13] Information provided by Dr. T. Minello, National Marine Fisheries Service, Galveston, TX.

thiobencarb in tailwaters, particularly around June, when the arrival of the planktonic larvae begins in the estuaries of the Gulf. The exposure of young commercial shrimp would probably continue beyond June as thiobencarb is considered to be at least moderately persistent in some conditions. In habitats with high turbidity or deep water, the lack of penetration of light could make the rate of photolysis considerably slower than was measured in the laboratory. In these environments, thiobencarb might remain associated with sediments and organic matter on the bottom for several weeks. Being that the juvenile shrimp are benthic, they would be exposed to these contaminated sediments.

The case regarding chronic toxicity to penaeid shrimp is considered strong. However, there is some uncertainty in that the exposures observed in the field are of shorter duration than those in chronic laboratory tests. Even the shortest chronic marine crustacean tests are 28 days long. Monitoring data from all site (other than the flooded paddies themselves) do not show continuous aquatic residues in the range of the mysid LC_{05} (approximately 9 ppb) for a duration this long. On the other hand, it is impossible to know whether the full 28 days are required for adverse effects to occur. Therefore, it is prudent to assume exposure to shrimp and other crustaceans represent a high risk of chronic effects.

Risk to Aquatic Plants

The risk of thiobencarb to aquatic plants is uncertain. Although highly toxic to nontarget plants, thiobencarb appears to act mainly through preventing seed germination and/or early seedling growth. The reproduction of some aquatic plants, especially annuals that reproduce mainly through seeds, may be at risk. This may cause some damage to vegetation growing along the edge of waterways where thiobencarb is discharged.

Thiobencarb is quite toxic to some algae including the very important green algae. There is a high risk of thiobencarb causing some effects, but our current algae toxicity studies cannot be used to judge whether the effects would have permanent impacts on algae populations.

(2) Rice in California

(a) Terrestrial Ecosystems

In the California rice-growing region, thiobencarb is applied mainly in granular form to flooded rice fields. This use of granular thiobencarb is not expected to pose a significant acute risk to birds and mammals. Because of the relatively low toxicity to mammals, the mass of granules required to equal an LD50 substantially reduces the likelihood of significant acute risk to mammals. For example, based on the rat oral LD_{50} of 1080 mg ai/kg, a 100-g mammal has a 50% probability of being killed if it ingests approximately 110 mg of active ingredient in one day. Since thiobencarb granules contain 10% active ingredient, this is equivalent to ingesting 1.1 g of granules in one day. This

is much more than a mammal of that size would be expected to ingest incidentally while foraging. Furthermore, most of the granular product would land in standing water and thus would not be available to mammals foraging on land. There is also some use of liquid thiobencarb in California for rice grown with pin-point flood culture. The acute risk from this use would be similar to that for the southeastern region, that is, there would be an acute risk to mammals but not to birds.

All uses of thiobencarb in California potentially pose a high risk of causing reproductive and chronic physiological effects in terrestrial vertebrates. The characterization of chronic risk from the use of liquid thiobencarb in California is identical to that described above for the Southeast. For use of granular thiobencarb on flooded rice fields, a quantitative assessment of chronic risk could not be performed; however, the Agency considers that exposure of terrestrial vertebrates to granular thiobencarb poses a chronic risk. The numerous waterfowl and wading bird species that breed in flooded rice fields of California[14] could be adversely affected if they are exposed . The active ingredient should rapidly dissipate from the pesticide granules once it enters a body of water. Therefore, granules that fall in the flood water should not pose a hazard to terrestrial organisms. However, some granules also will fall on the ground and in vegetation on levees and around the edges of rice paddies. Birds may intentionally ingest these granules for grit. Many birds pick up grit, which helps to grind food in the gizzard. Birds and other terrestrial animals may also ingest granules, contaminate food items, and contaminated soil when foraging for food on the levees and field edges. Birds, mammals, reptiles, and amphibians that live in the water would also be exposed to thiobencarb dissolved in the water through dermal absorption and by drinking, although the concentrations in water are expected to be relatively low.

The granular formulation of thiobencarb uses a clay carrier. Best and Gionfriddo (1994) found that house sparrow were less likely to ingest granules made of clay, corncob, or gypsum than those made of silica. However, further studies under different conditions showed conflicting results. Stafford et al. (1996) found that the hazard to house sparrows was no greater for silica granules than for clay granules. Compared to clay granules, granules made from corncobs were found to pose less risk to house sparrows when abundant food was provided (Stafford et. al, 1996), but greater risk when food was restricted (Stafford and Best, 1997). The relative hazard of clay, silica, and corncob granules is dependent on soil moisture and weather conditions, and thus cannot be generalized. There is not sufficient evidence to conclude that the use of clay as a granular carrier either increases or decreases the hazard of granular thiobencarb to birds compared to if silica or corncob carriers were used.

[14] Waterfowl species that breed in the California rice-growing region include the mallard, wood duck, cinnamon teal, northern shoveler, gadwall, redhead, ruddy duck, pied-billed grebe and eared grebe. Breeding wading bird s include the great egret, snowy egret, green-backed heron, black-crowned night heron, Virginia rail, sora rail, common moorhen, American coot, black-necked stilt, and American avocet.

Avian reproductive effects observed in laboratory tests were associated with long-term exposure to thiobencarb for approximately 20 weeks. Exposure in the wild via ingestion of granules likely would be for a much shorter duration. Thiobencarb is applied only once a year, and rainfall will cause the active ingredient to wash out of the granules and cause the granules to become incorporated into the soil. These factors would cause the exposure from granules to be relatively short-lived. Some hazard would remain from ingestion of contaminated soil and vegetation, but these routes of exposure are likely less important than direct ingestion of granules. It is thus uncertain if the exposure from granular applications of thiobencarb would be long enough or great enough to cause reproductive impairment in birds.

The predominance of the use of the granular formulation in California reduces the risk of harming nontarget terrestrial and semiaquatic plants. Granules generally will fall rapidly from the air without drifting to off-site habitats. Also, as discussed in the risk assessment, the presence of levees around rice fields precludes exposure from runoff into terrestrial habitat. The Agency therefore assumes minimal exposure, and hence minimal risk, to nontarget terrestrial and semiaquatic plants from the use of granular thiobencarb in California. Aerial application of liquid thiobencarb on rice with pin-point flooding is predicted to pose a high risk to these plants; however, this is currently a minor type of use in California.

(b) Aquatic Ecosystems

The state of California has vast acreage of rice in the Sacramento River Basin and some acreage in the San Joaquin River Basin. The State has imposed mandatory holding periods before treated water from farms can be discharged. Holding periods are practical in California because rainfall is quite low and emergency discharges of flood water are generally unnecessary. Monitoring of California waterways indicate that water concentrations of thiobencarb rarely reach toxic levels in agricultural drains and never approach toxic levels in the Sacramento and San Joaquin Rivers. Therefore, the Agency concludes that risk to aquatic habitats in California is limited to these agricultural drains in areas with intensive rice production.

(3) Vegetables in Florida

(a) Terrestrial Ecosystems

Thiobencarb is registered for use on celery, lettuce, and endive in Florida. The maximum use rate for these crops is 50-100% greater than that for rice. The risk posed to terrestrial and aquatic organisms is likewise greater. Although these uses are limited in area, the risks they pose to local terrestrial and aquatic ecosystems are extremely high.

Use of thiobencarb on lettuce, celery, and endive poses a risk of causing acute effects to mammals. This risk is somewhat more significant for these crops than for rice.

The risk is highest for use on celery, for which the maximum EEC on food items exceeds the estimated rat LC_{50}. Nevertheless, since the RQs are not very large (about 1 or less), this risk is characterized as low to moderate.

In contrast, the risk of reproductive and chronic effects to terrestrial vertebrates is very high. On lettuce, chronic RQs are as high as 14 for birds and 72 for mammals. RQs are even greater for celery, as high as 19 for birds and 57 for mammals. Because thiobencarb is moderately persistent in the terrestrial environment, the high risk from a single application is predicted to persist for one to two months (Tables E and H). The long duration of this exposure increases the certainty that chronic effects will occur, and also provides a greater opportunity for more organisms to be exposed.

Birds, mammals, and reptiles will likely be exposed as they feed in and around these fields. The greatest exposure would likely be to resident ducks and geese and herbivorous small mammals. Because thiobencarb is applied during the spring, these animals would be exposed during the time of breeding. Therefore, serious impairment of reproduction may occur.

For the above reasons, the Agency characterizes the chronic risk to terrestrial vertebrates from use of thiobencarb on celery, lettuce, and endive as very high.

Use of thiobencarb on celery, lettuce, and endive is expected to result in little exposure to nontarget plants from spray drift because aerial application is not allowed on these crops. Nevertheless, the risk assessment indicates that spray drift from ground applications of thiobencarb on celery at 8 lb ai/A poses a risk of harming the vegetative vigor of nontarget plants. As the RQ was very close to 1, this risk is considered to be of minor importance.

The primary mode of action of thiobencarb in controlling weeds is killing weeds before they emerge. Not surprisingly, then, thiobencarb poses a high risk to emerging seedlings of nontarget plants. Unlike use on rice, use of thiobencarb on vegetable crops in Florida may contaminate soil in off-site terrestrial habitats through runoff. Seedling emergence phytotoxicity studies have shown that some plants, especially grasses, are highly sensitive to thiobencarb at the seedling stage. The primary endpoint affected appears to be mortality of the plant rather than just reduction in growth. Furthermore, the EECs are 5 to 44 times greater than the level predicted to kill 50% of seedlings (i.e. the LC_{50}) of sensitive plants. These results indicate that thiobencarb will kill most or all of the emerging seedlings of sensitive plants exposed to levels equivalent to the EEC.

The exposure to nontarget terrestrial and semiaquatic plants is predicted to occur more from runoff than from spray drift. The exposure from runoff may be overestimated because thiobencarb has a high potential to bind to soil over time. The model used in the risk assessment does not take this soil binding into account. If rainfall occurs within a day or two after application, then exposure from runoff would be great and the high risk

predicted by the risk quotients probably would be accurate. If rainfall does not occur for several days, however, then much of the chemical would be bound to the soil at the site of application and would not be transported by runoff. The Agency still believes that a high risk to these plants exists because the RQs are quite high and because heavy rain is frequent and unpredictable in Florida.

The ecological impact of killing emerging seedlings of nontarget plants is largely unknown. Frequent exposure within a given area to a herbicide of this nature may potentially reduce the number of sensitive plants such as annual grasses. This may alter the composition of the plant community, which may cause unpredictable effects on the ecosystem.

(b) Aquatic Ecosystems

Thiobencarb is used on lettuce, endive, celery and rice in Florida. The total acreage of these crops in Florida is probably less than 40,000 acres (1992 Census of Agriculture). Runoff to surface water will likely cause aquatic concentrations that greatly exceed the Levels of Concern for crustaceans and perhaps fish. Given the very small number of acres on which this pesticide is applied in Florida, risk to aquatic organisms should be quite localized; however, the impact to aquatic habitats within these local areas is likely to be severe.

Most of the use of thiobencarb in Florida is concentrated in Palm Beach and Hendry Counties. These counties lie on the northern edge of The Everglades. Water draining from agricultural fields treated with thiobencarb may be contributing to the degradation of water quality of northern sections of this very important habitat, including the Loxahatchee National Wildlife Refuge in Palm Beach County. Water samples are being collected along the Hillsboro canal in Palm Beach counties as part of the NAWQA Program of the USGS. Once completed, these data should indicate the degree that thiobencarb residues are contaminating the Loxahatchee National Wildlife Program and the northern everglades.

(4) Threatened and endangered species

Protecting threatened and endangered species from thiobencarb will be unusually difficult. Adverse effects are possible for many types of plants and animals. Probably the greatest threat from thiobencarb is to aquatic organisms in freshwater and estuarine habitats near areas with extensive rice production, or near large celery, lettuce and endive farms in Florida. Thiobencarb can clearly cause direct detrimental effects to aquatic organisms, especially small invertebrates. Additionally, thiobencarb may reduce the abundance of phytoplankton and zooplankton which form the base of aquatic food webs. This may cause additional indirect effects to animals at higher trophic levels. It is therefore important that thiobencarb be prevented from contaminating occupied habitats of threatened and endangered aquatic species. Finally, extreme care should be taken to

prevent contamination of the habitat of threatened and endangered plants that occur in areas of Florida where celery, lettuce, or endive is grown.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing thiobencarb active ingredients. 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 thiobencarb. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of thiobencarb, 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 thiobencarb and to determine that thiobencarb can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that at this time all products containing thiobencarb as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient in this case, the Agency has sufficient information on the health effects of thiobencarb, but has certain limitations on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that thiobencarb products, if labeled and used

as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality and Protection Act of 1996, the Agency has determined that there is reasonable certainty that no harm will result to infants and children or the general population from aggregate exposure to thiobencarb. Therefore, the Agency concludes that all products containing thiobencarb are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of thiobencarb are eligible for reregistration subject to conditions imposed in this RED.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Populations

EPA has determined that the established tolerances for thiobencarb meet the safety standards under the FQPA amendments to Section 408 (b)(2)(D) for the general population. In reaching this determination, EPA has considered available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from thiobencarb and other chemicals with a similar mechanism of toxicity.

Since there are no residential or lawn uses of thiobencarb, no dermal or inhalation exposure is expected in and around the home. No acute toxicity endpoints of concern have been identified for thiobencarb.

In assessing chronic dietary risk , EPA estimates that thiobencarb residues in food sources account for $\leq$ 42.9 percent (%) of the RfD, and includes the highest-at-risk subgroup, non-nursing infants. In drinking water thiobencarb residues account for 0.29 percent (%) of the RfD. Thus, the aggregate exposures from all sources of thiobencarb (in this case, only dietary and drinking water exposures are relevant) account for 43.2 percent (%) of the RfD. Therefore, the Agency concludes that aggregate risks for the general population resulting from thiobencarb uses are not of concern.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for thiobencarb meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children.

The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to toxic effects of thiobencarb residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from thiobencarb residues, EPA considered the completeness of the data base for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on current data requirements, thiobencarb has a complete data base for developmental and reproductive toxicity. In the developmental studies, effects were seen in the fetuses only at the same or higher dose levels than effects on the mothers. In the reproduction study, no effects on reproductive performance were seen. EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, the Agency has no epidemiological information suggesting special sensitivity of infants and children to thiobencarb. Therefore, EPA finds that an additional uncertainty factor is not warranted for assessing the risks of thiobencarb.

EPA estimates that thiobencarb residues in the diet of infants and children account for 42.9 percent of the RfD (29.5 for children 1-5) and residues in drinking water account for 0.29 percent of the RfD. Thus the aggregate exposure from all sources of thiobencarb account for 43.2 percent of the RfD for infants and children. Therefore, the Agency concludes that aggregate risks for infants and children resulting from uses of thiobencarb are not of concern.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

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

2. Risk Mitigation

To lessen worker risk, and ecological and water quality risks posed by thiobencarb, EPA is requiring the following mitigation measures from registrants of thiobencarb-containing products.

- *To protect handlers:*

    - For liquid formulations: mixers and loaders must used closed systems in addition to wearing a chemical-resistant apron, chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks. Applicators and flaggers must use enclosed cabs or cockpits and wear long-sleeve shirt, long pants, shoes, and socks.
    - For granular formulations: loaders must wear a chemical-resistant apron, chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks. Applicators and flaggers must wear chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks.

- *To protect workers:*

    - A restricted-entry interval of 24 hours is being imposed. Early entry workers must wear coveralls, chemical-resistant gloves, shoes, and socks.

- *To protect non-target organisms:*

    - Application restrictions are being mandated in the states of Louisiana and Texas. In Louisiana, thiobencarb application will not be allowed south of the Intracoastal Waterway. In Texas, thiobencarb application will not be allowed within two miles inland from the shorelines of Galveston Bay, and not within two miles of Matagorda Bay.
    - Include label warnings preventing application to rice fields with catfish/crayfish farming, and preventing application to rice fields adjacent to catfish or crayfish ponds.
    - Where weather conditions permit, it is required that flood waters not be released within 14 days.
    - Require that thiobencarb not be applied within 24 hours of rainfall, or when heavy rain is expected to occur within 24 hours.
    - Require that thiobencarb not be mixed/loaded or otherwise handled within 100 feet of aquatic habitat.
    - Continue existing label warnings addressing environmental hazards, such as restricting application aerially within one mile of the St. Francis Floodway where the Fat Pocketbook Pearly Mussel is known to occur. Comparable warnings would be appropriate where use on rice can expose other threatened and endangered mussels.
    - Work with the EPA to reassess in the Fall of 1998 thiobencarb use on leafy vegetables in Florida based on the results of the currently ongoing environmental monitoring study for muck soils in Florida from the U.S. Geological Survey's National Water Quality Assessment Program (NAWQA).

The Agency's concerns and risk mitigation measures are discussed in more detail below.

3. Tolerance Reassessment Summary

The tolerances for plant and animal commodities listed in 40 CFR §180.401(a) and (b) are expressed in terms of the combined residues of thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moiety. A summary of thiobencarb tolerance reassessments is presented in Table 41.

a. Tolerances Listed Under 40 CFR §180.401(a): Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities listed in 40 CFR §180.401(a): cattle, fat; cattle, mbyp (meat byproducts); cattle, meat; eggs; goats, fat; goats, mbyp; goats, meat; hogs, fat; hogs, mbyp; hogs, meat; horses, fat; horses, mbyp; horses, meat; milk; poultry, fat; poultry, mbyp; poultry, meat; rice, grain; rice, straw; sheep, fat; sheep, mbyp; sheep, and meat.

b. Tolerances Listed Under 40 CFR §180.401(b): Sufficient data are available to ascertain the adequacy of the established tolerances with regional registration in accordance with 40 CFR §180.1(n), for the following commodities listed in 40 CFR §180.401(b): celery, endive (escarole), and lettuce.

Table 41. Tolerance Reassessment Summary for Thiobencarb.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)
Tolerances Listed Under 40 CFR 180.401(a):		
Cattle (fat, meat, mbyp)	0.2	0.2
Goat (fat, meat, mbyp)	0.2	0.2
Hog (fat, meat, mbyp)	0.2	0.2
Sheep (fat, meat, mbyp)	0.2	0.2
Poultry (fat, meat, mbyp)	0.2	0.2
Horse (fat, meat, mbyp)	0.2	0.2
Eggs	0.2	0.2
Milk	0.05	0.05
Rice, grain	0.2	0.2
Rice, straw	1.0	1.0
Tolerances Listed Under 40 CFR 180.401(b):		
Celery, Lettuce, Endive (escarole)	0.2	0.2

4. Codex Harmonization

No maximum residue limits (MRLs) have been established by the Codex Alimentarius Commission for thiobencarb residues in/on raw agricultural, animal, or

processed commodities. Therefore, no compatibility questions exist with respect to U.S. tolerances.

5. Reference Dose (RfD)

The RfD/Peer Review Committee met on February 8, 1996, to discuss and evaluate the existing and/or recently submitted toxicology data in support of the thiobencarb reregistration and to reassess the RfD for this chemical.

The Committee recommended that the existing RfD for thiobencarb remain unchanged. The RfD for this chemical was based on the two-year rat feeding study (MRID# 00154506) with a NOEL of 20 ppm (1 mg/kg/day). At the next higher dose level of 100 ppm (5mg/kg/day), decreased body weights and increased blood urea nitrogen levels were observed. An uncertainty factor of 100 was applied to account for both inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated by the Committee to be 0.01 mg/kg/day.

6. Cancer Risk Assessment

The Agency has classified thiobencarb as a Group D chemical (not classifiable as to human carcinogenicity). The carcinogenic potential of thiobencarb was evaluated by the RfD/Peer Review Committee on February 8, 1996. The Committee considered the carcinogenicity phases of the combined chronic toxicity/carcinogenicity studies in rats (MRID# 00154506) and the carcinogenicity study in mice (MRID# 00086004) for carcinogenic classification.

The highest dose level tested in the rat (500 ppm, or 25 mg/kg/day) was considered to be adequate for carcinogenicity testing based on depression of cholinesterase activity and reduced body weight gain. The highest dose level tested in the mouse (1600 ppm, or 235 mg/kg/day in males and 302 mg/kg/day in females) was considered to be adequate based on body weight gain depression.

7. Occupational Exposure

At this time, all products containing thiobencarb are intended primarily for occupational use (i.e. mixed, loaded, and applied by commercial applicators only; generally not available to homeowners). No registered use is likely to involve applications at residential sites.

The Worker Protection Standard (WPS)

EPA's Worker Protection Standard for Agricultural Pesticides (WPS) affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. In general,

WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. At this time all registered uses of thiobencarb are within the scope of the WPS.

a. Handler Exposure and Risk

For each end-use product, personal protective equipment and engineering control requirements for pesticide handlers are set during reregistration as follows:

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient specific (a-i specific) handler requirements for end-use products containing that active ingredient. If such risks are minimal, EPA may choose not to establish a-i specific handler requirements.

- EPA establishes handler PPE requirements for most end-use products, based on each product's acute toxicity characteristics.

- If a-i specific requirements have been established, they must be compared to the PPE specified for the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product. Engineering controls are considered more stringent than PPE requirements.

EPA is establishing a-i specific requirements for all occupational handlers for thiobencarb. The risks to handlers from short-term exposures exceeded 100 for all scenarios with the use, in some cases, of risk mitigation measures, such as additional personal protective equipment or engineering controls. The risks to handlers from intermediate-term exposures were less than 100 even at maximum risk mitigation for several scenarios involving the liquid formulations and for loading granular formulations to support aerial application. However using its experience and expertise, the Agency has determined that risk to handlers resulting from intermediate-term exposures are acceptable, provided appropriate risk mitigation measures are taken for each formulation type.

Granular Formulations: The Agency believes the risks resulting from intermediate-term exposures to the granular formulation are overestimated due to the use of the 60.2 percent dermal absorption value for the granular scenarios. In general, dermal absorption of granular formulations has been found to be significantly lower than for liquid formulations. Therefore, the Agency has determined that risks to handlers of granular formulations will be acceptable with the addition of personal protective equipment. Handlers will be required to wear chemical-resistant gloves in addition to

baseline attire consisting of long-sleeve shirts, long pants, shoes, and socks. In addition, loaders must wear a chemical-resistant apron.

Liquid Formulations: The Agency believes that risks resulting from intermediate-term exposures to persons handling liquid formulations are overestimated due to limitations with the hazard identification and dose-response assessment for the intermediate-term endpoint, particularly in light of the absence of serious effects to these target organs in either the subchronic neurotoxicity or rat chronic feeding study, which suggest the lack of a deleterious response to thiobencarb by the kidney and/or liver. Therefore, the Agency, drawing on its experience and expertise, has determined that risks to handlers of liquid formulations will be adequately mitigated with the use of engineering controls and personal protective equipment. Mixers/loaders will be required to use closed systems and wear chemical-resistant gloves and aprons in addition to baseline attire. Applicators and flaggers will be required to use enclosed cabs or cockpits and wear baseline attire.

b. Post-Application Exposure and Risk

Restricted-entry intervals, early-entry PPE, and "double" notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REI's) for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. In addition, the WPS retains two types of REI's established by the Agency before the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces.

"Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement was imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

During the reregistration process, EPA establishes REI's, early-entry PPE, and double notification requirements based on consideration of all available relevant information about the active ingredient, including acute toxicity, other adverse effects, epidemiological information, and post-application data. EPA is establishing a 24-hour REI and the following early-entry PPE for all in-scope WPS uses of products containing thiobencarb: coveralls, chemical-resistant gloves, socks, and shoes. EPA has determined that double notification is not required.

The surrogate post-application exposure and risk assessment indicates that risks to post-application (reentry) workers should be acceptable provided entry is postponed until at least 24 hours following application. Since thiobencarb is applied early in the season, when crops and weeds are small, the agency anticipates that the dermal exposures will be relatively low. The Agency also concluded that the types of post-application tasks, including scouting, thinning, or hoeing, performed at this point in the crop cycle are not likely to result in intermediate-term exposures. The Agency also determined that early-entry personal protective equipment consisting of coveralls, chemical-resistant gloves, and socks plus shoes would be adequately protective, if workers must enter during the restricted-entry interval as permitted under the Worker Protection Standard.

c. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing thiobencarb. For the specific labeling statements, refer to Section V of this document.

8. Ecological Effects Risk Management

In general, the risk assessment showed various levels of concern (LOC) regarding chronic effects to fish and freshwater invertebrates, including shrimp and mollusks, and high risk of causing acute effects to freshwater and estuarine invertebrates. The following is a regional account of thiobencarb risk mitigation measures for ecological effects.

a. Southeastern United States (Texas, Louisiana)

Study findings indicate that the use of thiobencarb on rice in the southeast regions poses a high acute risk to estuarine fish, crustaceans (including shrimp), and mollusks at times of high exposure resulting from heavy rainfall occurring soon after application.

For acute effects to aquatic invertebrates, calculated risk quotients are 0.83 and 0.64, respectively, which are greater than the LOC for presumption of high risk, 0.5. These results indicate that the risk to freshwater invertebrates posed by use of thiobencarb on rice in the southeastern regions range from low to high, depending on the weather and local conditions. High risk probably is limited to aquatic habitats near the discharge of tailwater and during times when heavy rainfall occurs soon after thiobencarb is applied.

For chronic effects to aquatic invertebrates, based on a chronic toxicity study with the *Daphnia magna*, thiobencarb is predicted to cause chronic effects in freshwater invertebrates when concentrations remain near or above 1 to 2 ppb for an extended period of days. Aquatic residues measured during biological field studies indicate that this condition will commonly occur in areas where thiobencarb is applied. Findings indicate that use of thiobencarb on rice in the southeast regions poses a definite high risk of causing

chronic effects to freshwater invertebrates. Adverse effects to freshwater invertebrates are expected to occur frequently.

For effects to estuarine and marine organisms, based on aquatic residues measured in the biological field study at Halls Bayou, use of thiobencarb on dry-seeded rice can result in concentrations of thiobencarb of 690 ppb. This represents a near worst-case scenario when heavy rainfall occurs immediately after thiobencarb is applied. Concentrations this great would exceed the acute LC_{50} for the mysid (150 ppb) and eastern oyster (320 ppb), and would be close to the LC_{50} for the sheepshead minnow (660 ppb). They would also approach or exceed the LC_{50} values that Borthwick *et al*. (1985) reported for the Atlantic silverside, tidewater silverside, and California grunion.

Other than the one measurement of 690 ppb, however, concentrations in Halls Bayou were not greater than 83 ppb. Furthermore, two years of sampling in the biological field study near Matagorda found that residues reached a maximum of 21 ppb. Using the exposure value of 83 ppb, the risk quotients for fish, mollusks, and shrimp are 0.13, 0.26, and 0.55, respectively. This indicates that, under conditions other than those described above, the acute risk is minimal to fish and mollusks. The RQ still exceeds the LOC, however, for high risk for shrimp and other crustaceans.

The measured concentration of 690 ppb, representing a high exposure associated with heavy rainfall, indicates a high chronic risk to fish and crustaceans. In addition, a high chronic risk to crustaceans exists even for exposures measured not associated with heavy rainfall. The MATC from chronic studies with crustaceans found MATCs that ranged from 4.5 to 35 ppb. Water concentrations measured near Matagorda exceed the lower bound of this range, and those measured at Halls Bayou exceed even the upper bound of this range. The lower end of the range was sometimes exceeded for several consecutive days in both of the biological field studies (for example, 8 days in Area II of Halls Bayou, 4 days at Station 1 on the canal in the Matagorda study in 1984). It is evident that use of thiobencarb on rice in the southeastern regions poses a high chronic risk to shrimp and other aquatic crustaceans.

In summary, based on the results of these tests, the Agency has decided to prohibit application of thiobencarb south of the Intracoastal Waterway in Louisiana; prohibit application within two miles of Galveston Bay, in Texas, and within two miles of Matagorda Bay, in Texas; and prohibit the release of permanent flood water within 14-days of application of thiobencarb, when feasible (depending on weather patterns).

Additionally, the Agency mandates that thiobencarb is not applied within 24 hours of rainfall, or when heavy rain is expected to occur within 24 hours. Lastly, the Agency requires that thiobencarb is not mixed/loaded or otherwise handled within 100 feet of an aquatic habitat.

b. Florida

Study results indicate that use of thiobencarb on vegetables in Florida, at the maximum label rate, poses an risk to freshwater invertebrates due to both acute and chronic effects. Because the chronic risk quotients are extremely high, chronic effects on aquatic invertebrates may be high, depending on the environmental transport of thiobencarb through the muck soils on which the active ingredient is applied. The risk to aquatic habitat in Florida, primarily the nothern stretches of the Everglades and the Loxahatchee National Wildlife Refuge, at this time is uncertain.

Study results indicate that use of thiobencarb on vegetables in Florida, at the maximum label rate, may pose a high acute risk to marine/estuarine oysters, shrimp, and other aquatic invertebrates. The RQ for chronic effects to shrimp and other marine/estuarine invertebrates is imprecise because only supplemental data are available. Nevertheless, based on the range of findings from the four available supplemental studies, it is clear that the RQ for these organisms is well above the LOC of 1, signifying a high chronic risk. The acute RQ for marine estuarine fish in Florida is less than the LOC of 0.5, indicating the acute risk is not high, but it is greater than the LOC of 0.1, indicating that restricted use may be applied, depending on the results of ongoing environmental monitoring studies.

At this time, the Agency believes that the main concern for thiobencarb use on leafy vegetables in Florida is the fate and transport of thiobencarb to aquatic ecosystems, again, due to the proximity of thiobencarb application to the northern portion of the Everglades and the Loxahatchee National Wildlife Refuge. At this time, very limited information is available on thiobencarb concentrations in the ground and surface water travelling to these habitats. The National Water Quality Assessment Program (NAWQA), currently being conducted by the U.S. Geological Survey, is collecting water samples in southern Florida and analyzing the samples for pesticides, including thiobencarb[15]. Interpretation of the NAWQA monitoring data will be delayed until the collection, quality control, and analysis of the data have been completed in the Fall of 1998. At that time, the Agency will reevaluate the exposure that thiobencarb poses to aquatic habitats in Florida, and reassess the need for any risk mitigation measures for thiobencarb use in the state of Florida.

c. California

Granular thiobencarb is used only on rice grown in California. Granular thiobencarb is estimated to pose chronic risk to terrestrial species, but the risk is uncertain.

[15]To date, testing for thiobencarb has only been completed for approximately 16 samples that were taken in the Fall of 1996 into the Winter of 1997. Thiobencarb was not detected in these samples. However, the Agency believes that it is premature to draw any conclusions from these data since these data do not include sampling for the application period for thiobencarb (April/May).

Measured aquatic residues from monitoring in California were no greater than 37 ppb. An acute risk quotient based on this value is 0.37, which is less than the LOC of 0.5. Therefore, use of thiobencarb on rice in California is expected to pose minimal acute risk to freshwater invertebrates.

Use of thiobencarb on water-seeded rice in California is predicted to pose less of a chronic risk to aquatic invertebrates than in the southern rice-growing regions. Water sampling from the Sacramento River and San Joaquin River show that thiobencarb concentrations never exceeded 1 ppb, the NOEC for *Daphnia magna*. The majority of readings were less than 0.05 ppb. In contrast, concentrations in smaller waterways occasionally approached or exceeded the NOEC of 1 ppb, as well as the MATC of 1.7 ppb.

The use of the thiobencarb granular formulation in California is regulated under the Basin Plan for the Sacramento River Basin established by the California Regional Water Quality Control Board, Central Valley Region. A performance goal of 1.5 ppb is strictly monitored, and growers must adhere to a program of approved management practices, including a 30-day water holding restriction.

The Agency proposes no risk mitigation measures for granular thiobencarb use in California.

9. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

10. Endangered Species Program

The Agency has developed a program (the "Endangered Species Protection Program") to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in Federal Register Notice 54 FR 27984-28008 (July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register Notice.

The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product-use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of thiobencarb for the above eligible uses has been reviewed and determined to be substantially complete. For confirmatory purposes, the following information will need to be submitted:

- *Dermal Penetration Study [GLN 85-2];*
  The dermal absorption factor in the current risk assessment is 60.2 percent, observed at 10 hours. This factor is considered by the Agency as a worst-case scenario since the skin was washed approximately 1 hour prior to dosing rather than the recommended 24 hours (which would allow for normal replacement of skin oils). The Agency views this as an over-estimate of absorption, resulting in significantly lower estimates for margin of exposure to workers, specifically intermediate-term exposure. A new dermal penetration study is requested for the granular and liquid thiobencarb formulations to confirm that intermediate-term exposure to workers is acceptable.

- *Life-Cycle Freshwater Fish Study [GLN 72-5];*
  There is currently no core data on the chronic effects of thiobencarb on fish (freshwater or saltwater). Use of thiobencarb on rice is expected to result in extensive exposure to freshwater habitats, thiobencarb degrades slowly in water, and the EEC for thiobencarb exceeds 1/10 the NOEC determined in a fish early life-stage study/invertebrate life-cycle study, thus triggering the need for the study.

- *Avian Subacute Toxicity Study [GLN 71-2(b)];*
  No acute toxicity data are available for a waterfowl species. Therefore, an additional study must be submitted testing the avian dietary toxicity of technical thiobencarb to a waterfowl species, preferable the mallard. The value added of these data is moderate. There is a chance that the mallard may be more sensitive to thiobencarb than the bobwhite, and this could change the conclusion of the risk assessment. In general, however, the acute toxicity of thiobencarb is not a major concern.

- *Avian Reproduction Study [GLN 71-4(b)];*
  A core avian reproduction study has been submitted for an upland game species (the bobwhite), but only a supplemental study is available for a waterfowl species (the mallard). This supplemental data for the mallard indicates that it is the more sensitive species and was thus used in the risk assessment. The data requirement for an avian reproduction study with a waterfowl is still outstanding. The conclusion of the risk assessment is not dependent on these data since high risk could be concluded based on the results of the core study with the bobwhite.

- *Seedling Emergence Testing Study [GLN 123-1(a)];*
  The guideline requirement for seedling emergence testing is currently only partially fulfilled. The test was classified supplemental for the two most sensitive species, lettuce and ryegrass, because there was significant mortality of plants at the lowest test concentration. The Agency requests that additional testing be done for these two sensitive species using lower test concentrations that do not result in mortality of plants. The value added of this information is moderate. It would increase the confidence of the risk assessment on terrestrial plants. Also, this information would be required for comparative analysis of thiobencarb with other herbicides.

2. Labeling Requirements for Manufacturing-Use Products

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

> "Only for formulation into an Herbicide for the following use(s):rice weed control in California, Louisiana, Texas, Mississippi, Missouri and Arkansas, and lettuce, endive and celery weed control in Florida."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

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

The reregistration requirements for magnitude of the residue in water will be considered fulfilled when revisions are made to Valent's end-use product labels (EPA Reg. Nos. 59639-79 and 59639-80) to prohibit use of treated water for livestock watering or for drinking or irrigation for a specified time period after treatment. Based on the results of an acceptable magnitude of residue in potable water study (MRIDs 43404003, 43404004, and 43404005), thiobencarb and thiobencarbsulfoxide residues in runoff and receiving waters associated with rice fields did not fall to acceptable levels until 14 days after treatment.

The use of the thiobencarb granular formulation (Bolero® 10G, EPA Reg. No. 59639-80) in California is regulated under the Basin Plan for the Sacramento River Basin established by the California Regional Water Quality Control Board, Central Valley Region. A performance goal of 1.5 ppb is strictly monitored, and growers must adhere to a program of approved management practices, including a 30-day water holding restriction.

The reregistration requirements for nature and magnitude of the residue in fish will be fulfilled when label revisions are made on Valent's end-use products (EPA Reg. Nos. 59639-79 and 59639-80) to specify the following use restrictions: "Do not use on rice paddies where commercial catfish or crayfish farming is practiced. Do not use adjacent to catfish or crayfish ponds."

Valent's thiobencarb end-use labels specify a 6-month plantback interval following rice and all other crops, except celery, endive and lettuce for which rotational crop plant-back intervals are 4-months. These currently specified plant-back intervals are appropriate.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

a. PPE and Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain thiobencarb:

- Revise the product labeling to adopt the handler personal protective equipment/engineering control requirements set forth in this section.
- Remove any conflicting PPE requirements on the current labeling.

For **multiple-active-ingredient** end-use products that contain thiobencarb:

- Compare the handler personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.
- Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7.)

3. Products Intended Primarily for Occupational Use

a. Active-Ingredient Specific Engineering Control Requirements

EPA is establishing active-ingredient specific engineering controls for some occupational uses of thiobencarb end-use products.

For liquid formulations:

"Mixers and loaders are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4)."

"Applicators and flaggers are required to use enclosed cabs or enclosed cockpits. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5-6)."

4. Active-Ingredient Specific Personal Protective Equipment Requirements

EPA is establishing active-ingredient specific personal protective equipment requirements for all occupational uses of thiobencarb end-use products.

For liquid formulations:

"In addition to using closed systems, mixers and loaders must wear:
-- long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--socks plus shoes, and
--chemical-resistant apron."

"Applicators and flaggers using enclosed cabs or cockpits must wear:
-- long-sleeved shirt and long pants, and
--socks plus shoes."

"For other handling activities and in case of a spill or other emergency exposure, handlers must wear:
--coveralls over long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--chemical-resistant footwear, and
--chemical-resistant apron when cleaning equipment."

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

For granular formulations:

"Applicators and other handlers must wear:
-- long-sleeved shirt and long pants,
--chemical-resistant gloves*,
-- shoes plus socks
--chemical-resistant apron when loading formulation into equipment or cleaning equipment."

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

5. Determining PPE Labeling Requirements for End-use Products Containing This Active Ingredient

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

6. Placement in Labeling

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

7. Entry Restrictions

For **sole-active-ingredient** end-use products that contain thiobencarb:

- Revise the product labeling to adopt the entry restrictions set forth in this section.
- Remove any conflicting entry restrictions on the current labeling.

For **multiple-active-ingredient** end-use products that contain thiobencarb:

- Compare the entry restrictions set forth in this section to the entry restrictions on the current labeling.
- Retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

8. Products Intended Primarily for Occupational Use

a. WPS Uses

(1) Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all thiobencarb end-use products.

(2) Early-entry personal protective equipment (PPE):

The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves,
-- shoes plus socks,

b. Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted

into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

Other Labeling Requirements

Application Restrictions

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

"Do not apply this product south of the Intracoastal Waterway in Louisiana."
"Do not apply this product within two (2) miles from the shorelines of Matagorda Bay in Texas."
"Do not apply this product within two (2) miles from the shorelines of Galveston Bay in Texas."

"Do not apply this product to rice fields with catfish/crayfish farming."
"Do not apply this product on rice fields adjacent to catfish or crayfish ponds."

"When applying to rice fields, do not release permanent flood water within 14-days of application of this product (where weather permits)."

"Avoid application of this product within 24 hours of rainfall, or when heavy rain is expected to occur within 24 hours."

"Do not mix/load or otherwise handle this product within 100 feet of aquatic habitat."

User Safety Requirements

1. Registrants: place the following statement on the labeling if coveralls are required for pesticide handlers on the end-use product label:

   "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrants always place the following statement on the end-use product labeling:

   "Follow manufacturer's instructions for cleaning/maintaining PPE. If not such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

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

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

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

C. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

It is recommended that the applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE: The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE:

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- Maintainance of Nozzles - periodic inspection and subsequent replacement of nozzles to ensure proper chemical application is recommended.

BOOM LENGTH: For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT: Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT: When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of

the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND: Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY: When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS: Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS: The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and

other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

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

VI. APPENDICES

APPENDIX A REPORT

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
CELERY				Use Group: TERRESTRIAL FOOD CROP									
Soil treatment, Posttransplant, Low volume ground sprayer	EC	NA	8 lb A	*	1	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(70)
	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(70)
	EC	NA	8 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, CAU, H01(70)
ENDIVE (ESCAROLE)				Use Group: TERRESTRIAL FOOD CROP									
Soil treatment, Posttransplant, Boom sprayer	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, CAU, H01(60)
Soil treatment, Posttransplant, Low pressure ground sprayer	EC	NA	6 lb A	*	1	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, CAU, H01(60)
Soil treatment, Seed bed, Boom sprayer	EC	NA	6 lb A	*	1	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
LETTUCE				Use Group: TERRESTRIAL FOOD CROP									
Soil treatment, Posttransplant, Boom sprayer	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, CAU, H01(60)
Soil treatment, Posttransplant, Low pressure ground sprayer	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)
	EC	NA	6 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, CAU, H01(60)
Soil treatment, Seed bed, Low pressure ground sprayer	EC	NA	6 lb A	*	1	NS	NS	NS	NS	.5 d	FL		C46, C92, H01(60)

APPENDIX A REPORT

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	/year	Max. Rate unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
RICE			Use Group: AQUATIC FOOD CROP										
Flooded area treatment, Preplant, Not on label	G	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	LA		
Water application, Postemergence, Not on label	G	NA	4 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d	CA		CAL, CAU, CWB
	G	NA	4 lb A	*	NS	1/1 yr	NS	NS	NS	.5 d	CA		CAU
	G	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	AR		CAU, CWB
	G	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	MS		CAU
	G	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	TX		CAU
			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil treatment, Early postemergence, Aircraft	EC	NA	2 lb A 2 lb A 2 lb A	F M C	NS	NS	NS	UC	NS	.5 d	AR		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92
Soil treatment, Early postemergence, Sprayer	EC	NA	2 lb A 2 lb A 2 lb A	F M C	NS	NS	NS	UC	NS	.5 d	AR		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92
Soil treatment, Preemergence, Aircraft	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	UC	NS	.5 d	AR		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92
Soil treatment, Preemergence, Sprayer	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	UC	NS	.5 d	AR		C46, C92

APPENDIX A REPORT

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	/year	Max. Rate [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
RICE (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
	EC	NA	4 lb A	*	NS	NS	NS	NS	NS	.5 d	FL		C46, C92
Soil treatment, Seed bed, Aircraft	EC	NA	4 lb A	*	1	NS	NS	NS	NS	.5 d	CA		C46, CAU
Soil treatment, Seed bed, Sprayer	EC	NA	4 lb A	*	1	NS	NS	NS	NS	.5 d	CA		C46, CAU
Spray, Early postemergence, Aircraft	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d			C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d			C46, CAU
	EC	NA	UC	*	NS	NS	NS	UC	NS	.5 d	AR		C46, CAU
	EC	NA	3 lb A 2 lb A 2 lb A 2 lb A	* F M C	NS	NS	NS	UC	NS	.5 d	MO		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	MS		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	TX		C46, C92
	EC	NA	3 lb A	*	NS	NS	NS	UC	NS	NS	MS		C46, C92
Spray, Early postemergence, Ground	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d			C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d			C46, CAU
	EC	NA	UC	*	NS	NS	NS	UC	NS	.5 d	AR		C46, CAU
	EC	NA	3 lb A 2 lb A 2 lb A 2 lb A	* F M C	NS	NS	NS	UC	NS	.5 d	MO		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	MS		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	TX		C46, C92

APPENDIX A REPORT

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year cycle	Max. Rate unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
RICE (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	EC	NA	3 lb A	*	NS	NS	NS	UC	NS	NS	MS	C46, C92
Spray, Early postemergence, Sprayer	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	AR	C46, CAU
Spray, Preemergence, Aircraft	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d		C46, CAU
	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	UC	NS	.5 d	LA	C46, CAU
	EC	NA	4 lb A 4 lb A 4 lb A 3 lb A	* F M C	NS	NS	NS	UC	NS	.5 d	MO	C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	MS	C46, C92
	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	UC	NS	.5 d	MS	C46, CAU
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	TX	C46, C92
	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	.5 d	MO	C46, CAU
Spray, Preemergence, Ground	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d		C46, C92
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d		C46, CAU
	EC	NA	4 lb A 4 lb A 3 lb A	F M C	NS	NS	NS	UC	NS	.5 d	LA	C46, CAU

APPENDIX A REPORT

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]

SITE Application Type, Application Timing, Application Equipment) & Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
RICE (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	MO	C46, C92
			4 lb A	F								
			4 lb A	M								
			3 lb A	C								
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	MS	C46, C92
	EC	NA	4 lb A	F	NS	NS	NS	UC	NS	.5 d	MS	C46, CAU
			4 lb A	M								
			3 lb A	C								
	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	TX	C46, C92
	EC	NA	4 lb A	F	NS	NS	NS	NS	NS	.5 d	MO	C46, CAU
			4 lb A	M								
			3 lb A	C								
Spray, Preemergence, Sprayer	EC	NA	4 lb A	*	NS	NS	NS	UC	NS	.5 d	AR	C46, CAU

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE
- * : Non-specific
- C : Coarse
- M : Medium
- F : Fine
- O : Others

FORMULATION CODES
- EC : EMULSIFIABLE CONCENTRATE
- G : GRANULAR

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

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

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

Case 2665 [Thiobencarb] Chemical 108401 [Thiobendicarb]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

USE LIMITATIONS CODES (Cont.)
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

CAL : Do not contaminate water, food or feed.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
CWB : Poisonous to fish and shellfish. Avoid use where they will be endangered.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AR : Arkansas
CA : California
FL : Florida
LA : Louisiana
MO : Missouri
MS : Mississippi
TX : Texas

REENTRY INTERVAL ABBREVIATIONS
d   : day(s)

UNIT DESCRIPTIONS
A   : acre
lb   : pound

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2665 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2665 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 Thiobencarb

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	41609003
61-2A	Start. Mat. & Mnfg. Process	ALL	44507, 41609001
61-2B	Formation of Impurities	ALL	44507, 41609001
62-1	Preliminary Analysis	ALL	44507, 41609002
62-2	Certification of limits	ALL	140158, 41609002
62-3	Analytical Method	ALL	44507, 41609002
63-2	Color	ALL	44507, 41609002
63-3	Physical State	ALL	44507, 41609002
63-4	Odor	ALL	44507, 41609003
63-6	Boiling Point	ALL	140158
63-7	Density	ALL	44507
63-8	Solubility	ALL	140158
63-9	Vapor Pressure	ALL	140158
63-11	Octanol/Water Partition	ALL	44507
63-12	pH	ALL	44507
63-13	Stability	ALL	44507
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	43121201
71-2A	Avian Dietary - Quail	ALL	55224
71-2B	Avian Dietary - Duck	B, D	57225
71-4A	Avian Reproduction - Quail	B, D	43075401
71-4B	Avian Reproduction - Duck	B, D	25778
72-1A	Fish Toxicity Bluegill	B, D	50665
72-1B	Fish Toxicity Bluegill - TEP	B, D	50665
72-1C	Fish Toxicity Rainbow Trout	ALL	50664
72-1D	Fish Toxicity Rainbow Trout- TEP	B, D	50664

Data Supporting Guideline Requirements for the Reregistration of Thiobencarb

REQUIREMENT		USE PATTERN	CITATION(S)
72-2A	Invertebrate Toxicity	ALL	25788
72-2B	Invertebrate Toxicity - TEP	B, D	40031001
72-3A	Estuarine/Marine Toxicity - Fish	B, D	79110, 79112
72-3B	Estuarine/Marine Toxicity - Mollusk	B, D	79114
72-3C	Estuarine/Marine Toxicity - Shrimp	B, D	50667, 79117
72-3D	Estuarine/Marine Toxicity Fish- TEP	B, D	79111
72-3E	Estuarine/Marine Toxicity Mollusk - TEP	B, D	79115
72-3F	Estuarine/Marine Toxicity Shrimp - TEP	B, D	79113
72-4A	Early Life Stage Fish	B, D	79112
72-4B	Life Cycle Invertebrate	B, D	42680401
72-6	Aquatic Organism Accumulation	B, D	133563
122-1A	Seed Germination/Seedling Emergence	B, D	41690902
122-1B	Vegetative Vigor	B, D	41690902
122-2	Aquatic Plant Growth	B, D	41690901,41690902
123-1A	Seed Germination/Seedling Emergence	B, D	41690902
123-1B	Vegetative Vigor	B, D	41690902
123-2	Aquatic Plant Growth	B, D	41690901, 41690902
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	42130701
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	42130701
81-3	Acute Inhalation Toxicity - Rat	ALL	40585, 134976
81-4	Primary Eye Irritation - Rabbit	ALL	40581
81-5	Primary Dermal Irritation - Rabbit	ALL	40583, 81900
81-6	Dermal Sensitization - Guinea Pig	ALL	161699
81-7	Acute Delayed Neurotoxicity - Hen	ALL	42987001, 43148202
81-8-SS	Acute Neurotoxicity		42987001
82-2	21-Day Dermal - Rabbit/Rat	ALL	42893001
82-4	90-Day Inhalation - Rat	ALL	42893001
82-7-SS	90-Day Neurotoxicity		43001001

Data Supporting Guideline Requirements for the Reregistration of Thiobencarb

REQUIREMENT		USE PATTERN	CITATION(S)
83-1A	Chronic Feeding Toxicity - Rodent	ALL	154506
83-1B	Chronic Feeding Toxicity - Non-Rodent	ALL	144742
83-2A	Oncogenicity - Rat	ALL	154506
83-2B	Oncogenicity - Mouse	ALL	86004
83-3A	Developmental Toxicity - Rat	ALL	86873, 93691, 115248
83-3B	Developmental Toxicity - Rabbit	ALL	164313
83-4	2-Generation Reproduction - Rat	ALL	40446201, 40985701
84-2A	Gene Mutation (Ames Test)	ALL	135285, 84131, 41174
84-2B	Structural Chromosomal Aberration	ALL	84133, 40352401
84-4	Other Genotoxic Effects	ALL	40352401
85-1	General Metabolism	ALL	42340302
85-2	Dermal Penetration	ALL	41215311
ENVIRONMENTAL FATE			
160-5	Chemical Identity	ALL	41609003
161-1	Hydrolysis	B, D	41609012
161-2	Photodegradation - Water	B, D	42257801
161-3	Photodegradation - Soil	B	41215312
162-1	Aerobic Soil Metabolism	B	43300401
162-3	Anaerobic Aquatic Metabolism	B, D	43252001
162-4	Aerobic Aquatic Metabolism	D	42052001
163-1	Leaching/Adsorption/Desorption	B, D	43150601
164-1	Terrestrial Field Dissipation	B	43404004, 42003405
164-2	Aquatic Field Dissipation	D	43404004, 42003405
165-2	Field Rotational Crop	B	41609011
165-3	Accumulation - Irrigated Crop	D	43148201
165-4	Bioaccumulation in Fish	B, D	42460401
201-1	Droplet Size Spectrum	B, D	TASK FORCE
202-1	Drift Field Evaluation	B, D	TASK FORCE

Data Supporting Guideline Requirements for the Reregistration of Thiobencarb

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	ALL	42340301
171-4B	Nature of Residue - Livestock	B	43492301
171-4C	Residue Analytical Method - Plants	B, D	43075402
171-4D	Residue Analytical Method - Animal	B	92182073
171-4E	Storage Stability	ALL	43182501
171-4F	Magnitude of Residues - Potable H2O	D	43404003, 43404004
171-4H	Magnitude of Residues - Irrigated Crop	D	124278
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	42962801, 42962802
171-4K	Crop Field Trials	B, D	92182080
171-4L	Processed Food	ALL	42987002

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION

00025778 Beavers, J.B.; Fink, R.; Joiner, G.; et al. (1979) Final Report: One-Generation Reproduction Study--Mallard Duck: Project No. 162-117. (Unpublished study including letters dated Apr 10, Apr 25, May 25, Jul 9, Jul 24, Aug 28, 1979 from J. Grimes, J.B. Beavers, J.B. Leary, J. Grimes, J. Grimes, J. Grimes, respectively, to Francis X. Kamienski and addendum, received Dec 11, 1979 under 239-2450; prepared by Wildlife International, Ltd., submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 241489-G)

00025788 Wheeler, R.E. (1978) 48 Hour Acute Static Toxicity of Bolero (SX796) to 1st Stage Nymph Water Fleas (*Daphnia magna* Straus). (Unpublished study received Dec 11, 1979 under 239-2450; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241489-W)

00040581 Rittenhouse, J.R.; Narcisse, J.K. (1974) S-717: The Eye Irritation Potential of Bolero Technical: SOCAL 653/XX:106. (Unpublished study received Mar 18, 1976 under 239-EX-78; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095493-P)

00040583 Rittenhouse, J.R.; Narcisse, J.K. (1974) S-718: The Skin Irritation Potential of Bolero Technical: SOCAL 654/XX:106. (Unpublished study received Mar 18, 1976 under 239-EX-78; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095493-R)

00040585 Narcisse, J.K. (1976) S-959: The Acute Inhalation Toxicity of Bolero Technical Vapor: SOCAL 885/XXI:148. (Unpublished study received Mar 18, 1976 under 239-EX-78; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095493-T)

00041174 Shirasu, Y.; Moritani, M.; Kato, K. (1974) Test Report on Mutagenicity of S-(4-Chlorobenzyl)-N,N-diethylthiolcarbamate in Microorganisms. (Unpublished study received Mar 18, 1976 under 239EX-78; prepared by Institute of Inbiomental Toxicology, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095491-D)

00044507 Leary, J.B. (1976) Benthiocarb-Distribution between n-Octanol and Water: File No. 741.11. (Unpublished study received Mar 18, 1976 under 239-2449; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095095-N)

00050664 Thompson, C.M.; Griffen, J.; Boudreau, P.; et al. (1980) Acute Toxicity of Bolero 10G (SX-1252) to Rainbow Trout (*Salmo gairdneri*): S-1819: ABC Report # 26078. (Unpublished study received Oct 23, 1980 under 239-2449; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:243574-B)

BIBLIOGRAPHY

MRID **CITATION**

00050665 Thompson, C.M.; Griffen, J.; Boudreau, P.; et al. (1980) Acute Toxicity of Bolero 10G (SX-1252) to Bluegill Sunfish (*Lepomis macrochirus*): S-1820: ABC Report # 26077. (Unpublished study received Oct 23, 1980 under 239-2449; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:243574-C)

00050667 Hollister, T.A. (1980) Acute Toxicity of Bolero® 4 Technical to Mysid Shrimp (*Mysidopsis bahia*): Report No. BP-80-9-161. (Unpublished study received Oct 23, 1980 under 239-2449; prepared by EG&G Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:243574-E)

00057224 Fletcher, D. (1974) Report to Chevron Chemical Company, Ortho Division: 8-Day Dietary LC_{50} Study with Bolero in Bobwhite Quail: IBT No. 651-05214. (Unpublished study received Mar 18, 1976 under 239-2449; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 095494-H)

00057225 Fletcher, D. (1974) Report to Chevron Chemical Company, Ortho Division: 8-Day Dietary LC_{50} Study with Bolero in Mallard Ducklings: IBT No. 651-05213. (Unpublished study received Mar 18, 1976 under 239-2449; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Corp., Richmond, Calif.; CDL:095494-I)

00079110 Heitmuller, T. (1979) Acute Toxicity of Bolero Technical to Sheepshead Minnows (C*yprinodon variegatus*): Report No. BP-79-9-133. (Unpublished study received Dec 11, 1979 under 239-2449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-L)

00079111 Heitmuller, T. (1979) Acute Toxicity of Bolero 8 EC to Juvenile Sheepshead Minnows (*Cyprinodon variegatus*): Report No. BP79-9-134. (Unpublished study received Dec 11, 1979 under 2392449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-M)

00079112 Ward, G.S. (1979) Effects of Bolero® 4 Technical on Survival, Growth, and Development of Sheepshead Minnows (*Cyprinodon variegatus*): Report No. BP-79-9-140. (Unpublished study recieved Dec 11, 1979 under 239-2449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-N)

00079113 Heitmuller, T. (1979) Acute Toxicity of Bolero 8 EC to Fiddler Crabs (*Uca pugilator*): Report No. BP-79-9-135. (Unpublished study received Dec 11, 1979 under 239-2449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-P)

BIBLIOGRAPHY

MRID	CITATION
00079114	Hollister, T. (1979) Acute Toxicity of Bolero Technical to Embryoslarvae of Eastern Oysters (*Crassostrea virginica*): Report No. BP-79-9-131. (Unpublished study received Dec 11, 1979 under 239-2449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-Q)
00079115	Hollister, T. (1979) Acute Toxicity of Chevron's Bolero 8 EC to Embryos-larvae of Eastern Oysters (*Crassostrea virginica*): Report No. BP-79-9-132. (Unpublished study received Dec 11, 1979 under 239-2449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-R)
00079117	Hollister, T.A. (1979) Acute and Chronic Toxicity of Bolero® 4 Technical to Mysid Shrimp (*Mysidopsis bahia*): Report No. BP79-9-141. (Unpublished study received Dec 11, 1979 under 2392449; prepared by EG & G, Bionomics, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:241494-T)
00081900	Rittenhouse, J.R.; Narcisse, J.K. (1974) The Skin Irritation Potential of Bolero Technical: SOCAL 654/XX:106 (S-718). (Unpublished study received Jan 10, 1975 under 5G1582; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:094343-N)
00084131	Bullock, C.H. (1977) The Potential of Benthiocarb Technical and Benthiocarb Standard to Mutate Histidine-deficient Strains of *Salmonella typhimurium*: SOCAL 1017/XXV:8 (S-1071). (Unpublished study received Dec 11, 1979 under 6F1763; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:099125-G)
00084133	Bootman, J.; Whalley, H.E. (1978) Bolero® 4 (Thiobencarb): Dominant Lethal Study in Mice after Acute and Subacute Oral Administration: LSR Report No. 78/KCI38/294. (Unpublished study received Dec 11, 1979 under 6F1763; prepared by Life Science Research, England, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:099125-I)
00086004	Macrae, S.M.; Amyes, S.J.; Holmes, P.; et al. (1981) Technical Bolero® 4: Potential Oncogenicity in Dietary Administraiton to Mice: LSR Report No. 81/KCI040/527. Final rept. (Unpublished study received Nov 30, 1981 under 0F2322; prepared by Life Science Research, England, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:070480-A; 070479; 070483; 070484; 070485; 070491; 070488; 070489)
00086873	Science Applications, Incorporated (1981) Teratology Study in Rats with Bolero® 4: CHE/SAI 581007. (Unpublished study received Nov 30, 1981 under 0F2322; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:070494-A)
00093691	Chevron Chemical Company (1981) Additional Data for the Teratology Study in Rats with Bolero: Ortho Test No. S-1947. (Unpublished study, including letter dated Jan 11, 1982 from J.A. Parker to D.F. Dye, received Jan 15, 1982 under 0F2322; CDL:070594-A)

BIBLIOGRAPHY

MRID	CITATION

00115248 Harris, S.; Holson, J.; Fite, K.; et al. (1982) Teratology Study in Rats with Bolero Technical: CHE/SAI 581007. (Unpublished study received Oct 7, 1982 under 239-2449; prepared by Science Applications, Inc., submitted by Chevron Chemical Co., Richmond, CA; CDL:248485-A)

00124278 Chevron Chemical Co. (1981) Results of Analysis for Water, Soil, Vegetation, Straw and Grain Treated with Bolero 8 EC in a Rice Environment. (Compilation; unpublished study received Jan 24, 1983 under 239-EX-77; CDL:249348-A)

00133563 Kennedy, J. (1983) Baseline Assessment of a Brackish Water Ecosystem, April 1, 1982 through March 31, 1983, Matagorda, Texas: [Bolero]: S-2132. Final rept. (Unpublished study received Dec 21, 1983 under 239-2449; prepared by Biospherics, Inc., submitted by Chevron Chemical Co., Richmond, CA; CDL:252022-A)

00134976 Narcisse, J. (1976) The Acute Inhalation Toxicity of Bolero Technical Vapor: SOCAL 885/XXI: 148 (S-959). (Unpublished study received Mar 18, 1976 under 239-EX-77; submitted by Chevron Chemical Co., Richmond, CA; CDL:095492-T)

00135285 Bullock, C. (1977) Purified Benthiocarb and Technical Benthiocarb: The Potential of Benthiocarb Technical and Benthiocarb Standard To Mutate Histidine-deficient Strains of *Salmonella typhimurium*: SOCAL 1017/XXV:84 (S-1071). (Unpublished study received Dec 1, 1978 under 239-EX-77; submitted by Chevron Chemical Co., Richmond, CA; CDL:097658-E)

00140158 Chevron Chemical Co. (1979) Bolero Herbicide. (Compilation; unpublished study received Dec 11, 1979 under 6F1763; CDL: 099122-A)

00144742 Johnson, D. (1985) One Year Subchronic Oral Toxicity Study with Thiobencarb Technical in Dogs: 415-042. Unpublished study prepared by International Research and Development Corp. 408 p.

00154506 Cummins, H. (1984) Technical Bolero: Combined Oncogenicity and Toxicity Study in Dietary Administration to the Rat: Amended Final Report: 84/KCI045/579. Unpublished study prepared by Life Science Research Ltd. 2135 p.

00161699 Silveira, R. (1982) Modified Buehler Test for the Skin Sensitization Potential of Bolero 8EC: SOCAL 1943. Unpublished study prepared by Chevron Environmental Health Center. 15 p.

00164313 Tauchi, K. (1979) Teratology Study of Thiobencarb in the Rabbit: Pilot Study: ?and Main Reportσ: Laboratory Project ID IIAR Study No. 158-A: IIAR Study No. 158-B. Unpublished study prepared by Imamichi Institute for Animal Reproduction. 125 p.

BIBLIOGRAPHY

MRID	CITATION

40031001 Rich, E. (1986) Toxicity Bioassay Effect of Bolero 8 EC on Hatching Apple Snails: Lab. Proj. ID 8616165. Unpublished study prepared by Rio Palenque Research Corp. 31 p.

40352401 Boatman, J.; Hodson-Walker, G.; Dance, C. (1985) In Vitro Assessment of the Clastogenic Activity of Benthiocarb in Cultured Human Peripheral Lymphocytes: LRS Report No. 85/KC1050/723. Unpublished study prepared by Life Science Research. 33 p.

40446201 Hatakeyama, Y. (1987) Reproduction Study by Oral Forced Administration of Thiobencarb in Rats--Main Experiment: CIEA Study No.: ML-289A2. Unpublished study prepared by Preclinical Research Laboratories. 351 p.

40985701 Richter, W. (1988) A Discussion of Issues Related to Systemic NOEL and Reproductive NOEL and a Report and Discussion of Liver and Kidney Tissues for Reproductive Study by Oral Forced Administration of Thiobencarb in Rats Main Experiment (MRID 40446201): Proj. No. ML-289A2. Unpublished supplemental study prepared by Chevron Environmental Health Center. 112 p.

41215301 Mayer, F.; Elersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. Unpublished study prepared by the U. S. Deptartment of the Interior. 5 p.

41215311 Brorby, G.; Beatty, P. (1989) The Percutaneous Absorption of (Carbon 14)-Bolero 8 EC in Male Rats: Project ID S-3145. Unpublished study prepared by Chevron Environmental Health Center, Inc. 47 p.

41215312 McGovern, P. (1988) Soil Surface Photolysis of [Carbon 14]-Thiobencarb in Natural Sunlight: Project ID MEF-0010. Unpublished study prepared by the Pharmacology and Toxicology Research Laboratory. 89 p.

41609001 Updyke, J. (1990) Thiobencarb Technical Product Chemistry: Product Identity and Composition: Lab Project Number: 9009745. Unpublished study prepared by Chevron Chemical Co. 76 p.

41609002 Updyke, J. (1990) Thiobencarb Technical Product Chemistry [Analysis and Certification of Product Ingredients]: Lab Project Number: 9009746. Unpublished study prepared by Chevron Chemical Co. 79 p.

41609003 Updyke, J. (1990) Thiobencarb Technical Product Chemistry [Physical and Chemical Characteristics]: Lab Project Number: 9009747. Unpublished study prepared by Chevron Chemical Co. 39 p.

BIBLIOGRAPHY

MRID	CITATION
41609011	Leary, J. (1990) Bolera-Rotational Crops: Compilation of Field Rotational Crop Studies [Field Dissipation Study]: Lab Project Number: VC7403. Unpublished study prepared by Chevron Chemical Co. 3 p.
41609012	Chen, Y. (1990) Hydrolysis of [Phenyl-U-[carbon 14]]-Thiobencarb in Water: Lab Project Number: MEF-0149/9007557. Unpublished study prepared by Chevron Chemical Co. 32 p.
41690901	Giddings, J. (1990) Thiobencarb Technical-Toxicity to Five Species of Aquatic Plants: Lab Project Number: 90-9-3477. Unpublished study prepared by Springborn Laboratories, Inc. 116 p.
41690902	Hoberg, J. (1990) Thiobencarb Technical: Determination of Effects on Seed Germination, Seedling Emergence and Vegetative Vigor of Ten Plant Species: Lab Project Number: 90-9-3462. Unpublished study prepared by Springborn Laboratories, Inc. 170 p.
42003404	Lai, J. (1991) Field Dissipation of Bolero 8EC in Rice: Lab Project Number: 1641/90/7538. Unpublished study prepared by Chevron Chemical Co. 411 p.
42015301	Mulkey, N. (1991) The Aerobic Aquatic Metabolism of [Ring-Carbon 14]-Thiobencarb: Lab Project Number: ADC 1238. Unpublished study prepared by Analytical Development Corp. 159 p.
42130701	Nishimura, N. (1985) Acute Toxicity Study of Benthiocarb by Oral and Dermal Administration in the Rat: Lab Project ID: BOZO/B671. Unpublished study prepared by Bozo Research Center, Inc. 80 p.
42257801	Chen, Y. (1988) Photodegradation of [Phenyl-U-14C]-Thiobencarb in Water: Lab Project Number: MEF-0091. Unpublished study prepared by Chevron Chemical Co. 45 p.
42340301	Downs, J.; Marsh, D.; Krautter, G. (1992) The Metabolism of [Ring-carbon 14] Thiobencarb in Laying Hens: Lab Project Number: 544: 1345. Unpublished study prepared by PTRL East, Inc. 186 p.
42340302	Jiang, J.; Gibson, N.; Marsh, J. (1992) Rat Metabolism Study of [Phenyl-U-carbon 14]-Thiobencarb: Lab Project Number: 553E/313W. Unpublished study prepared by PTRL East, Inc. and PTRL West, Inc. 371 p.
42460401	Thacker, J.; Strauss, K.; Smith, G. (1992) Thiobencarb: A Metabolic Fate Study with the Bluegill (Lepomis macrochirus): Lab Project Number: 263E-101. Unpublished study prepared by Wildlife International Ltd. 165 p.

BIBLIOGRAPHY

MRID	CITATION
42680401	Putt, A. (1993) Thiobencarb (Bolero Technical): The Chronic Toxicity to Daphnia magna under Flow-through Conditions: Lab Project Number: 93-1-4582: 12707.0792.6116.130. Unpublished study prepared by Springborn Labs, Inc. 98 p.
42893001	Machado, M. (1993) Three-Week Repeated-Dose Dermal Toxicity Study in Adult Male and Female Rats with BOLERO 8EC (SX-1843) MRID 42003401: Revised Report Number One: Lab Project Number: 5510. Unpublished study prepared by Chevron Research & Technology Co. 391 p.
42962801	Lai, J. (1993) Meat and Milk Magnitude of the Residue Study in Lactating Dairy Cows with Thiobencarb: Lab Project Number: VP10015: 133-001-10: 1714-92-10015. Unpublished study prepared by Valent U.S.A. Corp. 506 p.
42962802	Lai, J. (1993) Phase 3 Reformat of Thiobencarb Meat and Egg Poultry Feeding Study MRID 92182075: Response to Comments Upon Review: Lab Project Number: T3481R. Unpublished study prepared by Valent U.S.A. Corp. 13 p.
42987002	Lai, J. (1993) Magnitude of Thiobencarb Residues in Processed Rice Commodities: Lab Project Number: V1048: 1714-92-1048. Unpublished study prepared by Valent U.S.A. Corp. Dublin Lab. 200 p.
43001001	Lamb, I. (1993) A Subchronic (13-Week) Neurotoxicity Study of Bolero Technical in Rats: Lab Project Number: WIL/194011: 194011: VP/10008. Unpublished study prepared by WIL Research Labs., Inc. 1634 p.
43075401	Bavers, J.; Chafey, K.; Mitchell, L.; et al. (1993) A Reproduction Study With The Northern Bobwhite: Lab Project Number: 263-128. Unpublished study prepared by Wildlife International Ltd. 188 p.
43075402	Hughes, D. (1993) FDA Multiresidue Method Testing of Thiobencarb Metabolites: 4-Chlorobenzylmethylsulfone, 4-Chlorobenzylmethylsulfoxide, and 4-Chlorobenzoic Acid: Lab Project Number: HWI 6320-116. Unpublished study prepared by Hazleton Wisconsin, Inc. 143 p.
43121201	Schocken, M. (1994) (carbon 14) Thiobencarb--Determination of Adsorption/Desorption Coefficients for Soil Degradates: Lab Project Number: VP-10011: 93-12-5074. Unpublished study prepared by Springborn Laboratories, Inc. 71 p.
43148201	Green, C. (1994) Accumulation of Thiobencarb and Metabolites in Crops Irrigated with Water Treated with BOLERO 8 EC Herbicide: Lab Project Number: V/93/10610: 3/288/0859: 3/288/0861. Unpublished study prepared by Valent U.S.A. Corp., A&L Mid West Lab., Inc., Chemtec. 381 p.

BIBLIOGRAPHY

MRID	CITATION
43148202	Lamb, I. (1994) A Range-Finding Study of BOLERO Technical in Rats: Lab Project Number: WIL/194009. Unpublished study prepared by WIL Research Lab., Inc. 206 p.
43150601	Christensen, K. (1994) 4-Chlorobenzoic Acid--Determination of the Adsorption and Desorption Properties: Lab Project Number: 12709.1093.6132.710: 93-11-5051: VP-10804. Unpublished study prepared by Springborn Labs., Inc. 73 p.
43182501	Fay, D. (1994) Storage Intervals and Conditions for Samples from Magnitude of the Residue Studies Conducted in Support of Thiobencarb Raw Agricultural Commodity Tolerances: Lab Project Number: 94-THI-01. Unpublished study prepared by Valent U.S.A. Corp. 30 p.
43252001	Esser, T.: Shepler, K. (1994) Anaerobic Aquatic Metabolism of (phenyl-carbon 14) Thiobencarb: Lab Project Number: 397W: VP-10505. Unpublished study prepared by PTRL West, Inc. 116 p.
43300401	Patterson, T. (1994) Aerobic Metabolism of (Phenyl-(carbon 14))-Thiobencarb in Soil: Lab Project Number: PRT-08-2VNA-01: 10210: PRT-08-2VNA-01-011. Unpublished study prepared by Plant Research Technologies, Inc. 145 p.
43404003	Beiver, R. (1994) THIOBENCARB: Magnitude of the Residue in Discharged Waters and Receiving Waters Associated with Rice Production in Arkansas and Texas: Lab Project Number: 93-11-5039. Unpublished study prepared by Valent U.S.A. Corp. & Springborn Laboratories, Inc. 580 p.
43404004	Fay, D. (1994) Discussion of Factors Potentially Influencing Magnitude of the Residue of Thiobencarb in Potable Water: Lab Project Number: 94-THI-02. Unpublished study prepared by Valent U.S.A. Corp. 31 p.
43404005	Ho, B. (1994) Aquatic Field Dissipation of BOLERO 10G in Rice: Lab Project Number: T-7230. Unpublished study prepared by Chevron Chemical Co. 303 p.
43492301	Green, C. (1994) Validation of the Extraction Efficiency of Thiobencarb Residues in Meat and Milk from Lactating Goats: Lab Project Numbers: V-93-10802: RM-16D-3. Unpublished study prepared by Valent U.S.A. Corp. 127 p.
92182073	Ho, B. (1990) Chevron Chemical Company Phase 3 Reformat of MRID 00042023 and Related MRIDs 00040950, 00072529, 00072984, 00042026, 00042027, 00042028, 00086773. Residue Analysis of Benthiocarb and the Metabolites 4-Chlorobenzylmethyl sulfone in Rice Grain: Method RM-16A-2. Prepared by Chevron Agchem Technical Center. 260 p.
92182080	Ho, B. (1990) Chevron Chemical Company Phase 3 Reformat of MRID 00042029 and Related MRIDs 00042024, 00124278. Rice Grain, Rice Grain Processed Parts, Rice Straw, Soil, and Water: Bolero Tolerance Petition 6F1763; and Rice Weed Control, Bolero 8 EC, 239-EUP-77. Prepared by Chevron Chemical Co. 45 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 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(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five 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 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

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

B. SCHEDULE FOR SUBMISSION OF DATA

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

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 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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

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

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.

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 2) and the Requirements Status and Registrant's Response Form (Attachment 3). 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 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) 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. 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) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, 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(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). 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(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) 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 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for 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.

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 time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

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

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

Option 1, Developing Data --

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. 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 requirement(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. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study --

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), 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 a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

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

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

This option 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.

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 ingredient(s) 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(s) 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(s) 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(s) 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. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), 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.

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

c. Total direct production cost of product(s) containing the active ingredient(s) 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.

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

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

f. 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.

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

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), 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(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) 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

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; or,

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.

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.

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 Federal Insecticide, Fungicide, and Rodenticide 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(s) 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 1, the Data Call-In Chemical Status Sheet.

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

THIOBENCARB DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 thiobencarb. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this thiobencarb 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 generic database for thiobencarb are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on thiobencarb are needed. These data are needed to fully complete the reregistration of all eligible thiobencarb products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dennnis Deziel at (703) 308-8173.

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

Dennis Deziel, Chemical Review Manager
Reregistration Branch I
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Thiobencarb

SPECIFIC INSTRUCTIONS FOR THE GENERIC 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 ease number, ease 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. Cheek 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 if 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 an 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 3. Requirements Status and Registrants' Response Forms Inserts (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- 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/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
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 protocol 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-ln 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.

Attachment 4. List of Registrant(s) sent this DCI (Insert)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of

your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a

Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed

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

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

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

Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

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

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

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

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of

submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

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

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

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

THIOBENCARB DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 thiobencarb. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this 2665 Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

RE: **2665**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

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

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

Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not

reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

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

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Thibencarb (S-((4-Chlorophenyl)methyl) N,N-diethylthiocarbamate) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. Registrants have the option of participating with all or some other registrants of products in their product's batch, to deal 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 or 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 or she may do so provided that the data base is complete and valid by today's standards (see the attached acceptance criteria), 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. Registrants may not support their product using data conducted on a product from a different batch. TRB must approve any new or canceled formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he or 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 or 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 or 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 or her studies and offering to cost share (Option 3) those studies.

Table 1 displays the products that were batched.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	59639-79	Thiobencarb … 84%	liquid
	63588-6	Thibencarb … 84%	liquid
2	59639-80	Thibencarb … 10%	solid
	63588-5	Thiobencarb … 10%	solid

Table 2 displays the product that was not batched. The registrant is responsible for submitting acute toxicity data to support this product. The Technical Review Branch will not accept reviews submitted on any of the batched products to support the one "No Batch" product.

Table 2.

Registration Number	Percent Active Ingredient
63588-4	Thiobencarb … 97.4%

Attachment 5. List of Registrant(s) sent this DCI (Insert)

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

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

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

Certification of Offer to Cost Share in the Development of Data

Form Approved OMB No. 2070-0106, 2070-0057 Approval Expires 3-31-99

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-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an 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 firms on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

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

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

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

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using WWW (World Wide Web) on WWW.EPA.GOV., or contact CP Moran at (703)-308-8590.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for 2665.

The following documents are part of the Administrative Record for 2665 and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

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

1. The Label Review Manual.

2. EPA Acceptance Criteria