United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA 738-R-98-022 December 1998

Reregistration Eligibility Decision (RED)

THIODICARB

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 thiodicarb. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "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 date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA 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 Bonnie Adler (703) 308-8523. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Myers (703) 308-8589.

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 703-605-6000).

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

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

e. **Certification With Respect to Citation of Data and Data Matrix**. Complete and sign EPA forms 8570-34 and 8570-35 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

THIODICARB

LIST B

CASE 2675

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

TABLE OF CONTENTS

THIODICARB REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Steve Jarboe	Science Information and Administration Branch
Alan Halvorson	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Larry Liu	Environmental Risk Branch IV
Nick Federoff	Environmental Risk Branch IV
Nelson Thurman	Environmental Risk Branch IV
Ann Stavola	Environmental Risk Branch IV

Health Effects Risk Assessment

Felicia Fort	Reregistration Branch I
Linda Taylor	Reregistration Branch I
John Leahy	Chemistry and Exposure Branch I
David Miller	Chemistry and Exposure Branch II
Brian Steinwand	Chemistry and Exposure Branch I

Registration Support Risk Assessment

Tom Harris	Insecticide-Rodenticide Branch

Risk Management

Tom Myers	Reregistration Branch II

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.
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 © 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

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the pesticide thiodicarb, dimethyl N,N'-(thiobis((methylimino)carbonyloxy)) bis(ethanimidothioate). Thiodicarb is used primarily on cotton, sweet corn, and soybeans. The remaining usage is spread among leafy vegetables, cole crops, ornamentals, and other minor use sites. Thiodicarb acts as an insecticide against major Lepidopterous, and suppresses Coleopterous and some Hemipterous insect pests. Thiodicarb acts as an ovicide against cotton bollworms and budworms.

Thiodicarb was first registered in the United States in 1984 for use as an insecticide. In April, 1991, the Agency issued a Phase IV Data Call-In for thiodicarb requiring additional studies on ecological effects, environmental fate, residue chemistry, and human toxicity.

Reregistration Eligibility

EPA has completed its reregistration eligibility decision of the pesticide thiodicarb. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. This decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA, Public Law 104-170) that amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. These are the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions signed after August 3, 1996 are, accordingly, being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, 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 effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues.

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and exposure. Although the data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to thiodicarb, data gaps exist for the acute and subchronic neurotoxicity studies. These studies would have yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the central and peripheral nervous system which are not presently available for evaluation. The Agency determined that the 10x safety factor to account for increased sensitivity of infants and

children should be reduced from 10x to 3x. Regarding aggregate exposure, the Agency only considered dietary exposure from food and water because there are no homeowner uses of thiodicarb.

The Agency has determined that thiodicarb has a metabolite, methomyl, which is also a registered pesticide. Therefore, methomyl residues resulting from applications of both thiodicarb and methomyl were considered in an aggregate dietary risk assessment and compared to appropriate toxicological endpoints for methomyl. In addition, for post application exposure to workers, the methomyl short and intermediate-term dermal endpoints were used in the risk assessment because thiodicarb degrades rapidly to methomyl.

The Agency does not have, at this time, available data to determine whether thiodicarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this assessment, therefore, the Agency has not assumed that thiodicarb has a common mechanism of toxicity with other substances.

The Agency has determined that thiodicarb, labeled and used as specified in this Reregistration Eligibility Decision document, will not cause unreasonable risks to humans or the environment and that these uses are eligible for reregistration. The Agency is requiring additional data for toxicology, ecological effects, and residue chemistry that are expected to confirm the risk assessment.

Health Effects

Thiodicarb has been classified as a Group B2 - probable human carcinogen. The B2 classification was based on statistically significant increases in hepatocellular adenomas, carcinomas, and combined adenoma/carcinoma in both sexes of the mouse and statistically significant increases in testicular interstitial cell tumors in male rats.

A linear methodology (Q_1*) was applied for the estimation of human cancer risk and was calculated to be 1.88×10^{-2}. The assessment was conducted for the total U.S. Population only. Cancer exposure is estimated by multiplying the Q_1* (1.88×10^{-2}) by the chronic dietary exposure (0.000020 mg/kg/day). This chronic dietary exposure utilized both anticipated residue and percent crop treated information. The upper bound cancer risk was calculated to be 3.76×10^{-7}. This upper bound risk is below the range the Agency considers neglible for excess lifetime cancer risk and is not cause for concern.

The RfD for thiodicarb was calculated to be 0.03 mg/kg/day from a chronic rat toxicity study with a NOEL of 3.3 mg/kg/day for males and 4.5 mg/kg/day for females. The RfD was based on an increased incidence of extramedullary hemopoiesis in males and decreased RBC cholinesterase in females at the LOEL. An uncertainity factor of 100 was used for deriving the RfD and includes 10x for inter-species extrapolation and 10x for intra-species variation. An FQPA safety factor of 3x (due to data gaps) was applied to derive an FQPA adjusted RfD of 0.01

mg/kg/day. Exposure must be less than 100% of the FQPA adjusted RfD to be considered below EPA's level of concern.

For acute dietary risk assessment for thiodicarb alone, a MOE of 1000 is required for women 13 years and older, as well as for the general population including infants and children. This MOE includes the conventional MOE of 100 for inter- and intra-species variation, 3x for FQPA, and another 3x for the use of a LOEL, instead of a NOEL, in the critical study. The FQPA Safety Factor (3x) is required because of data gaps (acute and subchronic neurotoxicity studies).

The results of the Monte Carlo acute dietary exposure analyses, for thiodicarb alone, indicate that there are adequate margins of exposure for the general U.S. population (MOE=2450), women 13 years and older (MOE=2100), children 1 to 6 years of age (MOE=2900), and infants (MOE=1680). The Monte Carlo acute analyses incorporated a 93% decline in methomyl residues in cabbage following cooking, an average decline of 75% in celery following trimming of celery tops, anticipated residues and percent crop treated information.

For the acute aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the endpoint for methomyl was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application. A MOE of 300 is required for women 13 years and older, as well as for the general population including infants and children. This MOE includes the conventional MOE of 100, and another 3x for FQPA. The FQPA Safety Factor (3x) is required because of data gaps (acute and subchronic neurotoxicity studies). The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl show that there are adequate margins of exposure for the general U.S. population (MOE=912), children 1 to 6 years of age (MOE=417) and infants (MOE=756). This analysis used a Monte Carlo simulation which included anticipated residues and percent crop treated information for all commodities.

The results of the chronic dietary risk evaluation system (DRES) analyses, for thiodicarb alone, indicate that the anticipated residue contribution for the U.S. Population occupies 68% of the FQPA adjusted RfD. For females (13 years and older) 67% of the FQPA adjusted RfD is occupied. For children (1 to 6 years old) and infants, 104% and 43%, respectively, of the FQPA adjusted RfD is occupied. Although for children (1 to 6 years old), the FQPA adjusted RfD is slightly exceeded, if more refined estimates of dietary exposure were made (e.g. residues from field trials) significantly lower chronic risk would be estimated. Therefore, the chronic risk from exposure to thiodicarb from food sources is not of concern.

For the chronic aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the RfD for methomyl was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application.

Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl,

show that the most significantly exposed subpopulation is infants (<1 year old) with 6.5% of the RfD occupied. For children 1-6 years old 2.7% of the RfD is occupied. For the general U.S. population, only 1.9% of the RfD is occupied. For this aggregate exposure analysis, anticipated residues and percent crop treated information were utilized for all of the approximately 70 commodities. There are no chronic concerns associated with potential residues of methomyl on foods as the result of application of thiodicarb and methomyl.

Thiodicarb degrades rapidly to methomyl in the environment. Therefore, the Agency has calculated drinking water levels of concern (DWLOCs) for methomyl. Acute exposures in surface and ground water for the U.S. population and children (1-6 years) are 470 and 56 ppb, respectively. For chronic (non-cancer) exposure to methomyl in surface and ground water, the drinking water levels of concern are 275 and 78 ppb for the U.S. population and children (1-6 yrs old), respectively.

Estimated maximum (acute exposure) concentrations of methomyl in surface and ground water are 30 and 20 ppb, respectively. The estimated average (chronic exposure) concentration of methomyl in surface water is 26 ppb. Average concentrations in ground water are not expected to be higher than the maximum concentrations. The maximum estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute aggregate exposure. The estimated average concentrations of methomyl in surface and ground water are less than OPP's levels of concern for methomyl in drinking water as a contribution to chronic aggregate exposure.

Therefore, the Agency concludes that aggregate exposure to all sources of thiodicarb and methomyl does not exceed the Agency's risk concerns.

To minimize the risks of potential systemic toxicity to mixers/loaders and other handlers the Agency is requiring the use of personal protective equipment and/or the use of engineering controls (water soluble bags).

Environmental Fate and Ecological Effects

Available environmental fate studies show that thiodicarb degrades rapidly into methomyl under most conditions. While the parent chemical does not appear to be very persistent or highly mobile, the degradate methomyl is more persistent, more mobile, and more toxic.

Chronic laboratory studies show that thiodicarb is moderately to highly toxic to small mammals and will result in chronic risks to certain species of avians that frequent short grass (e.g. ducks, geese and swans). Methomyl, the primary degradate for thiodicarb, is very highly toxic to mammals and poses acute and chronic risks to mammals that feed on short and tall grasses, broadleaf plants, and small insects. In summary, thiodicarb poses potential chronic risks to birds and mammals, primarily due to the build-up of the degradate methomyl from multiple applications of thiodicarb at short intervals.

Acute and chronic toxicity studies show that thiodicarb is very highly toxic to freshwater invertebrates. Toxicity data on the degradate methomyl suggest that methomyl is also highly toxic to aquatic invertebrates on an acute and chronic basis. Both thiodicarb and its degradate methomyl can present high acute risk to freshwater invertebrates.

The major concerns are chronic risks to non-target avian, mammalian, and freshwater invertebrate organisms. Risk to non-target mammalian and freshwater invertebrate organisms have been addressed by limiting the maximum number of applications of thiodicarb on cole crops to 4 per season at the maximum rate of 1.0 lbs ai/A. Currently, the maximum of 6.0 lbs ai/A equals a total of 6 applications at the maximum rate per season. The number of applications on cotton will be limited to 6. These measures will result in less loading of thiodicarb and its degrate methomyl in the environment. Reductions in risk to non-target aquatic organisms is also expected from measures that reduce the potential for spray drift during aerial or ground applications. These restrictions include buffer zones. All agricultural products containing thiodicarb are being reclassified as restricted use pesticides. In addition, label statements are required to minimize the potential for ground water and surface water contamination. A statement supporting the use of an Integrated Pest Management (IPM) plan and a bee hazard statement will also be added to the labels.

Product Reregistration

Before reregistering the products containing thiodicarb, 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. 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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.136 *et seq.* The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency will, therefore, continue its ongoing reregistration program while it determines how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the currently registered uses of thiodicarb. The document consists of six sections. Section I is the introduction. Section II describes thiodicarb, 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 thiodicarb. Section V discusses the reregistration requirements for thiodicarb. Finally, Section VI contains 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:** Thiodicarb
- **Chemical Name:** dimethyl N,N'-(thiobis((methylimino)carbonyloxy)) bis(ethanimidothioate)
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 59669-26-0
- **OPP Chemical Code:** 114501
- **Empirical Formula:** $C_{10}H_{18}N_4O_4S_3$
- **Trade and Other Names:** Larvin
- **Basic Manufacturer:** Rhône-Poulenc AG Company

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 these uses of thiodicarb is contained in Appendix A.

Type of Pesticide: Carbamate insecticide and molluscicide

Use Sites:

TERRESTRIAL FOOD CROP
broccoli, cabbage, cauliflower, corn (sweet), cotton, leafy vegetables, soybeans

TERRESTRIAL FEED CROP
cotton, leafy vegetables

TERRESTRIAL NON-FOOD CROP
agricultural rights-of-way/fencerows/hedgerows, agricultural uncultivated areas, rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, citrus fruits (non-bearing), tree nuts (non-bearing), pome fruits (non-bearing), stone fruits (non-bearing), ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and/or shade trees

GREENHOUSE NON-FOOD CROP
ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and/or shade trees

FORESTRY
shelterbelt plantings

Target Pests:

Invertebrates (insects and related organisms, molluscs, fouling organisms and miscellaneous invertebrates) including: alfalfa looper and larvae, armyworm and larvae, bagworm, beanleaf beetle and larvae, beet armyworm and larvae, boll weevil and larvae, bollworm and larvae, Rown garden snail, budworms, cabbage flea beetle and larvae, cabbage looper and larvae, cankerworms, corn earworm and larvae, cotton boll weevil and larvae and eggs, cotton leaf perforator and larvae, cotton leafworm and larvae, cutworms and larvae, diamondback moth and larvae, european corn borer, fall armyworm and larvae, fall cankerworm and larvae, fall webworm fleahoppers and larvae, fruittree leafroller, gray garden slug, green cloverworm and larvae, gypsy moth, heliothis caterpillars and larvae, imported cabbageworm and larvae, leafrollers, loopers, mexican bean beetle and larvae, mimosa webworm, oakworms, omnivorous leafroller, pink bollworm and larvae, plant bugs and larvae, podworms and larvae, sawflies, skippers, slugs, snails, southern armyworm and larvae, soybean looper and larvae, spring cankerworm, spruce budworm, stink bugs and nymphs, tent caterpillars, three cornered alfalfa hopper and larvae, tobacco budworm and larvae, tomato fruitworm and larvae, velvetbean caterpillar and larvae, webworms, western bean cutworm, woolybear caterpillar and larvae, yellowstriped armyworm and larvae.

Types/Formulations Registered:
Technical grade (96%), manufacturing product (90%), end use product (1.75% to 80%); liquid (unspecified, 90%, 96%), flowable concentrate (23.6%, 34%), granular (4%), pelleted/tableted (1.75%), water dispersible granules (dry flowable, 80%), wettable powder (75.2%)

Methods and Rates of Application:
Types of Treatment: Broadcast; Chemigation; Directed spray; High volume spray (dilute); Low volume spray (concentrate); Spray

Equipment: Aircraft; Ground (both high and low volume); Sprayer; Sprinkler irrigation

Rates: See Appendix A

Timing: For use on in-ground, containerized and/or non-bearing nurserystock. Silk and whorl stages for sweet corn. For use on a "when needed" basis for cotton, soybeans, and tomatoes as long as preharvest intervals are complied with.

Use Practice Limitations: (these do not apply to all uses on all products)
Do not apply directly to water, or to areas where surfacewater is present or to intertidal areas below the mean high water mark.
Do not contaminate water, food or feed.
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).
Do not feed treated corn silage or fodder to livestock.
Do not store or use in or around the home or home garden.
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: (these apply to specific methods and rates of application)
Do not graze livestock in treated areas.
Do not feed treated foliage to livestock or graze treated areas.
Do not feed treated forage or hay to livestock.
Do not feed to livestock.
Do not harvest or feed hay to livestock.
Do not graze treated areas.
Do not use for feed or forage.
Do not feed treated corn silage or fodder to livestock.
Do not use for food or feed.

__ day(s) or hours preharvest interval. (For example: 12 hours or 0, 7, 14 days)

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticidal uses of thiodicarb. 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 that results from using data from various information sources.

An estimated 1,150,000 pounds a.i. of thiodicarb are applied annually in the U.S., with usage appearing to be increasing. Most of this usage (87%) is allocated to three crops: cotton (70%), sweet corn (10%) and soybeans (7%). The remaining usage is spread among leafy vegetables, cole crops and some other minor use sites. The section 3 label for sweet corn is only for fresh market and only for use in Florida but this use pattern has been expanded to 19 other states by use of 24© SLN labels.

Crops with the highest percentages of acreage treated are fresh sweet corn (18%), head lettuce (15%), cotton (8%) and spinach (6%). Registered sites with little or no apparent usage include fruit (except oranges) and nuts (except almonds).

The table on the following page shows the estimated typical annual usage of thiodicarb.

Table 1 - Estimated Typical Annual Usage of Thiodicarb

Site	Acres (000) Planted	Acres Treated (000) Likely Average	Acres Treated (000) Likely Max	% of Crop Treated Likely Average	% of Crop Treated Likely Max	Lbs AI Applied (000) Likely Average	Lbs AI Applied (000) Likely Max	Ave Application Rates lb ai/ A/year	Ave Application Rates appl /year	Ave Application Rates lb ai/ A/appl	States of Most Lbs AI Usage and % of Usage in These States
FIELD CROPS --											
Alfalfa	24,338.3	4	10	<1	<1	<1	2	0.15	1.3	0.10	GA: 60%
Corn	77,234.7	42	85	<1	<1	76	175	1.52	2.6	0.67	FL OH: 95%
Cotton	13,468.1	1,067	2,155	8	16	808	1,615	0.80	2.2	0.36	AL GA LA MS FL: 95%
Soybeans	60,418.3	143	284	<1	<1	79	162	0.47	1.1	0.43	GA LA NC SC: 97%
VEGETABLES --											
Cole Crops	324.3	7	12	2	4	5	10	0.76	1.2	0.67	AZ NC TX: 90%
Broccoli	110.0	<2	3	<2	3	<2	3	0.86	1.1	0.75	AZ: 75%
Cabbage, fresh	84.4	3	6	4	7	2	4	0.70	1.3	0.55	NC TX: 68%
Cauliflower	55.3	2	4	4	8	2	3	0.78	1.0	0.78	AZ: 90%
Sweet Corn	767.0	49	92	6	12	111	216	2.14	3.9	0.58	FL GA NY PA: 92%
Fresh	238.7	44	84	18	35	110	221	2.56	4.8	0.53	FL NY: 91%
Processed	528.3	<5	11	<1	2	na	na	na	na	na	NY: 90%
Lettuce											
Head	207.9	31	39	15	19	61	77	1.93	3.2	0.60	AZ: 90%
Leaf & Romaine	61.5	<1	1	<1	2	<2	2	na	na	na	AZ FL: 90%
Other Leafy Veget	73.7	3	10	4	13	2	5	0.49	1.0	0.49	FL TX: 95%
Celery	31.3	1	3	4	10	<1	1	0.31	1.0	0.31	FL: 90%
Spinach	36.1	2	6	6	17	1	4	0.59	1.0	0.59	TX: 90%
Onions, Dry	157.6	1	2	1	2	1	2	1.22	2.0	0.61	TX: 90%
FRUITS AND NUTS --											
Almonds	404.3	3	6	1	1	5	9	1.67	1.1	1.50	CA: 100%
Oranges	913.0	1	2	<1	<1	1	2	1.00	1.1	0.90	CA: 95%
TOTAL	178,368.9	<1,353	2,697			<1,151	2,278				

Sources:
- Gianessi and Anderson, Pesticide Use in U.S. Crop Production, Feb. 1995.
- US EPA proprietary sources.
- USDA/NASS, Agricultural Chemical Usage, 1991-1994 Field Crops Summaries.
- USDA/NASS, Crop Production, 1994 Summary.
- USDA/NASS, Agricultural Chemical Usage, Vegetables, 1992 and 1994 Summaries.
- USDA/NASS, Vegetables, 1994 Summary.
- USDA/NASS, Noncitrus Fruits and Nuts, 1994 Preliminary.

NOTES:
- Usage probably is either zero or small for the following sites since no usage was found in available data sources: fruits (except oranges), nuts (except almonds), greenhouse/nurseries, cemeteries, educational facilities, road rights-of-way, landscape contractors and pest control operators.
- Usage is unknown for the following sites since data sources are not readily available: minor vegetables such as rhubarb, specific ornamental flowers, shrubs and trees, irrigation systems, uncultivated nonagricultural areas and fencerows. - "na" means not available.

D. Data Requirements

In addition to data requirements imposed to obtain the original registration of this active ingredient, data were required in the reregistration Phase IV Data Call-In issued in April of 1991. Data required included studies on ecological effects, environmental fate, residue chemistry, and human toxicity. Appendix B includes all data requirements identified by the Agency for currently registered uses which are required to support reregistration.

E. Regulatory History

Thiodicarb products were first registered under the tradename Larvin by Union Carbide in 1984 and transferred to Rhone-Poulenc in 1987.

Methomyl is a degradate of thiodicarb. In August 1997, a reassessment of all tolerances for thiodicarb was completed in order to make a decision on certain time-limited tolerances which were due to expire. This analysis included both the residues from all thiodicarb uses as well as residues from application of methomyl. All tolerances were found to be satisfactory and made permanent. Subsequently, changes to the toxicological dietary endpoint have resulted in significant changes to the risk assessment. These changes are reflected in the dietary sections of this document.

The table on the following page shows the major registration actions for thiodicarb.

Table 2 -Major Registration Actions for Thiodicarb

Date	Formulation added	Use Added	Comments
9/8/80	---	---	initial application for registration of active ingredient filed by Union Carbide
2/10/84	96% MP	---	first product registered (manufacturing use)
2/27/84	23.5F, 34F, 75WP, 80DF	sweet corn (fresh market only) ground application	first end use products registered restricted for use in Florida only
10/29/84	90% MP	---	second manufacturing use product registered
1986 - 1995	---	sweet corn (fresh market only)	24© SLN labels submitted to expand use to AL, CT, DE, GA, LA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, PR, RI, VA, VT (all still active)
9/87	---	---	Union Carbide registrations transferred to Rhone-Poulenc
9/21/87	---	cotton, soybeans, aerial application, application through irrigation systems	use pattern expanded
4/18/89	---	ornamentals, non-crop areas	use pattern expanded
2/11/92	---	broccoli, cabbage, cauliflower	use pattern expanded
7/7/92	---	leafy vegetables	use pattern expanded
4/7/93	80 DF in WSP	---	dry flowable packaged in water soluble packages to minimize mixer exposure
3/24/97	4G, 1.75P/T	slug baits in ornamentals	use pattern expanded

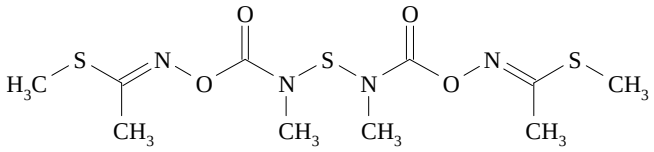
MP = manufacturing use product; F = flowable; WP = wettable powder, DF = dry flowable; WSP = water soluble packaging; G = granular; P/T = pelleted/tableted

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The following figure shows the chemical structure of thiodicarb.

Thiodicarb [dimethyl N,N'-(thiobis((methylimino)carbonyloxy)) bis(ethanimidothioate)]



Empirical Formula:	$C_{10}H_{18}N_4O_4S_3$
Molecular Weight:	354.46
CAS Registry No.:	59669-26-0
OPP Code No.:	114501

Identification of Active Ingredient

Thiodicarb is a white to light tan crystalline powder with a slight sulfurous odor and melting point of 168-174°C. Thiodicarb is soluble in water at 35 ppm, and in dichloromethane, acetone, methanol, and xylene at 15%, 0.8%, 0.5%, and 0.3% by weight, respectively.

Manufacturing-use Products

There are two thiodicarb manufacturing-use products (MPs) registered to Rhône-Poulenc AG Company, under OPP Code No. 114501: the 96% technical (T; EPA Reg. No. 264-343) and the 90% formulation intermediate (FI; EPA Reg. No. 264-411).

Product Chemistry Data Requirements

All pertinent generic and product-specific product chemistry data requirements are satisfied for the Rhône-Poulenc 96% T/TGAI, except for GDLN 830.7050 pertaining to UV/VIS absorption spectrum. This guideline is required. In addition, the registrant must certify that the suppliers of beginning materials and the manufacturing process for the thiodicarb TGAI have not changed since the last comprehensive product chemistry reviews or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Toxicology Assessment

The available toxicological database for thiodicarb is adequate and will support a reregistration eligibility determination. An acute neurotoxicity study (81-8) and a subchronic neurotoxicity study (82-7) are required.

a. Acute Toxicity

The following table presents the results of the acute mammalian toxicity studies conducted with technical thiodicarb:

Table 3 - Acute Mammalian Toxicity Studies

Route	Species	Results	Tox Category
Oral	Rat	LD_{50} (m) = 46.5 mg/kg LD_{50} (f) = 39.1 mg/kg	I
Dermal	Rabbit	LD_{50} >2000 mg/kg	III
Inhalation	Rat	LC_{50} (m) 0.13, (f) 0.12 mg/L and > 0.32 mg/L for dust	II
Eye Irritation[a]	Rabbit	Slight Irritant	III
Skin Irritation[a]	Rabbit	No Irritation	IV
Dermal Sensitization[a]	Guinea Pig	Weak Sensitivity	N/A
Acute Delayed Neurotoxicity	Hens	Negative	N/A

[a] Not required for TGAI, however, presented here for informational purposes.

In several acute oral toxicity studies with rats, the LD_{50} ranged from 46.5 mg/kg for males and 39.1 mg/kg for females, which is Toxicity Category I, to 398 mg/kg for males and 248 mg/kg for females, which is Toxicity Category II (MRID 00025791, 00115604, 00115607). In a mouse study, the LD_{50} was 73 mg/kg in males and 79 mg/kg in females (MRID 43784501).

The LD_{50} in an acute dermal toxicity study with rabbits was found to be greater than 2000 mg/kg. This is Toxicity Category III (MRID 44025501).

In an acute inhalation toxicity study with rats, the LC_{50} for males was 0.13 mg/L, for females 0.12 mg/L, and greater than 0.32 mg/L for dust for both sexes. These results are all considered to be in Toxicity Category II (MRIDs 00041432 and 00045467).

Thiodicarb is a Toxicity Category III primary eye irritant in rabbits. Instillation resulted in slight irritation (MRID 44025502).

Thiodicarb produced no irritation during the primary dermal irritation study in rabbits, placing thiodicarb in Toxicity Category IV for skin irritation (MRID 44025503). Thiodicarb induced a weak dermal sensitization reaction in guinea pigs (MRIDs 41891004 and 43373201).

An acute delayed neurotoxicity study with thiodicarb in atropine-pretreated hens, using a dose level of 660 mg/kg (LD_{50}) was negative (MRIDs 00044961 and 00053253). No data are available on the acute and subchronic neurotoxicity of thiodicarb in rats. Although no neurotoxic signs per se have been observed in the various studies performed using thiodicarb to date, thiodicarb is a carbamate, and confirmatory acute and subchronic neurotoxicity studies are required for a thorough investigation of this parameter.

b. Subchronic Toxicity

The following table summarizes the results of the sub-chronic toxicity studies for thiodicarb.

Table 4 - Summary of Thiodicarb Sub-Chronic Toxicity Studies

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
82-2	13-week dietary - rat	3	10	decreased body weight gain, RBC cholinesterase activity and hemoglobin
82-2	13-week dietary - dog	15	45	decreased RBC parameters
82-2	6-month dietary - dog	15	45	increased liver weight and SGPT
82-2	21-day dermal - rabbit[1]	1000	2000	macrocytic anemia, erythema, and edema
82-2	16-day dermal - rabbit[1]	1000	4000	decreased body weight, erythrocytes and hemoglobin
82-2	9-day inhalation - rat	not determined	4.8 mg/m^3	pinpoint pupils and tremors at LDT
82-2	4-week dietary - mice	6.2 males 8.3 females	346 males 491 females	increased liver weight in females and increased spleen weight in both sexes
82-2	28-day dietary - rat	10	30	decreased plasma and RBC cholinesterase activity

[1] The NOELs from these studies were used for short term and intermediate term dermal occupational toxicological endpoints.

In a subchronic toxicity study, Fisher 344 (COBS CD F/Crl BR) rats, 10/sex/group, were administered thiodicarb (97% a.i.) via the diet at dose levels of 1, 3, 10, and 30 mg/kg/day for 13 weeks. The NOEL was 3 mg/kg/day, and the LOEL was 10 mg/kg/day, based on decreased body-weight gain, decreased RBC cholinesterase activity,

and decreased hemoglobin (MRID 00044965).

In a subchronic feeding study in Beagle dogs, thiodicarb was administered via the diet at dose levels of 0, 15, 45, and 90 mg/kg/day for 13 weeks. The high dose was lowered to 76 mg/kg/day in females after day 36 due to the deaths of 2 high-dose females. The NOEL was 15 mg/kg/day, and the LOEL was 45 mg/kg/day, based on decreased RBC parameters (RBCs, hematocrit and hemoglobin) in both sexes (MRID 00044966).

In another subchronic toxicity study in dogs, thiodicarb was administered via the diet at dose levels of 0, 5, 15, and 45 mg/kg/day for 6 months. The NOEL was 15 mg/kg/day, and the LOEL was 45 mg/kg/day, based on liver effects of increased serum glutamic pyruvic transaminase (SGPT) and increased liver weight (MRID 00079474).

In a 21-day dermal toxicity study, New Zealand White rabbits were administered thiodicarb via the skin at dose levels of 1000, 2000, and 4000 mg/kg/day for 6 hours a day, 5 days a week for 3 weeks. The NOEL was 1000 mg/kg/day, and the LOEL was 2000 mg/kg/day, based on macrocytic anemia, erythema, and edema (MRIDs 00043737 and 00044967).

In a 16-day dermal toxicity study, New Zealand white rabbits were administered thiodicarb via the skin at dose levels of 1000 and 4000 mg/kg for 6 hours a day, 5 days a week for 3 consecutive weeks. The NOEL was 1000 mg/kg/day, and the LOEL was 4000 mg/kg/day, based on decreased erythrocytes, decreased hemoglobin, and decreased body weight (MRID 00043738).

In a 9-day dust inhalation study, Sprague-Dawley rats were administered thiodicarb particulates via the inhalation route at dose levels of 0, 4.8, 17.7, and 59.5 mg/m^3 for males, and 0, 4.8, 19.6, and 54.0 mg/m^3 for females (mean measured atmospheric concentrations) for 6 hours a day for 9 days. A NOEL could not be determined. At 4.8 mg/m^3, two clinical signs typically associated with cholinesterase effects (pinpoint pupils and tremors) were observed in both sexes. There were no significant body-weight effects at this dose level in either sex, and no statistically significant effects were observed in any cholinesterase measurement (plasma, RBC, and brain) at 4.8 or 17.7/19.6 mg/m^3 in either sex (MRIDs 00045467 and 00053252).

In a 4-week feeding study, CD-1 mice of both sexes were administered thiodicarb via the diet at dose levels for males of 0, 6.2, 346, 734, and 1538 mg/kg/day, and for females of 0, 8.3, 491, 954, and 2030 mg/kg/day for 4 weeks. The NOEL was 6.2 and 8.3 mg/kg/day for males and females respectively. The LOEL was 346 and 491 mg/kg/day for males and females respectively. These results are based on increased liver weight in females and increased spleen weight in both sexes (MRID 43611701).

In a subchronic feeding study, male and female Fischer 344 rats were administered

thiodicarb via the diet at dose levels of 0, 1, 3, 10, and 30 mg/kg/day for 28 days. The NOEL for effects on cholinesterase activity was 10 mg/kg/day, and the LOEL was 30 mg/kg/day, based on decreased plasma and RBC cholinesterase activity (MRID 00098292).

c. Chronic Toxicity and Carcinogenicity

Thiodicarb is classified as a B2 (probable human) carcinogen (HED Cancer Peer Review Committee, document dated June 10, 1996). The B2 classification was based on statistically significant increases in hepatocellular adenomas, carcinomas, and combined adenoma/carcinoma in both sexes of the CD-1 mouse and statistically significant increases in testicular interstitial cell tumors in male Sprague-Dawley rats.

The table on the following page summarizes the results of the chronic/carcinogenicity toxicity studies for thiodicarb.

Table 5 - Summary of Thiodicarb Chronic/Carcinogenicity Toxicity Studies

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
83-1(b)	1-year chronic - dog	4.4 males 4.5 females	12.8 males 13.8 females	Cholinesterase inhibition
	same study	12.8 males 13.8 females	38.3 males 39.5 females	Systemic effects based on reduced hematology parameters
83-1(a)	2-year chronic/ carcinogenicity-rat[1,2]	3.3 males 4.5 females	12 males 15 females	Systemic effects based on increased incidence of extramedullary hemopoiesis in males and decreased RBC cholinesterase in females. High-dose males displayed an increased incidence of interstitial cell tumors in the testes compared to the concurrent control males. There were no compound-related tumors observed in the females.
83-1(a)	97-week carcinogenicity-mice[2]	70	1000	Increased mortality, clinical chemistry, liver and spleen weights; and incidences of kidney, liver, and spleen lesions, and decreased hemoglobin, hematocrit, and erythrocytes. There were increased incidences of hepatocellular tumors in both sexes.
83-1(a)	2-year mouse carcinogenicity	3	10	Mortality in females.

[1] The NOEL from this study was used to calculate the thiodicarb reference dose (RfD), multiplied by the uncertainty factor of 300.
[2] The toxic effects from this study were used to determine the B2 cancer classification for thiodicarb.

Beagle dogs were administered technical thiodicarb via the diet at dose levels of 0, 4.4, 12.8, and 38.3 mg/kg/day for males at dose levels of 0, 4.5, 13.8, and 39.5 mg/kg/day for females, for one year. The NOEL is 4.4 mg/kg/day for males and 4.5 mg/kg/day for females. The LOEL is 12.8 mg/kg/day for males and 13.8 mg/kg/day for the females, based on cholinesterase inhibition. The systemic NOEL is 12.8 mg/kg/day for males and 13.8 mg/kg/day for females. The systemic LOEL is 38.3 mg/kg/day for males and 39.5 mg/kg/day for females, based on reduced hematology parameters including erythrocytes, hemoglobin, and hematocrit (MRID 00159813).

In a chronic toxicity/carcinogenicity study, Sprague-Dawley rats were administered thiodicarb via the diet at dose levels of 0, 3.3, 12, and 60 mg/kg/day for males and dose levels of 0, 4.5, 15 and 80 mg/kg/day for females for 104 weeks. The systemic NOEL was 3.3 mg/kg/day for males and 4.5 mg/kg/day for females. The LOEL was 12 mg/kg/day for males and 15 mg/kg/day for females, based on the increased incidence of extramedullary hemopoiesis in males and decreased RBC cholinesterase in

females. There were no compound-related tumors observed in the females. The high-dose males displayed an increased incidence of interstitial cell tumors in the testes compared to the concurrent control males, and the incidence was also greater than the historical control (MRIDs 43308201, 43405001, 43596401).

In a carcinogenicity study, Charles River CD-1 mice of both sexes were administered thiodicarb via the diet at dose levels of 0, 5, 70, and 1000 mg/kg/day for 97 weeks. The NOEL was 70 mg/kg/day, and the LOEL was 1000 mg/kg/day, based on decreased body-weight gain in males, and in both sexes toxic effects noted consisted of increased mortality; decreased hemoglobin, hematocrit, and erythrocytes; increased alanine aminotransferase and total bilirubin; increased liver and spleen weights; and increased incidences of kidney, liver, and spleen lesions. There were increased incidences of hepatocellular tumors in both sexes. In both male and female mice, there were statistically significant increases in hepatocellular adenomas, carcinomas and combined adenomas/carcinomas at the highest dose (1000 mg/kg/day). There were also statistically significant positive dose-related trends for adenomas and carcinomas, alone and combined. The incidence of adenomas and carcinomas at the highest dose exceeded that of historical controls in both sexes; in addition, in male mice, the incidence of adenomas at the mid-dose (70 mg/kg/day) exceeded that of historical controls (MRIDs 43000501 and 43619301).

In another carcinogenicity study, Charles River CH:COBS CD-L (ICR)BR mice of both sexes were administered thiodicarb via the diet at dose levels of 1, 3, and 10 mg/kg/day for 104 weeks. The NOEL was 3 mg/kg/day, and the LOEL was 10 mg/kg/day, based on mortality in females (MRID 00041407).

Other Carcinogenic Issues

Methomyl is a metabolite of and is structurally-related to thiodicarb. Methomyl was classified as a Group E, not likely to be carcinogenic to humans via relevant routes of exposure (HED/RfD/ Peer Review Committee document dated October 25, 1996). There are two animal metabolites acetamide and acetonitrile. Acetamide, a metabolite of methomyl, has been evaluated by the the Agency and classified as a Group C, possible human carcinogen. However, after a thorough investigation, the Agency concluded that the ingestion of methomyl and acetamide in the diet should not represent a significant carcinogenic hazard to the consuming public based on the following: 1) the conversion rate of methomyl to acetamide is low, approximately 2-3 percent, therefore, residue levels of acetamide in edible meat should be low, 2) carcinogenicity studies with methomyl in two rodent species indicated no increase in any type of tumor under the test conditions, 3) the product is comprised of 98.7 percent syn-isomer and 0.092 percent anti-isomer, syn-isomer must be converted to anti-isomer before acetamide is formed, and 4) acetamide induced liver tumors in rats only when administered at very high dosages, i.e. more than 1000 mg/kg/day. Ingestion of acetonitrile from application of thiodicarb and/or methomyl

would not represent a significant carcinogenic hazard because it is volatile, residues are small, it has little or no cancer potential, and since it is a rat metabolite its toxicity was accounted for in the toxicity studies.

d. Developmental and Reproductive Toxicity

The following table summarizes the results of the developmental and reproductive toxicity studies for thiodicarb.

Table 6 - Summary of Thiodicarb Developmental and Reproductive Toxicity Studies.

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
83-3(a)	developmental - rat[1]	maternal; N/A developmental; N/A	maternal 10 developmental 10	Decreased body weight gain. Decreased fetal body weights and increased incidence of litters and fetuses with developmental variations.
83-3(b)	developmental - rabbit	maternal; 20 developmental; 40, HDT	maternal; 40	Decreased body weight gain and food consumption.
83-3(a)	developmental - mice	maternal; 100 developmental; 200, HDT	maternal; 200	Increased mortality.
83-4	2-generation - rat	reproductive; 5 systemic; 5	reproductive; 15 systemic; 15	Decreased fetal body weight and viability. Decreased body weight/gain and food consumption.

[1] The LOELs from this study were used for the acute dietary endpoint.

In a rat developmental toxicity study, pregnant Charles River CD COBS rats were administered thiodicarb via gavage on gestation days 6-19 at dose levels of 0 [0.5% methocel], 10, 20, and 30 mg/kg/day. Maternal toxicity was observed at the 20 and 30 mg/kg/day dose levels, as evidenced by inactivity, tremors, and a clear oral discharge observed for 1-4 hours post dose. Negative body-weight gain was observed during the first 3 days of dosing at the mid- and high-dose levels, and overall body-weight gain was decreased at all dose levels [81%, 73%, and 65% of control at 10, 20, and 30 mg/kg/day, respectively].

Developmental toxicity was observed at all dose levels. There was a dose-related decrease in fetal body weight [89%, 75%, and 69% of control at 10, 20, and 30

mg/kg/day, respectively] that was statistically significant at all dose levels. There was a dose-related increase in the number of litters and fetuses with developmental variations [unossification of the hyoid, sternebrae #5 and/or #6 and other sternebrae], and increases in reduced ossification of the skull and vertebrae, and unossification of the pubis and entire sternum were observed at the 20 and 30 mg/kg/day dose levels.

The maternal LOEL is 10 mg/kg/day, based on decreased body-weight gain. The developmental LOEL is 10 mg/kg/day, based on decreased fetal body weight and an increase in the number of litters and fetuses with developmental variations. No NOEL was established for either maternal or developmental toxicity (MRID 099223).

In a developmental toxicity study, artificially-inseminated New Zealand white rabbits were administered thiodicarb via gavage on gestation days 6 through 19 at dose levels of 0 (vehicle 0.5% aqueous methylcellulose), 5, 20, and 40 mg/kg/day. The maternal toxicity NOEL was 20 mg/kg/day, and the maternal toxicity LOEL was 40 mg/kg/day, based on reduced body-weight gain and food consumption. The developmental toxicity NOEL was 40 mg/kg/day, the highest dose tested (MRIDs 00159814, and 40280001).

In a developmental toxicity study, Charles River CD-1 mice were administered thiodicarb on gestation days 6 through 16 via gavage at dose levels of 0 (vehicle 0.5% methocel), 50, 100, and 200 mg/kg body weight/day. The maternal toxicity NOEL was 100 mg/kg/day, and the maternal toxicity LOEL was 200 mg/kg/day, based on increased mortality. The developmental toxicity NOEL was 200 mg/kg/day, the highest dose tested (MRIDs 00043742, 00043743, 00053257, 00053258).

In a two-generation reproduction study, Crl:CD®BR/VAF/Plus® rats were fed doses of 0, 5, 15, and 45 mg/kg/day of thiodicarb. The reproductive/developmental toxicity NOEL is 5 mg/kg/day, and the reproductive/developmental toxicity LOEL is 15 mg/kg/day, based on decreased fetal body weight and viability. The systemic NOEL is 5 mg/kg/day and the systemic LOEL is 15 mg/kg/day, based on decreased body weight/gain and food consumption in both sexes (MRIDs 42381301, 42381302, 42735101).

e. Mutagenicity

Thiodicarb did not induce a mutagenic response in the Ames assay, with or without metabolic activation (MRIDs 00044872, 00135792). Thiodicarb induced dose-related increased mutant frequencies in mouse lymphoma $TK^{+/-}$ cells, with and without metabolic activation and is considered to have an equivocal weak effect in the mouse lymphoma forward mutation assay (MRID 00151574). Thiodicarb, with or without metabolic activation, did not cause a clastogenic response in the chromosomes of Chinese hamster ovary cells (MRID 00151572). Thiodicarb is considered inactive in the primary rat hepatocyte unscheduled DNA synthesis assay (MRID 00151573).

f. Metabolism

Metabolic studies were performed in rats using single low and single high doses of radiolabeled thiodicarb. The major routes of elimination were expiration (CO_2 and acetonitrile) and urination. Tissue residues contained 7-9% of the dose at 7 days post dose and may reflect the metabolism of ^{14}C-acetonitrile into the body's C-2 and C-1 pools and subsequent interaction with, or incorporation into natural products. The major terminal metabolites of thiodicarb in the rat are CO_2 and acetonitrile. The major urinary metabolite is a labile unknown that represents 50% of the urinary radiolabel. No acetamide was detected in any of the tissues. The RBCs contained only residue that cannot be extracted by organic solvents or water, indicating the presence of radiolabel incorporated into natural products or of material tightly bound to hemoglobin (MRID 41250006, 41250007).

In a metabolism study in monkeys, some thiodicarb [syn, syn-isomer] radiolabel was converted via in vivo metabolism to syn-methomyl and subsequently isomerized to anti-methomyl, with ≈0.8-1.0% (lower limit) to 2.6-3.3% (upper limit) by weight of thiodicarb being converted to acetamide and excreted in the urine (MRIDs 42667601, 43228901).

2. Dose Response Assessment

a. Potential Risk to Infants and Children and FQPA Safety Factor

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, exposure, and other information such as epidemiological data.

For purposes of assessing the pre- and post-natal toxicity of thiodicarb, EPA has evaluated three developmental and one reproduction study. The effects observed in the thiodicarb developmental and reproduction studies are summarized in Table 6, section II,B,d.

The Agency has determined that the data provided no indication of increased susceptibility of rats or rabbits to in utero or postnatal exposure to thiodicarb. In the prenatal developmental toxicity studies in rats and rabbits, effects in the fetuses were observed only at or above treatment levels that resulted in evidence of maternal toxicity. In the two-generation reproduction toxicity study, although the effects in the offspring were observed at a calculated lower dose (calculated NOEL =1.75 mg/kg/day) than in the

parental animals (NOEL =5 mg/kg/day), it was concluded that this is not a real indication of increased susceptibility for the following reasons: 1) the endpoint (decrease in pup body weight) was considered to be a systemic effect and not a developmental or reproductive effect since the decrease was seen from day 7 through 21 of lactation in male pups and from day 14 through 21 in female pups; 2) the decreased pup weight was seen only in one generation (F2b) and not in the other generations thus lacking in consistency in response; 3) the data showed that the body weight gain of pups in this litter was at a higher rate than the body weight gain of control pups; 4) the decrease (8%) in both sexes on day 0 was not statistically significant at day 4; 5) the lowest dose (5 mg/kg/day) is actually considered close to a NOEL for the offspring while the 1.75 mg/kg/day was derived using Bench Mark methodology; and 6) it is during the latter portion of lactation that pups consume approximately twice the diet per unit body weight as an adult rat and, because of the availability of the test material to the pups from both milk and the feed, the amount consumed by the pups is likely more than double the adult's.

There are, however, data gaps for acute and subchronic neurotoxicity studies in rats. These studies are considered data gaps because thiodicarb breaks down to methomyl, which has exhibited neurotoxic signs in two species (dogs and rabbits) by two different routes of exposure (oral and dermal). In addition, thiodicarb produced neurotoxic effects (tremors and inactivity in dams) in the rat developmental toxicity study as well as tremors in rats in a 9-day inhalation toxicity study. The requirement for a developmental neurotoxicity study in rats is in reserve status pending receipt of the acute and subchronic neurotoxicity studies.

Uncertainty Factor

The 10x FQPA Safety Factor for enhanced sensitivity to infants and children (as required by FQPA) for thiodicarb was reduced to 3x.

Although, there was no indication of increased susceptibility of rats or rabbits to in utero or postnatal exposure to thiodicarb, data gaps exist for acute and subchronic neurotoxicity studies. These studies will provide cholinesterase inhibition and field observation behavior data as well as histopathology of the central and peripheral nervous system which are not available for evaluation in any of the available toxicology studies on thiodicarb. Thiodicarb is not currently registered for any residential uses. The 3x safety factor and the use of generally high quality data and conservative models and/or assumptions in the exposure assessments provide adequate protection of infants and children.

The FQPA Safety Factor (3x) should be applied for acute and chronic dietary risk assessments for the general population including infants and children. Application of the FQPA Safety Factor is appropriate for these risk assessments because of the lack of data on the neurotoxic potential of thiodicarb following single and repeated exposures.

b. Reference Dose

An RfD (exclusive of the 3x FQPA safety factor) was calculated to be 0.03 mg/kg/day based on a chronic rat toxicity study with a NOEL of 3.3 mg/kg/day for males and 4.5 mg/kg/day for females (RfD Peer Review Committee; January 18, 1996). The LOEL was 12 mg/kg/day for males and 15 mg/kg/day for females, based on the increased incidence of extramedullary hemopoiesis in males and decreased RBC cholinesterase in females (MRID 43308201). An uncertainity factor of 300 was used and includes 10x for inter-species extrapolation, 10x for intra-species variation and an FQPA safety factor of 3x (based on the data gaps). The FQPA adjusted RfD is 0.01 mg/kg/day. Exposure must be less than 100% of the FQPA adjusted RfD to be considered below EPA's level of concern.

Thiodicarb has been reviewed by the WHO/FAO Joint Meeting on Pesticide Residues, and an Acceptable Daily Intake of 0.03 mg/kg/day was established.

c. Carcinogenicity Classification and Risk Quantification

The carcinogenic potential of Thiodicarb was evaluated by the HED Cancer Peer Review Committee (CPRC) on November 29, 1995 prior to issuance of the draft guidance, *Proposed Guidelines for Carcinogen Risk Assessment of April 1996.* The CPRC classified it as a Group B2 - Probable Human Carcinogen based on the evidence of carcinogenicity in both sexes of mice (liver tumors) and male rats (testicular tumors) and recommended a non-linear approach (i.e., Margin of Exposure) for human risk characterization. The CPRC determined that extrapolation should be based on the combined hepatocellular adenomas/carcinomas in male mice.

The CPRC recommended the MOE approach in part based on the fact that liver tumors were observed only at the high dose (1000 mg/kg/day) which is the Limit-Dose for carcinogencity testing and this dose may have been excessive due to the significant hepatoxicity seen in both sexes of mice at this dose level. Pronounced systemic toxicity that manifested as increased mortality (females), significant decreases in body weight gain (males), and alterations in the hematopoietic system (both sexes) was also observed at the high dose. Due to the poor dose selection, the increase in liver tumors observed in males at the next lower dose (70 mg/kg/day) could not be discounted. Additionally, testicular tumors were observed in male rats only at the high dose with a borderline significance. There is no evidence of genotoxicity.

The Agency's *Proposed Guidelines for Carcinogen Risk Assessment of April 1996* states that for human risk characterization, a linear default would be used unless the chemical was non-mutagenic and had a non-linear mode of action. Although Thiodicarb is non-mutagenic, no studies demonstrating a mode of action for the induction of liver tumors have been submitted to the Agency. Therefore, Thiodicarb did not meet one of the two criteria specified in the guidelines for using a non-linear approach for human risk

characterization.

Based on these factors, the Agency has determined that a linear (Q_1*) instead of the non-linear (MOE) approach is appropriate for human risk characterization at this time. This decision is primarily due to the lack of mode of action studies which are required for use of a non-linear approach as specified in the Draft guidelines of 1996.

d. Toxicological Endpoints

The following endpoints were selected for risk assessment (Health Effects Division's Toxicological Endpoint Selection Committee; document dated June 14, 1996).

Dermal Absorption

There are no dermal absorption data available. A study could not be identified. The NOEL of 20 mg/kg/day from the oral developmental toxicity study in rabbits was compared to the NOEL of 1000 mg/kg/day from the 21-day dermal toxicity study in rabbits (MRIDs 00043737 and 00044967). This indicates an estimated dermal absorption of approximately 2%. This estimation of low dermal absorption is supported by the lack of systemic toxicity in the 21-day dermal study. This estimate was used in the occupational risk assessment for cancer.

Acute Dietary (1 day) Females 13 Years and Older

The endpoint selected for this risk assessment is the developmental LOEL equal to 10 mg/kg/day, based on decreased fetal body weight and an increase in the number of litters and fetuses with developmental variations. This endpoint is applicable only for the females 13 years and older subgroup. For acute dietary risk assessment for thiodicarb alone, a MOE of 1000 is required. This MOE includes the conventional MOE of 100 for inter- and intra-species variation, 3x for FQPA, and another 3x for the use of a LOEL, instead of the NOEL, in the critical study. The FQPA Safety Factor (3x) is required because of data gaps (acute and subchronic neurotoxicity studies).

Acute Dietary (1 day) General U.S. Population, Including Infants and Children

The endpoint selected for this risk assessment is the maternal LOEL equal to 10 mg/kg/day, based on decreased body-weight gain. This endpoint is applicable for the general population including infants and children. For acute dietary risk assessment for thiodicarb alone, a MOE of 1000 is required for the general population including infants and children. This MOE includes the conventional MOE of 100 for inter- and intra-species variation, 3x for FQPA, and another 3x for the use of a LOEL, instead of the NOEL, in the critical study. The FQPA Safety Factor (3x) is required because of data gaps (acute and subchronic neurotoxicity studies).

Carcinogenic Exposure (Dietary and Occupational)

A Q1* of 1.88 x 10 -2 (mg/kg/day)-1 based on evidence of carcinogencity in both sexes of mice (liver tumors) and male rats (testicular tumors) will be used for estimating carcinogenic risk. Carcinoginic risk is estimated for adults only.

Short Term Dermal Occupational or Residential Exposure (1-7 days)

Short term or intermediate term dermal occupational and residential risk assessments are not required. No appropriate endpoint was identified. No treatment-related effects were observed at 1000 mg/kg/day in a 16-day repeated dose dermal toxicity study in rabbits (MRID 00043738). No dermal or systemic toxicity was observed at 1000 mg/kg/day in a 21-day dermal toxicity study in rats (MRID 00044967).

Intermediate Term Dermal Occupational or Residential Exposure (1 week to several months)

See Short Term exposure (above).

Chronic Occupational or Residential Exposure (several months to lifetime)

Chronic dermal occupational or residential exposure toxicity endpoints were identified for thiodicarb. However, based on the current use patterns, chronic exposures to thiodicarb are not expected, and a chronic risk assessment is not necessary. The Agency believes that a reasonable worst-case frequency of exposure would be six days per week for 2 - 3 months for harvesters working in crops where thiodicarb use is common. For nursery and greenhouse workers engaged in cultivation of herbaceous and woody ornamentals, a reasonable worst case frequency of exposure would be intermittent exposures of 2 - 3 weeks at a time, several times per year, but not continuous. This is representative of intermediate-term rather than chronic exposure.

Inhalation Occupational or Residential Exposure (any time period)

Assuming 100% inhalation absorption, the LOEL to be used for risk assessment for thiodicarb is 0.0048 mg/L, based on a 9-day dust inhalation study in rats (MRIDs 00045467 and 00053252). This was the lowest dose tested in this study. A NOEL could not be determined. The effects seen at the LOEL, of pinpoint pupils and tremors, are clinical signs typically associated with cholinesterase effects. These effects were observed in both sexes. Using the calculations shown below for route-to-route extrapolation to calculate dose, the LOEL is 1.2 mg/kg/day.

4.8 mg/m^3 is equal to 0.0048 mg/L because $mg/m^3/1000$ = mg/L

LOEL = 0.0048 mg/L; route to route extrapolation given by [0.0048 mg/L/day x 1 (for 100% inhalation absorption) x 8.46 L/hr x 6 hr exposure x 1 (for activity factor)/0.190 kg] = LOEL of 1.2 mg/kg/day.

An uncertainty factor of 3x is required since a LOEL was selected for use in this risk assessment instead of a NOEL. An MOE of at least 300 is required for acceptable occupational inhalation risks.

Methomyl Toxicological Endpoints of Concern

The Agency has determined that thiodicarb has a metabolite, methomyl, which is also a registered pesticide. Therefore, methomyl residues resulting from applications of both thiodicarb and methomyl will be considered in an aggregate risk assessment and compared to appropriate toxicological endpoints for methomyl.

The RfD for methomyl was established based on a 2-year dog feeding/carcinogenicity study with a NOEL of 2.5 mg/kg/day. An uncertainty factor of 100 was applied to account for both inter-species extrapolation and intra-species variability. The 10x FQPA safety factor to account for enhanced sensitivity to infants and children was reduced to 3x. The 3x results from the lack of acute and subchronic neurotoxicity studies. On this basis, the RfD was calculated to be 0.008 mg/kg/day.

The acute dietary endpoint for methomyl is the developmental NOEL of 6 mg/kg/day from a rabbit developmental study based on deaths in dams on days 1-3 after dosing with methomyl at 16 mg/kg/day. Because of the severity of effects observed, exposure to all population subgroups are of concern (MRID 00131257). For acute dietary risk assessment for application of thiodicarb and methomyl, an MOE of 300 is required for the general population including infants and children. This MOE includes the conventional MOE of 100 for inter- and intra-species variation, and 3x for FQPA. The FQPA Safety Factor (3x) is required because of data gaps (acute and subchronic neurotoxicity studies).

On plants, thiodicarb degrades to methomyl following application, yielding field residues of methomyl. Therefore, the Agency has considered potential worker exposure to methomyl following applications of thiodicarb. There are short- and intermediate-term; and chronic toxicological endpoints of concern for methomyl (Hazard ID Document dated March 3, 1998). The NOEL for both short- and intermediate-term occupational risk assessment for methomyl is 90 mg/kg/day based on no statistically or biologically significant differences in plasma or RBC cholinesterase inhibition at the dose tested. Because chronic risk to methomyl following applications of thiodicarb is not expected, chronic exposure is not considered. Also, although an inhalation endpoint for methomyl of 0.137 mg/L was identified, no post-application inhalation exposure assessment for methomyl as the result of thiodicarb applications has been performed since the vapor

pressures of both methomyl and thiodicarb are in the range of 1 X 10^{-5} mm Hg, which is below that which would create an inhalation concern once sprays and dusts have settled.

3. Exposure Assessment

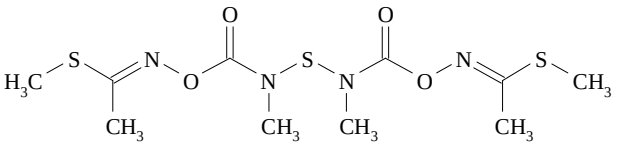
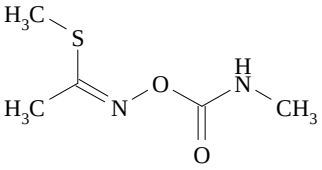
a. Dietary Exposure (food sources)

The information listed under "Summary of Science Findings" (below) outlines the Residue Chemistry Science Assessments with respect to the reregistration of thiodicarb.

Tolerances for residues of thiodicarb are currently expressed in terms of thiodicarb and its metabolite methomyl, in/on plant raw agricultural commodities (RACs) [40 CFR §180.407 (a)].

The Agency has determined that residues of acetamide and acetonitrile resulting from the application of thiodicarb or methomyl are not residues of concern in animals and will not be regulated (See discussion under B.1.c. "Chronic Toxicity and Carcinogenicity"). The residues of concern in plants and animals are thiodicarb and its metabolite methomyl. The chemical names and structures of the thiodicarb residues of concern are depicted in the table below.

Table 7 - Thiodicarb and its metabolite methomyl.

Common Name/Chemical Name	Chemical Structure
Thiodicarb dimethyl N,N'-(thiobis((methylimino)carbonyloxy)) bis(ethanimidothioate)	
Methomyl S-methyl N[(methylcarbamoyl)oxy] thioacetimidate	

Tolerances on plant commodities range from 0.2 ppm for soybeans to 35 ppm on leafy vegetables. In addition, a temporary tolerance of 150 ppm has been established for thiodicarb residues on sweet corn forage under 40 CFR §180.31. Food/Feed additive tolerances have been established for thiodicarb residues in soybean hulls (0.8 ppm) and

cottonseed hulls (0.4 ppm) [40 CFR §186.5650]. Adequate methods are available for the enforcement of established tolerances, as currently defined.

The Agency has updated the Livestock Feeds Table [Table 1 in the Residue Chemistry Test Guidelines, OPPTS Series 860, August 1996]. Additional residue data are now required for some commodities as a result of these changes. These data requirements have been incorporated into this document.

Summary of Science Findings

OPPTS GLN 860.1200 (formerly 171-1): Directions for Use

There are six registered thiodicarb end-use products (EPs) with food/feed uses. All are registered to Rhône-Poulenc Ag Company. These are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
264-341	7/88	75.2% WP	Larvin® Thiodicarb Insecticide 75 WP
264-378	5/96	80% WDG	Larvin® DF Thiodicarb Insecticide/Ovicide
264-379 [a]	5/96	3.2 lb/gal FlC	Larvin® 3.2 Thiodicarb Insecticide/Ovicide
264-406	11/88	3.2 lb/gal FlC	Larvin® SC Thiodicarb Insecticide
264-407	12/88	2.1 lb/gal FlC	Larvin® 250 Thiodicarb Insecticide
264-530	5/96	80% WDG	Larvin® DF WSP Thiodicarb Insecticide/Ovicide

[a] Includes SLN Nos. AL940004, CT890001, DE870002, GA870004, LA860006, MD880003, ME910006, MI860005, MS860002, NC860002, NH920002, NJ920001, NY860002, OH890005, PA870004, PR910001, RI950001, VA870005, and VT920002.

Directions for use are acceptable except that label directions for sweet corn should be amended to remove the restriction specifying use for "Florida Fresh Market Only" and to remove the restrictions against grazing of livestock in treated fields or the feeding of treated corn silage or fodder to livestock. Label directions for sweet corn should also specify a maximum use rate of 7.5 lb ai/A for the entire season, rather than just after silk initiation as is currently specified. Once label directions for sweet corn are amended, the 19 SLN labels for the use of thiodicarb on sweet corn can be canceled.

OPPTS GLN 860.1300 (formerly 171-4a): Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on soybean, tomato, cotton, sweet corn and peanut metabolism studies. The residues to be regulated in plants are thiodicarb and its methomyl metabolite.

OPPTS GLN 860.1300 (formerly 171-4b): Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The residues to be regulated in livestock are thiodicarb and its methomyl metabolite.

OPPTS GLN 860.1340 (formerly 171-4c,d): Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcement of tolerances for thiodicarb. Method I in the Pesticide Analytical Manual (PAM), Vol. II, is a GLC/sulfur specific flame photometric detector (FPD-S) method that has undergone a successful EPA method validation on soybean meal. This method involves extraction with acetone:methanol (90:10, v/v), an acetonitrile:hexane partition, and a base hydrolysis of thiodicarb and methomyl residues to methomyl oxime. Acidified residues of methomyl oxime are then partitioned into methylene chloride and determined by GLC/FPD-S. The reported limit of detection is 0.02 ppm for plant commodities.

An enforcement analytical method for livestock commodities is not necessary. The Agency concluded that there is no reasonable expectation of finite thiodicarb residues in ruminant commodities [180.6(a)(3)]. Therefore, no tolerances will be required for livestock commodities.

OPPTS GLN 860.1360 (formerly 171-4m): Multiresidue Method Testing

The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix I) indicates that thiodicarb is partially recovered using FDA Multiresidue Protocol A (PAM I Section 242.2) and methomyl is completely recovered using FDA Multiresidue Protocols A and D (PAM I Sections 242.2 and 232.4).

OPPTS GLN 860.1380 (formerly 171-4e): Storage Stability Data

Requirements for storage stability data are satisfied for purposes of reregistration. Adequate storage stability data have been submitted for meat and milk and RACs and processed commodities of soybeans, cottonseed, and sweet corn. The storage stability data for plant commodities indicate that thiodicarb and methomyl are reasonably stable at $\leq$-15 C in soybeans, soybean processed commodities, cottonseed, and cottonseed processed commodities (except meal) for at least 12 months. Thiodicarb and methomyl are stable at $\leq$-15 C for at least 3 months in cottonseed meal, sweet corn (K+CWHR), and sweet corn forage/cannery waste. Data are also available indicating that residues of thiodicarb and methomyl are stable in frozen apples for up to 14 months. These data adequately support the storage intervals and conditions of all previously submitted plant magnitude of the residue studies and no additional storage stability data for these studies are required.

The storage stability data for animal commodities indicate that thiodicarb and

methomyl are stable at -20 C for up to ~2 months in milk, muscle, and fat. In kidney, thiodicarb and methomyl are stable at -20 C for up to 43 days, but declined by ~40% after 69 days. Residues of thiodicarb and methomyl are not stable in liver. Within 2 days of storage at -20 C, residues of thiodicarb and methomyl were nondetectable (<0.1 ppm) in liver samples initially fortified with each analyte at 1 ppm. The available data adequately support the Agency's conclusion that there is no reasonable expectation of finite thiodicarb residues in ruminant commodities [180.6(a)(3)].

OPPTS GLN 860.1500 (formerly 171-4k): Magnitude of the Residue in Crop Plants

For purposes of reregistration, requirements for magnitude of the residue data in/on plants are fulfilled for the following crops: broccoli, cabbage, cauliflower, leafy vegetables (excluding Brassica), soybeans, and sweet corn. Adequate field trial data depicting thiodicarb residues following applications made according to the maximum or proposed use patterns have been submitted for all these commodities, except sweet corn fodder. The registrant did not submit residue data for sweet corn fodder; nevertheless, the Agency can calculate an appropriate tolerance for fodder based on a forage-to-fodder dry matter correction factor.

Although adequate field trial data have been submitted for the above-listed commodities, label modifications are required for several of these commodities to reflect use patterns for which adequate residue data are available (see OPPTS GLN 860.1200: Directions for Use). Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

As a result of the update to the Livestock Feeds Table (Table 1 in the Residue Chemistry Test Guidelines, OPPTS Series 860, August 1996), additional magnitude of the residue data are required on cotton gin by-products.

OPPTS GLN 860.1520 (formerly 171-4l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for cottonseed and soybeans. The processing data from these studies do not indicate the need to establish tolerances on processed commodities, except for soybean hulls.

Based upon the 3.6x concentration factor for soybean hulls and highest average field trial (HAFT) residues of 0.103 ppm, the maximum potential residues in hulls would be 0.37 ppm. Therefore, the current 0.8 ppm tolerance for soybean hulls should be lowered to 0.4 ppm.

Data from the soybean processing study also indicate that thiodicarb residues

concentrated 29x in aspirated grain fractions. The registrant should propose a tolerance for aspirated grain fractions. Based upon the 29x concentration factor and HAFT residues of 0.103 ppm, an appropriate tolerance would be 3 ppm.

OPPTS GLN 860.1480 (formerly 171-4j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for thiodicarb residues in livestock commodities. The requirement for a poultry feeding study has been waived. The Agency believes there is no reasonable expectation of finite residues, based upon the results of the poultry metabolism study, which used a 255x feeding level [180.6(a)(3)].

An adequate ruminant feeding study is available. Residues of thiodicarb and methomyl were not detected in milk, meat and meat-by-products of dairy cattle dosed for 28 days at the maximum tolerated dose. The Agency concluded that there is no reasonable expectation of finite thiodicarb residues in ruminant commodities [180.6(a)(3)]. Therefore, no tolerances will be required for livestock commodities.

OPPTS GLN 860.1850 (formerly 165-1): Confined Accumulation in Rotational Crops

An acceptable confined rotational crop study is available. The metabolism of thiodicarb in rotated crops is similar to that in primary crops. Combined residues of thiodicarb and methomyl were detected at >0.01 ppm in RACs of leafy vegetable, root, and grain crops planted at 31- and 125-day rotational intervals. Total radioactive residues were <0.01 ppm in all RACs at the 364-day rotational interval.

OPPTS GLN 860.1900 (formerly 165-2): Field Accumulation in Rotational Crops

Based upon the results of the confined rotational crop study, a plant-back interval must be added to EP labels. The registrant can choose to conduct limited field rotational crop trials at the desired plant-back interval following soil treatment at 1x the maximum registered rate (7.5 lb ai/A) at two test sites. If residues of concern are detected in rotated crops from the limited trials, extensive rotational crop field trials will be required to determine the need for tolerances for thiodicarb residues in rotated crops. Alternatively, the registrant can choose to revise their labels to impose a 1-year restriction on the planting of rotated crops not appearing on the label, and limited field trials and rotational crop tolerances would not be required. If the registrant chooses to conduct the limited field rotational trials, the labels must be changed in the interim to specify a 1 year plantback interval.

b. Dietary Risk Assessment and Risk Characterization

The Agency has determined that thiodicarb has a metabolite, methomyl, which is also a registered pesticide. Therefore, in addition to the thiodicarb risk assessment, methomyl residues resulting from applications of both thiodicarb and methomyl will be considered in an aggregate risk assessment and compared to appropriate toxicological endpoints for methomyl.

Chronic (Non-Cancer) Risk- Thiodicarb Alone (food source only)

A Dietary Risk Evaluation System (DRES) chronic exposure analysis was performed using tolerance level residues and percent crop treated information to estimate the Anticipated Residue Contribution (ARC) for the general population and 22 subgroups. Using existing tolerances (and pending tolerances on peppers, tomatoes and peanuts) and the higher tolerance level for cottonseed, the anticipated residue contribution for the U.S. Population occupies 68% of the FQPA adjusted RfD. For females (13 years and older) 67% of the FQPA adjusted RfD is occupied. For children (1 to 6 years old) and infants, 104% and 43%, respectively, of the FQPA adjusted RfD is occupied. Although for children (1 to 6 years old), the FQPA adjusted RfD is slightly exceeded, if more refined estimates of dietary exposure were made (e.g. using residues from field trials) significantly lower chronic risk would be estimated. Therefore, the chronic risk from exposure to thiodicarb from food sources is not of concern.

Chronic (Non-Cancer) Risk - Thiodicarb and Methomyl Combined (food source only)

Chronic exposures to methomyl residues from both thiodicarb and methomyl applications were combined and compared to the methomyl reference dose. The aggregated chronic exposure is shown in the table below (MRIDs 44328701, 44343601, 44360702).

Table 8 - Chronic Aggregate Risk - Thiodicarb and Methomyl Combined

Population Subgroup	Dietary %RfD[a]
U. S. General	1.9
Children (1 to 6 years)	2.7
Infants	6.5

[a] Dietary %RfD includes methomyl residues from application of thiodicarb and methomyl

Results of the chronic exposure analysis show that no single subpopulation exceeded 7% of the RfD. For the subpopulations, infants (<1 year old) and children (ages 1- 6 years old), 6.5% and 2.7% of the RfD is occupied, respectively. For the general U.S. population, only 1.9% of the RfD was occupied. In this analysis, percent crop treated information and anticipated residue data were used for all 70 commodities.

Cancer Risk- Thiodicarb Alone

A linear methodology (Q_1*) was applied for the estimation of human cancer risk and was calculated to be 1.88×10^{-2}. The assessment was conducted for the general U.S. Population only. The cancer exposure is estimated by multiplying the Q_1* (1.88×10^{-2}) by the chronic dietary exposure (0.000020 mg/kg/day). This chronic dietary exposure utilized both anticipated residue and percent crop treated information. The upper bound cancer risk was calculated to be 3.76×10^{-7}. This upper bound risk is below the range the Agency generally considers neglible for excess lifetime cancer risk and is not cause for concern.

Acute Dietary Risk - Thiodicarb Alone (food source only)

To estimate acute dietary exposure, the registrant conducted Monte Carlo simulations for the overall U.S. population, women 13 years and older, children 1 to 6 years of age, and infants. These analyses included residue levels determined from field trial studies, consumption data from the 1994 through 1996 USDA Continuing Survey of Food Intake by Individuals (CSFII), and information on the percent crop treated. The USDA provided statistical weights that permitted the data from the various years of the CSFII survey to be combined (MRIDs 44328701, 44343601, 44360702).

Field trial residue levels were used for all crops. In compliance with the EPA's guidance document, residue distributions from field studies conducted at maximum label conditions (e.g. maximum number of applications, maximum application rate, and minimum preharvest intervals) were used for foods considered to be single-serving commodities (e.g. cabbage, broccoli, lettuce); while mean field trial residues were used for blended/processed commodities (e.g. cottonseed meal, soybean oil).

Processing factors were calculated for cottonseed meal, cottonseed oil, and soybean oil. These factors were used in conjunction with the mean field trial residues to estimate residue levels in the processed commodities.

Residue values were adjusted for the percent of the crop estimated to be treated with thiodicarb. These percentages were provided by the Agency's Biological and Economic Analysis Division (BEAD). The maximum percentage reported for a particular crop was used in the acute exposure analyses. Percent crop treated information was not provided for swiss chard, parsley, watercress, and endive. The percent crop treated for spinach was assumed for these crops.

The Monte Carlo analysis incorporates a purported 93% decline in residues for some commodities as the result of cooking. These results were reported for methomyl. The cooking factor 0.07x (i.e., 1- 0.93 = 0.07) was applied to a variety of leafy vegetables (including broccoli, cabbage, spinach, and cauliflower). A confirmatory cooking study to

validate the 0.07x (93% reduction) cooking factor for thiodicarb is required to be submitted by June 30, 1999. The registrant must consult with the Agency concerning the conduct of these studies including the appropriate cooking methods and cooking time as well as the specific crops on which studies should be conducted. In addition to the cooking factor, an average decline of 75% in residues on celery following trimming of celery tops was included in the Monte Carlo analysis.

Acute exposure estimates to thiodicarb were compared to the developmental LOEL of 10 mg/kg/day for the population subgroup women 13 years and older. For the overall U.S. population, children 1 to 6 years of age, and infants, acute exposure estimates were compared to the maternal LOEL of 10 mg/kg/day.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/Exposure = MOE). A MOE of 1000 is required for acute dietary risk assessment for Females 13 years and older , as well as for the General Population including Infants and Children. This MOE includes the conventional MOE of 100, 3x for FQPA, and another 3x for the use of a LOEL instead of a NOEL. For this risk assessment the FQPA Safety Factor (3x) is required because of datagaps (acute and subchronic neurotoxicity studies). The MOEs for acute dietary exposure were calculated using the estimates at the 99.9 percentile of exposure for groups of concern. The acute MOEs for the application of thiodicarb are presented in the table below.

Table 9 - Acute Exposure MOEs from the Application of Thiodicarb

Group of Concern	Exposure	LOEL	MOE	Acceptable MOE
U.S. Population	0.013792	10 mg/kg/day	2450	1000
Woman 13 years and older	0.013500	10 mg/kg/day	2100	1000
Children 1 to 6 years	0.022758	10 mg/kg/day	2900	1000
Infants	0.010575	10 mg/kg/day	1680	1000

The results of the acute exposure analyses indicate that there are adequate margins of exposure for the general U.S. population, women 13 years and older, children 1 to 6 years of age, and infants.

Acute Risk - Thiodicarb and Methomyl Combined (food source only)

The registrant provided and the Agency has found acceptable, an acute dietary Monte Carlo distributional risk assessment which utilized combined residues of methomyl from the application of thiodicarb and residues of methomyl from the application of methomyl. For this analysis, percent crop treated information and field trial residue data were used for all commodoties. The methomyl acute dietary NOEL of 6 mg/kg/day was used to calculate the MOEs. The estimated MOEs are shown in the table below. An

MOE of at least 300 is considered acceptable (MRIDs 44328701, 44343601, 44360702).

Table 10: EPA-calculated Margins of Exposure (MOEs) for Various U.S. Subpopulations Based on Acute Effects and 24-hour intervals (NOEL = 6 mg/kg BW/day).

Population Group	Food	
	24 hour interval	
	mg/kg BW/day	MOE
U.S. Population		
95th percentile	0.000349	17192
99th percentile	0.001099	5460
99.9th percentile	0.006577	912
Infants		
95th percentile	0.000215	27907
99th percentile	0.000874	6865
99.9th percentile	0.007940	756
Children 1-6 years		
95th percentile	0.000482	12448
99th percentile	0.002108	2846
99.9th percentile	0.014396	417

Although refined using percent crop treated data, these estimates are still likely to be a conservative estimate of the Margin of Exposure. For example, they assume that residues, when present, are present as a result of application at the maximum permitted level and observance of the minimum PHI. No reduction as a result of transport time from farm gate to consumer is assumed to occur. The Agency concludes that sufficient margins of exposure exist at the 99.9th percentile value.

c. Aggregate Exposure

In examining aggregate exposure, FQPA directs The Agency to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. These other exposures include drinking water and non-occupational exposures, e.g., to pesticides used in and around the home. Risk assessments for aggregate exposure consider both short-term and long-term (chronic) exposure scenarios considering the toxic effects which would likely be seen for each exposure duration. There are no residential uses of thiodicarb, therefore aggragate exposure includes only those exposures from food and drinking water.

Thiodicarb degrades rapidly in water to methomyl. Methomyl is the pesticide monitored in ground water and surface water studies. Therefore, the relevant water exposure is to methomyl and the drinking water risk assessment was conducted for methomyl only. The aggregate dietary risk assessment was, therefore, based on exposure

from methomyl from the application of thiodicarb, methomyl from the application of methomyl, and methomyl in water.

d. Drinking Water Assessment

OPP has calculated drinking water levels of concern (DWLOCs) for methomyl in surface and ground water for the U.S. population and children 1 to 6 years old (Standard Operating Procedures for Drinking Water Exposure and Risk Assessments, 11/26/97 and Interim Guidance for Conducting Drinking Water Exposure Estimates, 12/2/97). For acute exposures, they are 470 and 56 ppb, for the U.S. population and children (1 - 6 yrs old), respectively. For chronic (non-cancer) exposures they are 275 and 78 ppb for the U.S. population and children (1-6 years old), respectively.

To calculate the DWLOC for acute exposure relative to the acute toxicity endpoint, the acute dietary food exposure (from the combined thiodicarb and methomyl Monte Carlo analysis) was subtracted from the ratio of the acute NOEL (used for acute dietary assessments) to the "acceptable" MOE for aggregate exposure to obtain the acceptable acute exposure to methomyl in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to methomyl in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

Estimated concentrations of methomyl in surface water are from PRZM/EXAMS modeling. The estimated maximum (acute exposure) concentration is 30 ppb and the estimated average (chronic exposure) concentration is 26 ppb. The estimated maximum concentration of methomyl in ground water is 20 ppb based on the Agency's Pesticides in Ground Water Database. Average concentrations in ground water are not expected to be higher than the maximum concentrations. These estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute and chronic aggregate exposure. Therefore, taking into account the present uses, the Agency concludes with reasonable certainty that residues of methomyl in drinking water when considered along with other sources of exposure for which the Agency has reliable data would not result in levels of aggregate human health risk that exceed levels of concern.

The estimates of methomyl in surface and ground waters are derived from models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because the Agency considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, the Agency will reassess the potential impacts of thiodicarb and methomyl from the application of thiodicarb on drinking water as a part of the aggregate

risk assessment process.

Endocrine Disruption

The Agency 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, the Agency may require further testing of this active ingredient and end use products for endocrine disrupter effects.

e. Cumulative Risk

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, the Agency does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. The Agency has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that the Agency will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which the common mechanism issues can be addressed. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in

which case common mechanism of activity will be assumed).

The Agency does not have, at this time, available data to determine whether thiodicarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this reassessment, therefore, the Agency has not assumed that thiodicarb has a common mechanism of toxicity with other substances.

4. Occupational and Residential

a. Occupational and Residential 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.

Occupational-use products and homeowner-use products

At this time, products containing thiodicarb are intended for occupational use only and not for homeowner use. Therefore, no residential risk assessment is required.

Epidemiological Information

The following data bases have been consulted for poisoning incident data for thiodicarb:

(1) OPP Incident Data System (IDS): There were two reported cases of incidents involving thiodicarb. Both individuals were treated by a physician.

(2) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991): No cases of thiodicarb illnesses or injuries have been reported in California during the reporting period of 1982-1993. However, almost no usage by commercial applicators has been reported for this chemical during this time period.

(3) National Pesticide Telecommunications Network (NPTN): Using the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, thiodicarb was not reported to be involved in any human incidents.

In summary, almost no information is available from any of the data bases consulted by the Agency on incidents related to the use of thiodicarb.

Handlers

Exposures and Assumptions

Inhalation exposure is the only exposure for which subchronic endpoints were selected and a risk assessment will be conducted. A dermal subchronic risk assessment was not conducted because no subchronic endpoints were identified. Dermal and Inhalation (total) exposures were considered for a cancer risk assessment using the Q_1* of 1.88×10^{-2} $(mg/kg/day)^{-1}$. No chronic exposure is expected from the uses of thiodicarb.

EPA has determined that there are potential dermal and inhalation exposures to mixers, loaders, applicators, and other handlers as a result of usual use-patterns associated with thiodicarb. Based on the use patterns, eleven major exposure scenarios were identified for thiodicarb: (1a) mixing/loading wettable powders for aerial/chemigation application; (1b) mixing/loading wettable powders for groundboom application; (2a) mixing/loading liquids for aerial/chemigation application; (2b) mixing/loading liquids for groundboom application; (3a) mixing/loading dry flowables for aerial/chemigation application; (3b) mixing/loading dry flowables for groundboom application; (4) applying sprays with a fixed-wing aircraft; (5) applying sprays with a helicopter; (6) applying sprays with groundboom equipment; (7) mixing/loading/applying sprays with a backpack sprayer; (8) mixing/loading/applying sprays with a low pressure handwand; (9) mixing/loading/ applying liquids with a high pressure sprayer; (10) belly-grinder spreader and, (11) flagging aerial spray applications.

Inhalation exposure estimates (developed using PHED Version 1.1 surrogate data) are presented in Table 11. No chemical-specific data were submitted. The calculations of the daily inhalation dose received by handlers are used to assess the inhalation risk to those handlers. Table 12 presents the corresponding risk assessment (MOEs) for inhalation exposures. Table 13 presents the baseline dermal and inhalation (total) exposures along with the cancer risk assessment. Table 14 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

The following assumptions were made:

Average body weight of an adult handler is 70 kg.

Application area treated in each scenario: 350 acres for aerial and chemigation, and for flaggers supporting aerial applications; 2 acres for belly-grinder spreader; 80 acres for groundboom; and 1 acre for backpack, low-pressure handwand, and high-pressure handwand.

Frequency data (i.e., days/yr) were not available. Label directions for use state “repeat application as needed”, therefore, a conservative estimate of 10 applications per year is

assumed to be the upper range of the number of applications that may be done by a commercial applicator.

In general, typical application rates are used in cancer assessments, however, typical rates were not available and the maximum rate was used.

A 2 percent dermal absorption and 100 percent inhalation absorption were used.

Table 11 - Inhalation Exposures for Thiodicarb

Exposure Scenario (Scen #)	Baseline Inhalation Unit Exposure (μg/lb ai)[a]	Application Rate (lb ai/acre)[b]	Daily Acres Treated[c]	Daily Inhalation Exposure (mg/day)[d]
Mixer/Loader Exposure				
Mixing/Loading Wettable Powder for Aerial and Chemigation Application (1a)	43.4	1	350	15.19
Mixing/Loading Wettable Powder for Groundboom Application (1b)			80	3.47
Mixing/Loading Liquids for Aerial and Chemigation Application (2a)	1.2	1	350	0.42
Mixing/Loading Liquids for Groundboom Application (2b)			80	0.096
Mixing/Loading Dry Flowable for Aerial and Chemigation Application (3a)	0.77	1	350	0.27
Mixing/Loading Dry Flowable for Groundboom Application (3a)			80	0.062
Applicator Exposure				
Fixed-wing Aerial Spray Application (4)	See Eng. Controls[e]	1	350	See Eng. Controls[e]
Helicopter Spray Application (5)	See Eng. Controls[e]	1	350	See Eng. Controls[e]
Groundboom Spray Application (6)	0.7	1	80	0.056
Mixer/Loader/Applicator Exposure				
Backpack Sprayer (7)	30.2	1	1	0.0302
Low Pressure Handwand (8)	31.2	1	1	0.0312
High Pressure Handwand (9)	117	1	1	0.117
Belly-Grinder Spreader (10)	61.8	0.9	2	0.111
Flagger Exposure				
Flagging Aerial Spray Application (11)	0.28	1	350	0.098

a Baseline inhalation exposure represents no respirator.
b Application rates are maximum values found in the thiodicarb labels [EPA Reg. Nos. 264-343, 264-378, 264-379, 264-530].
c Daily acres treated values are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.
d Daily inhalation exposure (mg/day) = Exposure (μg/lb ai) * (1mg/1000 ug)conversion * Appl. Rate (lb ai/A) * Acres Treated
e Engineering controls are on the next table (three right columns).

Table 12 - Inhalation Risk for Thiodicarb

Exposure Scenario (Scen #)	Baseline Inhalation Dose (mg/kg/day)[a]	Baseline Inhalation MOE[b]	PPE Inhalation Unit Exp. (ug/lb ai)	PPE Inhalation Dose (mg/kg/day)[a]	PPE Inhalation MOE (mg/kg/day)[b]	Engineering Controls Inhalation Unit Exp.(ug/lb ai)	Engineering Controls Inhalation Dose (mg/kg/day)[a]	Engineering Controls Inhalation MOE[b]
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial and Chemigation Application (1a)	0.217	6	8.68 (Dust/ Mist Respirator -- five fold PF)	0.043	28	0.24 (Water Soluble Packets)	0.0012	1,000
Mixing/Loading Wettable Powder for Groundboom Application (1b)	0.05	24		0.01	120		0.00027	4,400
Mixing/Loading Liquids for Aerial and Chemigation Application (2a)	0.006	200	0.24 (Dust/ Mist Respirator -- five fold PF)	0.0012	1,000	NA	NA	NA
Mixing/Loading Liquids for Groundboom Application (2b)	0.0014	857	NA	NA	NA	NA	NA	NA
Mixing/Loading Dry Flowables for Aerial and Chemigation Application (3a)	0.0039	308	NA	NA	NA	NA	NA	NA
Mixing/Loading Dry Flowables for Groundboom Application (3b)	0.00089	1348	NA	NA	NA	NA	NA	NA
Applicator Risk								
Fixed-wing Aircraft Spray Application (4)[c]	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.068	0.00034	3,529
Helicopter Spray Application (5)[c]	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See eng. Controls	0.0018	0.000009	133,333
Groundboom Application (6)	0.0008	1,500	NA	NA	NA	NA	NA	NA
Mixer/Loader/Applicator Risk								
Backpack Sprayer (7)	0.00043	2,891	NA	NA	NA	NA	NA	NA

Exposure Scenario (Scen #)	Baseline Inhalation Dose (mg/kg/day)[a]	Baseline Inhalation MOE[b]	PPE Inhalation Unit Exp. (ug/lb ai)	PPE Inhalation Dose (mg/kg/day)[a]	PPE Inhalation MOE (mg/kg/day)[b]	Engineering Controls Inhalation Unit Exp.(ug/lb ai)	Engineering Controls Inhalation Dose (mg/kg/day)[a]	Engineering Controls Inhalation MOE[b]
Low Pressure Handwand (8)	0.00045	2,667	NA	NA	NA	NA	NA	NA
High Pressure Handwand (9)	0.0017	706	NA	NA	NA	NA	NA	NA
Belly-Grinder Spreader (10)	0.0016	750	NA	NA	NA	NA	NA	NA
Flagger Risk								
Flagger for Aerial Spray Applications (11)	0.0014	857	NA	NA	NA	NA	NA	NA

NA Not applicable since the MOE already exceeded 300.

[a] Baseline Inhalation Dose (mg/kg/day) = daily inhalation exposure (mg/day) / 70 kg (average body weight of an adult handler).

[b] Inhalation MOE = LOEL (mg/kg/day) / Daily Inhalation Dose (mg/kg/day), where LOEL is 1.2 mg/kg/day [see calculation in section II.B,c; Inhalation Occupational or Residential Exposure (any time period)].

[c] Only closed cockpit data are available for scenarios 4 and 5.

Table 13. Occupational Cancer Assessment for Thiodicarb

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (μg/lb ai)[a]	Application Rate (lb ai/acre)[b]	Daily Acres Treated[c]	Inhalation Dose (mg/kg/day)[d]	Absorbed Dermal Dose (mg/kg/day)[e]	Total Dose (mg/kg/day)[f]	Frequency[g]	LADD (mg/kg/day)[h]	Risk[i]
Mixer/Loader Exposure/Risk										
Mixing/Loading Wettable Powder for Aerial and Chemigation Application (1a)	3.7	43.4	1	350	0.22	0.37	0.59	10	0.0080	1.5E-4
Mixing/Loading Wettable Powder for Groundboom Application (1b)				80	0.050	0.085	0.13	10	0.0018	3.5E-5
Mixing/Loading Liquids for Aerial and Chemigation Application (2a)	2.9	1.2	1	350	0.0060	0.29	0.30	10	0.0041	7.6E-5
Mixing/Loading Liquids for Groundboom Application (2b)				80	0.0014	0.066	0.068	10	0.00093	1.7E-5
Mixing/Loading Dry Flowable for Aerial and Chemigation Application (3a)	0.066	0.77	1	350	0.0039	0.0066	0.010	10	0.00014	2.7E-6
Mixing/Loading Dry Flowable for Groundboom Application (3a)				80	0.00088	0.0015	0.0024	10	3.3E-5	6.2E-7
Applicator Exposure/Risk										
Fixed-wing Aerial Spray Application (4)	0.005 (closed cockpit)	0.068 (closed cockpit)	1	350	0.00034	0.00050	0.00084	10	1.2E-5	2.2E-7
Helicopter Spray Application (5)	0.0019 (closed cockpit)	0.0018 (closed cockpit)	1	350	0.000009	0.00019	0.00020	10	2.7E-6	5.1E-8
Groundboom Spray Application (6)	0.014	0.7	1	80	0.0008	0.00032	0.0011	10	1.5E-5	2.9E-7
Mixer/Loader/Applicator Exposure/Risk										
Backpack Sprayer (7)	2.5 (gloves)	30.2	1	1	0.00043	0.00071	0.0011	10	1.6E-5	3.0E-7
Low Pressure Handwand (8)	100	31.2	1	1	0.00045	0.029	0.029	10	0.00040	7.5E-6
High Pressure Handwand (9)	2.5 (gloves)	117	1	1	0.0017	0.00071	0.0024	10	3.3E-5	6.1E-7
Belly-Grinder Spreader (10)	10	61.8	0.9	2	0.0016	0.0051	0.0067	10	9.2E-5	1.7E-6

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (μg/lb ai)[a]	Application Rate (lb ai/acre)[b]	Daily Acres Treated[c]	Inhalation Dose (mg/kg/day)[d]	Absorbed Dermal Dose (mg/kg/day)[e]	Total Dose (mg/kg/day)[f]	Frequency[g]	LADD (mg/kg/day)[h]	Risk[i]
Flagger Exposure										
Flagging Aerial Spray Application (11)	0.011	0.28	1	350	0.0014	0.0011	0.0025	10	3.4E-5	6.4E-7

a Baseline dermal and inhalation exposure represents long pants, long sleeved shirts, no gloves, and no respirator while using open systems. Exceptions include scenarios 4 and 5 which include closed cockpits for aerial application because there are no data available to assess open cockpits and scenarios 7 (backpacks) and 9 (high pressure sprayers) which include chemical resistant gloves because no data are available to assess a no glove scenario.

b Application rates are maximum values found in the thiodicarb labels [EPA Reg. Nos. 264-343, 264-378, 264-379, 264-530].

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

d Daily inhalation dose (mg/kg/day) = [Unit exposure (μg/lb ai) * (100% inhalation absorption) * (1mg/1000μg conversion) * Appl. Rate (lb ai/A) * Acres Treated] / 70 kg body weight.

e Daily absorbed dermal dose (mg/kg/day) = [Unit exposure (mg/lb ai) * 0.02 (2% dermal absorption) * Appl. Rate (lb ai/A) * Acres Treated] / 70 kg body weight.

f Total dose (mg/kg/day) = Inhalation dose (mg/kg/day) + Dermal absorbed dose (mg/kg/day).

g Frequency (days/year) data are not available, labels state “repeat application as needed” and, therefore, a conservative estimate of 10 applications per year are assumed to be the upper range of the number of applications that may be done by a commerical applicator.

h LADD (mg/kg/day) = Total dose (mg/kg/day) * (frequency/365 days per year) * (35 working years/ 70 lifetime years).

i Risk = LADD (mg/kg/day) * Q_1^* (1.88E-2 $(mg/kg/day)^{-1}$).

Table 14 - Exposure Scenario Descriptions for Uses of Thiodicarb

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure			
Mixing/Loading Wettable Powder (1a and 1b)	PHED V1.1	350 acres for aerial and chemigation, 80 acres for groundboom.	**Baseline:** "Best Available" grades: Inhalation = ABC grades. Inhalation = 44 replicates. Medium confidence in inhalation data. **Engineering Controls (water soluble packets):** "Best Available" grades: Inhalation = All grades. Inhalation = 15 replicates. Low confidence in Inhalation data. PHED data were used for baseline and engineering controls data. An 80% Protection Factor (PF) was added to the PPE scenario only to simulate a dust/mist respirator.
Mixing Liquid Formulations (2a and 2b)	PHED V1.1	350 acres for aerial and chemigation, 80 acres groundboom.	**Baseline:** "Best Available" grades: Inhalation acceptable grades. Inhalation = 85 replicates. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Mixing/Loading Dry Flowable Formulations (3a and 3b)	PHED V1.1	350 acres for aerial and chemigation, 80 acres groundboom.	**Baseline:** "Best Available" grades: Inhalation acceptable grades. Inhalation = 23 replicates. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Applicator Exposure			
Fixed-wing Aircraft Application (4)	PHED V1.1	350 acres	**Engineering controls:** "Best Available" grades: Inhalation = ABC grades. Inhalation = 23 replicates. Medium confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Helicopter Application (5)	PHED V1.1	350 acres	**Engineering controls:** "Best Available" grades: Inhalation = acceptable grades. Inhalation = 3 replicates. Low confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Groundboom Application (6)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Inhalation = acceptable grades. Inhalation = 22 replicates. High confidence in inhalation data. PHED data were used for baseline, no Pfs were necessary.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader/Applicator Exposure			
Backpack Sprayer (7)	PHED V1.1	1 acre	**Baseline:** "Best Available" grades: Inhalation = acceptable grades. Inhalation = 11 replicates. Low confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Low Pressure Handwand (8)	PHED V1.1	1 acre	**Baseline:** "Best Available" grades: Inhalation All grades. Inhalation = 96 replicates. Low confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
High Pressure Sprayer (9)	PHED V1.1	1 acre	**Baseline:** "Best Available" grades: Inhalation acceptable grades. Inhalation = 13 replicates. Low confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Belly-Grinder Spreader (10)	PHED V1.1	2 acres	**Baseline:** "Best Available" grades: Inhalation acceptable grades. Inhalation = 40 replicates. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.
Flagger Exposure			
Flagger (11)	PHED V1.1	350 acres	**Baseline:** "Best Available" grades: Inhalation = acceptable grades. Inhalation = 18 replicates. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary.

[a] Standard Assumptions based on an 8-hour work day as estimated by EPA. BEAD data were not available.

[b] "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Acceptable grades are matrices with grades A and B data. Data confidence is assigned as follows:

High = grades A and B and 15 or more replicates
Medium = grades A, B, and C and 15 or more replicates
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

b. Occupational Risk (Non-Cancer) Estimates

Estimates of exposure and risk indicate that, for some scenarios, measures to reduce handlers exposures should be considered. Table 12 shows the levels of mitigation needed to attain MOEs greater than 300, while Table 14 describes the data quality and confidence level for each scenario. Options to reduce handlers' exposures and risk range from personal protective equipment (dust mist respirator) to engineering controls (water soluble packets).

The calculations estimating inhalation risk from the previous table indicate that the MOEs are acceptable (300 or greater) at baseline (no respirator) for the scenarios identified below.

- (2b) mixing/loading liquids for groundboom application;
- (3a) mixing/loading dry flowables for aerial and chemigation application;
- (3b) mixing/loading dry flowables for groundboom application;
- (6) applying sprays with a groundboom sprayer;
- (7) mixing/loading applying liquid with a backpack sprayer;
- (8) mixing/loading applying liquid with a low pressure handwand;
- (9) mixing/loading applying liquid with a high pressure handwand; and,
- (10) mixing/loading applying granulars with a belly-grinder spreader; and,
- (11) flagging liquid aerial applications.

The calculations estimating inhalation risk indicate that the MOEs are acceptable (300 or greater) with PPE (a dust/mist respirator and single layer of clothing) for the following scenario:

- (2a) mixing/loading liquids for aerial and chemigation applications;

The calculations estimating inhalation risk indicate that the MOEs are acceptable (300 or greater) with the noted engineering controls and single layer of clothing for the following scenarios:

- (1a) mixing/loading wettable powder for aerial and chemigation application (water soluble packets);
- (1b) mixing/loading wettable powder for groundboom application (water soluble packets);
- (4) applying liquid sprays with a fixed-wing aircraft (closed cockpit); and,
- (5) applying liquid sprays with a helicopter (closed cockpit).

In the regulatory section this information has been integrated with other considerations, including the toxicity concerns pertaining to methomyl, a degradate of thiodicarb, in determining the required PPE.

When estimated MOEs for closed-cockpit exposure scenarios are an order of magnitude larger than the uncertainty factor (i.e., the acceptable MOE), then this scenario would also be acceptable using an open-cockpit plane. For thiodicarb, an occupational MOE of 300 or higher is required to be above the Agency's level of concern. The open cockpit MOEs range from 3,500 to 133,333. Therefore, an enclosed cockpit is not required for scenarios 4 and 5 above.

In summary, all handler scenarios have acceptable MOEs (300 or greater) at baseline or with the noted PPE or engineering controls.

c. Occupational Cancer Estimates

The estimations of cancer risks are within the 10^{-4} to 10^{-8} risk range for all scenarios at baseline except for the following scenarios:

Scenarios 4 (fixed-wing aerial spray application) and 5 (helicopter spray application) include closed cockpits for aerial applications because there are no data available to assess an open cockpit. However, since the estimated risks for closed-cockpit exposure scenarios (airplane 1×10^{-7} and helicopter 1×10^{-8}) are at least an order of magnitude larger than the acceptable risk (1×10^{-4}), use of an open-cockpit plane is acceptable.

Scenarios 7 (backpack sprayer) and 9 (high pressure handwand) which include chemical resistant gloves because no data are available to assess a no glove scenario.

d. Post-Application

Exposure and Assumptions

There are no short- or intermediate-term dermal endpoints of concern for thiodicarb, and a post-application inhalation risk assessment is not warranted. However, thiodicarb rapidly degrades to methomyl. Therefore, the toxicity concerns pertaining to methomyl, a degradate of thiodicarb, are considered in the post-application risk assessment. For methomyl, the short- and intermediate-term NOEL for dermal toxicity is 90 mg/kg/day.

A dislodgeable foliar residue (DFR) study was conducted for thiodicarb on lettuce, (MRID 43198102) to measure the amount of residue remaining on lettuce each day after treatment. In this study, residues of both thiodicarb and its breakdown product, methomyl, were measured. However, as explained above, only methomyl residues are included in the risk assessment. Four applications of thiodicarb were made to head lettuce at a rate of 0.75 pounds active ingredient (ai) per acre at 7-day intervals for a total application of 3.0 pounds a.i. per acre. Four trials were conducted: two in the Imperial

Valley, California, and two in the San Joaquin Valley, California. Residue samples were taken before and after each application and on days 1, 5, 7, 10, 14 and 18 following the last application. A review of the QA/QC results for this study indicate that the laboratory, field, and storage recoveries were all within an acceptable range of 70 to 120 percent. At the Imperial Valley site, the spring application (March/April of 1993) residue data were not used for this assessment because of a rain event that affected residue results. The residues from the other three test runs were averaged. This study has several limitations: (1) DFR samples were not collected on the day of application after the sprays had dried [day after treatment (DAT) is day 0]; (2) a longer duration for the study (>18 DAT) would have been more appropriate since measurable residues were still being found on the last day samples were measured; and (3) concurrent monitoring of dermal samples was not conducted.

Since no concurrent dermal samples were monitored during the lettuce study, transfer coefficients (Tc) are estimated to represent potential dermal transfer of residues. The Agency has estimated 1,000 cm^2/hr to represent the transfer coefficient for crops with relatively low potential for dermal transfer during routine post-application activities, and 10,000 cm^2/hr to represent the transfer coefficient for crops with medium to high potential for dermal transfer during routine post-application activities. The Agency believes these transfer coefficients are reasonable worst-case values. The following crops are considered to have relatively low potential for post-application dermal transfer: broccoli, cabbage, other cole crops, lettuce and other leafy vegetables, cotton, and soybeans. The following crops are considered to have high potential for post-application dermal transfer: sweet corn, citrus, ornamental and/or shade trees, and ornamental herbaceous plants. The Agency has determined that the anticipated frequency, duration, and degree of exposure following applications to rights-of-way, hedgerows, fencerows, and drainage areas are likely to be low and do not warrant an exposure and risk assessment.

The Agency has no data with which to assess the potential post-application exposure and risk resulting from applications of the granular formulation of thiodicarb to soil in nurseries and greenhouses. However, The Agency estimates that the exposure to persons transplanting such plants would be roughly equivalent to exposures to workers in crops where the potential level of dermal transfer is relatively low, since the majority of exposure will be to the hands. Therefore, the estimates of potential post-application exposures to workers in crops with potentially low dermal transfer will be used as a reasonable surrogate for estimates of the potential post-application exposures to workers following soil-directed granular applications.

The Agency believes the lettuce DFR study *overestimates* potential methomyl residues in lettuce and other leafy vegetables since the seasonal application rate used in the study with head lettuce was twice the labeled rate. The label states that application to lettuce and other leafy vegetables should not exceed 1.5 pounds active ingredient per acre per season, but the study was conducted at 3 pounds active ingredient per acre per season.

The Agency believes the DFR study *underestimates* the potential methomyl residues following thiodicarb applications to most other crops for several reasons: (1) several crops have an application rate (single application) greater than the 0.75 pounds ai per acre rate used in the study; (2) labels recommend applications to many crops more frequently than once per week as was used in the study; and (3) several crops have seasonal maximum rates of greater than the 3.0 pounds ai per acre applied in the study. For example, labels allow application of 0.75 pounds ai per acre to sweet corn at one- to two-day intervals up to a seasonal maximum of 7.5 pounds active ingredient per acre. For cole crops, the label allows application of 1.0 pounds ai per acre as often as needed up to a seasonal rate of 6.0 pounds ai per acre. Methomyl residues on these crops are likely to be significantly higher than those reported in the DFR study on lettuce.

In the absence of data specific to these other crops, the Agency has roughly estimated potential exposure and risk to workers using the data from the lettuce study. If, based on the higher application rate and greater frequency of exposure, the DFR levels for these crops on day 1 were double those reported for lettuce, (see following table under "Risk estimates") the day 1 MOEs would be 3,170 for crops with potentially low dermal transfer (assuming a transfer coefficient of 1,000 cm^2/hr), and 317 for crops with potentially high dermal transfer (assuming a transfer coefficient of 10,000 cm^2/hr).

While the Agency believes that doubling the reported DFRs from the lettuce study represents a reasonable high-end estimate for potential DFR levels for these other crops, some uncertainites exist about actual residue levels that would result if higher rates were used at shorter intervals, as is permitted by labels of these other crops. Additionally, the assumption of a transfer coefficients of 1,000 cm^2/hr to 10,000 cm^2/hr is believed to represent a realistic range of potential transfer coefficients for the crops considered, based on data from these crops for other chemicals with which the Agency is familiar. However, without actual exposure monitoring data a degree of uncertainty about actual levels of exposure exists.

Given these uncertainties, the Agency notes that, assuming the higher transfer coefficient, the lowest MOE is still three times higher than that which would be considered acceptable. Thus, if the DFR values for these crops were as much as 6 times the day 1 values reported in the lettuce study, MOEs for even crops with potentially high dermal transfer would still exceed 100.

The table below compares the maximum application rates, application frequency, and maximum seasonal application rates for each use pattern to the use pattern used in the lettuce study.

Table 15 - Maximum Application Rate, Application Frequency, and Seasonal Rates for Thiodicarb.

CROP	Maximum Application Rate (lb ai/acre)	Frequency of Applications	Maximum Seasonal Rate (lb ai/acre)
Lettuce Study (MRID 43198102)	0.75	7 days	3.0
Lettuce & Other Leafy Vegetables	0.75	as needed	1.5
Broccoli & Other Cole Crops	1.0	as needed	6.0
Cotton	0.9	3 to 5 days	5.4
Soybeans	0.75	none specified	3
Citrus	0.75	as needed	4.5
Ornamentals	0.75	as needed	4.5
Sweet Corn	0.75	1 to 2 days	7.5
Rights-of-way, Hedgerows, Fencerows	0.76	none specified	4.56
Drainage Systems	0.76	none specified	6.0

It should be noted that the registrant is a member of the task force that is developing more refined data on agricultural re-entry exposure. As these data become available, they will be used to refine re-entry exposure estimates.

e. Post-Application Risks

Using the DFR data from the lettuce study and estimated transfer coefficients discussed above, exposure, dose, MOEs, and cancer risks for post-application activities were estimated. The results are presented in the tables below.

Table 16 - Worker Reentry Exposure to Methomyl Residues Following Thiodicarb Application (Application rate of 0.75 lb for 4 applications at 7 day intervals for a total of 3.0 lb per acre per season)

Days After Treatment	Best Fit DFR (μg/cm^2)[a]	Tc (cm^2/hr)[b]	Exposure (mg/day)[c]	Dose (mg/kg/day)[d]	MOE[e]
1	0.1242	L[f] 1,000	0.994	0.0142	6338
		M/H[g] 10,000	9.936	0.142	634

[a] The average foliar dislodgeable residues from the lettuce study (MRID 43198102). These are also used as a surrogate for other crops. DFR (μg/cm^2) was derived by converting the measured DFR data into lognormal distribution then running a linear regression equation to estimate the dissipation over time.

[b] Transfer coefficients estimated by the Agency.

[c] Potential average daily exposure (ADE) (mg/day) = [(Best Fit DFR x Transfer Coefficient (1,000 or 10,000 cm^2/hr)) / 1,000 μg/mg] x 8 hrs/day. Because the toxicity data are from a dermal study, dermal absorption is not factored into the equation.

[d] Dose (mg/kg/day) = Exposure (mg/day) / 70 kg.

[e] MOE = NOEL (90 mg/kg/day) / Dose (mg/kg/day).

[f] L = crops with potentially low dermal transfer to post-application entry workers.

[g] M/H = crops with potentially medium to high dermal transfer to post-application entry workers.

The postapplication thiodicarb cancer assessment in Table 17 is a screening level (i.e., tier 1) assessment that has not been refined because the calculated risk was not a concern. For example, the transfer coefficient, the thiodicarb DFR value of 1.26 μg/cm^2 (without considering dissipation over time), and the number of days harvesting (30 days/year) were selected as conservative assumptions to provide a reasonable certainty that the risks would not be underestimated. Using these conservative exposure inputs, the calculated risk provides adequate protection for the worker and no refinements are necessary at this time.

Table 17. Worker Reentry Cancer Risk Assessment.

Days After Treatment	Average DFR (μg/cm^2)[a]	Tc (cm^2/hr)[b]	Absorbed Dermal Dose (mg/kg/day)[c]	LADD (mg/kg/day)[d]	Risk[e]
1	1.26	10,000	0.029	0.0012	2.3E-5

a The average foliar dislodgeable residues from the lettuce study (MRID 43198102). These are also used as a surrogate for other crops. The DFR (μg/cm^2) value is the arithmetic mean thiodicarb (excluding methomyl) residue for five sites.

b Transfer coefficient (Tc) estimated by the Agency.

c Absorbed Dermal Dose (mg/kg/day) = (DFR * Tc * 8 hrs/day * 0.001 mg/μg conversion * 0.02 dermal absorption) / 70 kg body weight.

d LADD (mg/kg/day) = Absorbed Dermal Dose (mg/kg/day) * (30 days worked/365 days per year) * (35 years worked/ 70 year lifetime). Assuming 30 days worked per year and a DFR with no dissipation.

e Risk = LADD (mg/kg/day) / Q_1^* of 1.88E-2 (mg/kg/day)$^{-1}$

The calculations estimating worker reentry exposure from the previous tables indicate that the MOEs are 100 or greater for the following:

- for crops with potentially low dermal transfer, on the day following application (24 hours); and

- for crops with potentially medium to high dermal transfer, on the day following application (24 hours).

Based on the results of this assessment, the Agency believes an REI of 24 hours is sufficiently protective of workers following applications of thiodicarb. In the regulatory section this information has been integrated with other considerations including incident data to determine the required REIs.

Additional Occupational/Residential Exposure Studies

Handler Studies

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

Post-Application Studies

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

C. Environmental Assessment

The Agency has adequate data to assess the hazard of thiodicarb to nontarget terrestrial organisms. However, an estuarine/marine fish early life-stage test, an estuarine/marine invertebrate life-cycle study and a field dissipation study on cotton and corn are required as confirmatory information.

The Agency's major concern with the use of thiodicarb is its relatively rapid degradation into the more toxic, mobile and persistent chemical, methomyl. Therefore, the environmental fate and effects exposure assessments for thiodicarb must also take into account the fate and exposure of methomyl.

1. Toxicity to Terrestrial Animals

a. Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of thiodicarb to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird).

Results of this test are tabulated below.

Table 18 - Avian Acute Oral Toxicity

Species	% ai	LD50 (mg/kg)	Toxicity Category	MRID No. Author/Year
Northern bobwhite quail *(Colinus virginianus)*	99	2023	Practically nontoxic	00044269; Fink, 1978

Since the LD50 is greater than 2000 mg/kg, thiodicarb is practically nontoxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 00044269).

Two subacute dietary studies using the TGAI are required to establish the toxicity of thiodicarb to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 19 - Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC50 (ppm)[1]	Toxicity Category	MRID No. Author/Year
Northern bobwhite quail *(Colinus virginianus)*	99	>5620	Practically nontoxic	00044271; Fink, 1978
Mallard duck *(Anas platyrhynchos)*	99	>5620	Practically nontoxic	00044270; Fink, 1978

[1] Test organisms observed an additional three days while on untreated feed.

Since the LC50 falls in the range of >5620 ppm, thiodicarb is practically nontoxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 00044270, 00044271).

The available acute toxicity data on the TGAI for methomyl indicate that it is highly toxic to birds (LD50 = 15.4 mg/kg) on an acute oral basis and slightly toxic to birds (LC50= 1100 ppm) on a subacute dietary basis.

b. Birds, Chronic

Avian reproduction studies using the TGAI are required for thiodicarb because birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 20 - Avian Reproduction

Species/ Study Duration	% ai	NOEC/LOEC[1] (ppm)	LOEC Endpoints	MRID No.Author/Year
Northern bobwhite quail *(Colinus virginianus)*	94.6	1000/>1000 (HDT)	No effects	43313003; Pedersen, 1994
Mallard duck *(Anas platyrhynchos)*	94.6	500/1000	Fewer eggs laid per hen	43313004; Pedersen, 1994

1 NOEC = No Observed Effect Concentration; LOEC = Lowest Observed Effect Concentration

The only effects observed were in the mallard duck study at concentrations greater than 500 ppm. The guideline (71-4) is fulfilled (MRID 43313003, 43313004).

A bobwhite quail avian reproduction study with methomyl established a NOEC of 150 ppm and a LOEC of 500 ppm based on fewer eggs laid and eggs set (MRID 41898602). A mallard duck avian reproduction study with methomyl established a NOEC of 150 ppm and a LOEC of 500 ppm based on female weight loss (MRID 41898601).

c. Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing.

In several acute oral toxicity studies with rats, LD_{50}s ranged from 46.5 to 398 mg/kg/day for males and 39.1 to 248 mg/kg/day for females. In the mouse, the LD_{50} was 73 mg/kg in males and 79 mg/kg in females. These results indicate that thiodicarb is moderately to highly toxic to small mammals on an acute oral basis (MRID 00025791, 00115604, 00115607, 43784501).

In a reproduction study, rats were fed at levels of 0, 5, 15, and 45 mg/kg/day thiodicarb for approximately 22 weeks. The reproductive/developmental toxicity No Observed Effect Level (NOEL) is 5 mg/kg/day, and the Lowest Observed Effect Level (LOEL) is 15 mg/kg/day, based on decreased fetal body weight and viability (MRID 42381301, 42381302, 42735101).

Methomyl has been classified as being highly toxic to mammals on an acute oral basis with values ranging from 17-24 mg/kg (laboratory rats) and 11-20 mg/kg for deer.

d. Insects

A honey bee acute contact study using the TGAI is required for thiodicarb because its use may result in honey bee exposure. Results of this test are tabulated below.

Table 21 - Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (μg/bee)	Toxicity Category	MRID No.Author/Year
Honey bee *(Apis mellifera)*	99.95	>25	Practically nontoxic	42528501; Petto, 1992

The results indicate that thiodicarb is practically nontoxic to bees on an acute contact basis. The guideline (141-1) is fulfilled (MRID 42528501).

For methomyl, an analysis of the results of the honey bee acute contact study indicates that methomyl is categorized as highly toxic to bees (LD50 = 0.3 µg/bee).

2. Toxicity to Aquatic Animals

a. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of thiodicarb to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 22 - Freshwater Fish Acute Toxicity

Species/(Flow-through or Static)	% ai	96-hour LC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year
Rainbow trout *(Oncorhynchus mykiss)* flow-through	94.9	3.45 (measured)	Moderately toxic	41605502; Bowman, 1990
Bluegill sunfish (Lepomis macrochirus) flow-through	99.9	1.47 (measured)	Moderately toxic	41605501

Since the LC50 falls in the range of >1-10 ppm, thiodicarb is moderately toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID 41605501, 41605502).

Methomyl has been classified as moderately to highly toxic to freshwater fish (LC_{50} = 0.5 ppm to 6.8 ppm) on an acute basis.

b. Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for thiodicarb because the end-use product may be expected to be transported to water from the intended use site, and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent. The preferred test species is rainbow trout.

Data from a valid freshwater fish early life-stage test with thiodicarb determined that based on mean measured concentrations, the MATC for fathead minnows exposed to thiodicarb technical was between 25 and 53 ppb active ingredient. The geometric mean MATC was determined to be 36 ppb active ingredient (MRID 44484101).

A freshwater fish life-cycle test using the TGAI is required for thiodicarb since the end-use product may be transported to water from the intended use site, and the following conditions are met: (1) the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test, or, (2) studies of other organisms indicate the reproductive physiology of fish may be affected. The preferred test species is fathead minnow. Therefore, the freshwater fish life-cycle test using the TGAI is required for thiodicarb.

In a fathead minnow freshwater fish early life-stage study with methomyl the NOEC was 57 ppb based on larvae survival and the MATC was greater than 57 ppb but less than 117 ppb.

c. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of thiodicarb to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 23 - Freshwater Invertebrate Acute Toxicity

Species/(Static or Flow-through)	% ai	48-hour LC50/ EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year
Waterflea *(Daphnia magna)* flow-through	99.95	0.027 (measured)	Very highly toxic	41605503; Burgess, 1990
Waterflea *(Daphnia magna)* flow-through	33.21	0.049 ppm ai (measured)	Very highly toxic	43052801; Blakemore et al., 1992

Since the LC50/EC50 falls in the range of <0.1 ppm, thiodicarb is very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID

41605503, 43052801).

Methomyl has been classified as very highly toxic to freshwater invertebrates (48-hour EC50 = 8.8 ppb).

d. Freshwater Invertebrates, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for thiodicarb since the end-use product may be expected to be transported to water from the intended use site, and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 24 - Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species/Static Renewal or Flow-through)	% ai	21-dayNOEC/LOEC (ppm)	MATC[1] (ppm)	Endpoints Affected	MRID No. Author/Year
Waterflea *(Daphnia magna)* static renewal	97.3	0.009/0.018	>0.009, <0.018 (0.0135)	Reduced number of young per female	00100688;Booth et al., 1982

[1] MATC = Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOEC and LOEC.

In this freshwater aquatic invertebrate life-cycle study with thiodicarb the NOEC is 0.009 ppm and the LOEC is 0.018 ppm based on reduced number of young per female. The MATC is 0.0135 ppm. The guideline (72-4) is fulfilled (MRID 00100688).

In a waterflea aquatic invertebrate life-cycle study, the data indicate that methomyl significantly reduced the number of young produced at concentrations greater than 0.4 ppb.

e. Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for thiodicarb because the active ingredient is expected to reach this environment due to its use in coastal counties. The preferred test species is sheepshead minnow. Results of these tests are tabulated below.

Table 25 - Estuarine/Marine Fish Acute Toxicity

Species/(Static or Flow-through)	% ai	96-hour LC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year
Sheepshead minnow *(Cyprinodon variegatus)* flow-through	95.8	0.53 (measured)	Highly toxic	41891005; Machado, 1991
Sheepshead minnow flow-through	33.21	0.47 ppm ai (measured)	Highly toxic	42738501; Sousa, 1992
Sheepshead minnow flow-through	82.1	0.49 ppm ai (measured)	Highly toxic	42738502; Sousa, 1992

Since the LC50 falls in the 0.1-1.0 ppm range, thiodicarb is highly toxic to estuarine/marine fish on an acute basis. The guideline (72-3a) is fulfilled (MRID 41891005, 42738501, 42738502).

Methomyl has been classified as moderately toxic to estuarine/marine fish (LC50=1.16 ppm).

f. Estuarine and Marine Fish, Chronic

An estuarine/marine fish early life-stage toxicity test using the TGAI is required for thiodicarb because the end-use product may be applied multiple times to the estuarine/marine environment and in areas adjacent to or near estuarine habitats. Thiodicarb may also be expected to be transported to this environment from the intended use site, and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent. Thiodicarb is highly toxic on an acute basis and methomyl is moderately toxic on an acute basis. Therefore, the life-stage tests are needed to determine whether potential chronic risks exist. The preferred test species is sheepshead minnow. The guideline (72-4) is not fulfilled.

An estuarine/marine fish life-cycle test using the TGAI may be required for thiodicarb since the end-use product may be expected to transport to water from the intended use site, and the following conditions are met: (1) the EEC is equal to or greater than one-tenth of the NOEC in the fish early life-stage or invertebrate life-cycle test, or, (2) studies of other organisms indicate the reproductive physiology of fish may be affected. The preferred test species is sheepshead minnow. This requirement is reserved pending review of a valid estuarine/marine fish early life-stage test.

g. Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for thiodicarb because the active ingredient is expected to reach this environment because of its use in coastal counties. The preferred test species are mysid shrimp and

eastern oyster. Results of these tests are tabulated below.

Table 26 - Estuarine/Marine Invertebrate Acute Toxicity

Species/Static or Flow-through	% ai.	96-hour LC50/EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year
Eastern oyster (shell deposition) *(Crassostrea virginica)* flow-through	95.8	1.0 (measured)	Highly toxic	41891006; Dionne, 1991
Eastern oyster (shell deposition) flow-through	33.21	1.1 ppm ai (measured)	Moderately toxic	42342501; Dionne, 1991
Eastern oyster (shell deposition) flow-through	82.1	0.55 ppm ai (measured)	Highly toxic	42834001; Dionne, 1993
Mysid *(Americamysis bahia)* static	94.5	0.029 (measured)	Very highly toxic	41891007; Sousa, 1991
Mysid flow-through	33.21	0.10 ppm ai	Highly toxic	42738503; Sousa, 1992
Mysid flow-through	82.1	0.075 ppm ai	Very highly toxic	42738504; Sousa, 1992

Since the LC50/EC50 falls in the range of <0.029 -1.1 ppm, thiodicarb is moderately to very highly toxic to estuarine/marine invertebrates on an acute basis. The guideline (72-3b and 72-3c) is fulfilled (MRID 41891006, 41891007, 42342501, 42834001, 42738503, 42738504).

Methomyl has been classified as practically non-toxic to highly toxic to estuarine/marine invertebrates (EC50>140 ppm/Threshold Level 50=4.9 ppm).

h. Estuarine and Marine Invertebrates, Chronic

An estuarine/marine invertebrate life-cycle toxicity test using the TGAI is required for thiodicarb because the end-use product may be expected to be transported to this environment from the intended use site, and the following conditions are met: (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 aquatic acute LC50 or EC50 is less than 1 mg/l, (3) the EEC in water is equal to or greater than 0.01 of any acute LC50 or EC50 value, or, (4) the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute LC50 or EC50 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 is persistent in water (e.g., half-life greater than 4 days). The preferred test species is mysid shrimp. The guideline (72-4) is not fulfilled.

3. Toxicity to Plants

a. Terrestrial

Currently, terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis.

b. Aquatic

Currently, aquatic plant testing is not required for pesticides other than herbicides and fungicides as mentioned above.

According to current policy, testing at either the Tier I (122-1) or Tier II (123-1) level may be conducted to satisfy the requirements for aquatic plant testing. The only data available on thiodicarb are from a Tier II study with a green alga, *Kirchneria subcapitata*. This study (MRID 42324801, TGAI, Core study) provided an NOEC = 1.6 mg/L, an LOEC = 2.4 mg/L, and an EC50> 8.3 mg/L (MRID 42324801, TGAI, Core study)

D. Environmental Fate

1. Environmental Fate Assessment

Thiodicarb degrades rapidly to methomyl under aerobic soil and anaerobic aquatic conditions. At a slower rate, thiodicarb also degrades to methomyl through hydrolysis and photolysis. Methomyl, is more persistent, mobile, and toxic than the parent compound. For comparison, the following table summarizes the basic fate properties of thiodicarb and methomyl. The environmental fate exposure assessment for thiodicarb must also take into account the fate and expsoure of methomyl.

Table 27 - Fate Properties of Thiodicarb and Methomyl.

Properties	Thiodicarb	Methomyl
Vapor pressure, mmHg (20 C)	$4.3x10^{-5}$	$5.0x10^{-5}$
Water solubility, ppm (25 C)	19	58,000
Henry's Law constant, atm-m^3/mol	$1.1x10^{-6}$	$1.8x10^{-10}$
Hydrolysis t1/2 - pH5	78 days	stable
Hydrolysis t1/2 - pH 7	32 days	stable
Hydrolysis t1/2 - pH 9	12 hours	30 days
Aqueous photolysis t1/2	8 days	1 day
Soil Photolysis t1/2	37 days	36 days
Aerobic soil metab. t1/2	1.5 days	45 days
Anaer. Aquatic metab. t1/2	3 hours	<7-14 days
K_{oc}	485	24[1]

[1] The Koc value for methomyl is 42. The value used in the calculations was 24 (corrected for organic matter). EPA believes that, given the variability inherent in the environmental fate parameters and the level of sensitivity of the existing models, the new value will not change the assessment.

Methomyl is more persistent than thiodicarb because it is more stable to hydrolysis, particularly under alkaline conditions, and degrades more slowly under aerobic soil and anaerobic aquatic conditions. The higher mobility of methomyl is reflected in the differences in water solubilities and organic carbon adsorption coefficients (K_{oc}). Results from a field dissipation study for thiodicarb showed that methomyl was present in higher concentrations in the 75-90 cm soil zone than was thiodicarb. These findings are consistent with the laboratory mobility data.

Thiodicarb has a low water solubility of 19 ppm at 25°C. It hydrolyzes quickly under alkaline conditions ($t_{1/2}$=0.5 days), but is more stable under neutral and acidic conditions ($t_{1/2}$=32 and 78 days, respectively). In all pHs, methomyl was the major hydrolytic product, comprising 20 and 36% of the residues recovered in pH 5 and 7 solutions, respectively, at 30 days. In the pH 9 solution, methomyl increased rapidly to 66% of the recovered radioactivity at 1 and 3 days after treatment, then declined to 40% at 14 days, and 19% at 30 days.

Thiodicarb photodegraded moderately in the pH 6 solution with a half-life of 8 days. Methomyl, the major photodegradation product in water, increased from 7% of the applied at 1 day, to 24% at 7 days, then to 47% at 23 days. In contrast to the moderate direct photolysis in water, thiodicarb was relatively stable to photodegradation on a sandy loam soil ($t_{1/2}$=37 days). Methomyl was the major photodegradation product detected on

soil; it increased from 4.2% of the applied at day 0, to 19.2% at 7 days, and then to 21% at 30 days.

Thiodicarb degraded very rapidly in a sandy loam soil under aerobic conditions ($t_{1/2}$=1.5 days) to form methomyl, which is persistent. Methomyl increased from 10.1% of the applied immediately posttreatment to 37.3% at 1 day and 79.6% at 7 days, then decreased to 50.2% at 30 days and 23.9% at 60 days. Carbon dioxide, the major volatile degradate formed, comprised 51.6% of the applied at 60 days. Minor degradates identified were: methomyl oxime and acetonitrile. According to the degradation pathway proposed by the registrant, the -N-S-N- bond in thiodicarb was initially cleaved to produce methomyl which was subsequently degraded to methomyl oxime through hydrolytic reaction. Methomyl oxime was short lived and degraded to produce mostly carbon dioxide and some acetonitrile.

Thiodicarb is readily degradable in the aquatic environment under anaerobic (redox potentials from -104 to -219 mV) conditions, with a half-life of 3.5 hours. The major non-volatile degradate detected in the floodwater and sediment was methomyl, which decreased from 7.2% of the applied immediately after treatment to 4.9% at 0.17 days, and $\geq$0.1% at 2 through 14 days. Acetonitrile, the major volatile degradate, comprised 72.5% of the applied at 14 days. The registrant proposed a degradation pathway for thiodicarb in an anaerobic aquatic system. Under anaerobic aquatic conditions, the -N-S-N- bond in thiodicarb was cleaved to form methomyl, which rapidly hydrolyzed to produce methomyl oxime. The latter compound was subsequently decomposed to form two volatile compounds (i.e., acetonitrile and carbon dioxide).

The soil adsorption coefficients for thiodicarb are very low in sodium azide-sterilized sand, silt loam, clay, and sandy loam soils (K_{ads}=5, with a range of 0.2-14; or K_{oc}=485, with a range of 64-1167). The Agency has concerns about the use of metabolic inhibitors for sterilization of soils because physical or chemical sterilization procedures may subtly alter the soil chemistry, thus complicating the interpretation of the results obtained in the batch equilibrium study. However, the Agency acknowledges the difficulty of conducting a scientifically-sound batch equilibrium study for thiodicarb since it is very unstable under aerobic and anaerobic conditions.

Methomyl is expected to be more mobile than thiodicarb in the environment. The K_{ads} for methomyl calculated from 4 soils -- two sandy loam, one silt loam, and one silt were 0.2-1.4 (average K_{ads}=0.8). The corresponding $K_{oc(des)}$s were 37-48.

Taking into account its moderate vapor pressure ($4.3x10^{-5}$ mmHg at 20°C) and Henry's Law constant ($1.1 x10^{-6}$ atm-m^3/mol), low water solubility (19 ppm at 25°C), and low adsorption coefficient (K_{ads}=5; K_{oc}=485), volatilization of thiodicarb from soils and water is not expected to be an important dissipation route. Results from a laboratory volatility study for thiodicarb suggested that only 1.0-1.2% of the applied were volatilized.

The low octanol/water partition coefficient (K_{ow}=30) suggests that thiodicarb will have a low tendency to accumulate in fish. A fish bioaccumulation study confirmed that thiodicarb does not accumulate in fish at a significant level upon exposure. Bioconcentration factors were 4.1x, 7.1x, and 5.7x for edible tissue, nonedible tissue, and whole fish, respectively. Acetic acid was the major degradate identified in the fish tissues, comprising 34.5% of the recovered residues in the Day 21 fish tissues and 21.6% in the Day 35 fish tissues. The 21-day nonedible tissue was the only fraction in which thiodicarb, methomyl oxime, and methomyl were identified; each comprised 0.9-1.4% of the recovered residues. After 28 days of depuration, 46-74% of the accumulated residues were eliminated from the fish tissues.

Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required for thiodicarb since the chemical may be applied by aircraft and due to concerns for potential risk to nontarget aquatic organisms. However, to satisfy these requirements the registrant and 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. While these data are being reviewed the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The rates are 1% of the applied spray volume from ground applications and 5% from aerial and orchard airblast applications at 100 feet downwind. After its review of the new studies the Agency will determine whether a reassessment is warranted.

A field dissipation study conducted in a sandy loam soil in Washington showed that thiodicarb dissipated with a half-life of 18 days after six weekly applications of 1.0 lb ai/A per application. Thiodicarb and its degradate, methomyl, appeared to leach rather than accumulate in the soil from repeated applications. Very small amounts of thiodicarb (3 ppb) were detected immediately after the fifth application in the 75-90 cm soil zone. Low levels of methomyl were also detected in the 75-90 cm soil zone: 1 ppb after the fourth application, 4 ppb after the fifth application, and 1-3 ppb 7 and 14 days after the last of six applications. Furthermore, results from this study showed that the degradate, methomyl, was more commonly detected in lower horizons than the parent compound. These findings are consistent with the laboratory mobility data that indicate that methomyl is expected to be more mobile than thiodicarb in the environment.

2. Terrestrial Exposure Assessment

The terrestrial exposure assessments following single applications, shown in the table below, are based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. EFED

assumes that the foliar dissipation rate is equal to the aerobic soil metabolism rate. Open literature data suggest that foliar dissipation rates are generally less than 20 days.

Hoerger-Kenaga estimates of day 0 residues are based on residue data correlated from more than 20 pesticides on more than 60 crops. They are representative of many geographic regions (7 states) and a wide array of cultural practices, Hoerger-Kenaga estimates also considered differences in vegetative yield, surface/mass ratio and interception factors. In 1994, Fletcher, Nellessen and Pfleeger, reexamined the Hoerger-Kenaga estimates to determine whether the terrestrial EECs were appropriate estimates. They compiled a dataset of pesticide day-0 and residue-decay data involving 121 pesticides (85 insecticides, 27 herbicides, and 9 fungicides from 17 different chemical classes) on 118 species of plants. After analyses, their conclusions were that Hoerger-Kenaga estimates needed only minor modifications to elevate the predictive values for forage and fruit categories from 58 to 135 and from 7 to 15, respectively. EECs resulting from a single application, for avian and mammalian food items, for thiodicarb at 1 lb. ai/A are in the table below.

Table 28 - Estimated Environmental Concentrations on Avian and Mammalian Food Items Following a Single Application of 1 lb. ai/A (Hoerger and Kenaga, 1972, as modified by Fletcher et al, 1994)

Food Items	EEC (ppm) Predicted Maximum Residue	EEC (ppm) Predicted Mean Residue
Short grass	240	85
Tall grass	110	36
Broadleaf plants and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

For multiple applications, EEC's, shown in the table below, were derived from maximum application rates for thiodicarb and fate/toxicity data for both thiodicarb and methomyl. Terrestrial exposure calculations incorporated simultaneous degradation scenarios for both compounds. Animals will be exposed to both chemicals in their diet in fields treated with multiple applications of thiodicarb. This method is given below.

[1] $P_n = P_{n-1} \times (1 - K_1) + P_o^*$

[2] $D_n = [(P_{n-1} \times K_1) + D_{n-1}] \times (1 - K_2)$

Where n = day n of pesticide application
P_o = parent (thiodicarb) concentration at day 0
P_n = parent concentration n days after application
P_o^* = repeated application of the parent

D_o = daughter (methomyl) concentration at day 0
D_n = daughter concentration n days after application
K_1 = decay rate for the parent (thiodicarb), 0.46 day^{-1}
K_2 = decay rate for the daughter (methomyl), 0.02 day^{-1}

Table 29 - Maximum EEC's (in ppm from Fletcher et al., 1994) for thiodicarb and methomyl using calculations incorporating simultaneous degradation scenarios for both compounds.

Crop	Compound	Short grass EEC	Tall Grass EEC	Broadleaf Plant EEC	Fruit/ seed EEC
Cole	Thiodicarb Methomyl	507 1245	232 571	285 701	32 79
Cotton	Thiodicarb Methomyl	256 1010	117 463	144 568	16 63
Corn	Thiodicarb Methomyl	389 1496	178 685	219 841	24 93
Soybean	Thiodicarb Methomyl	182 521	84 239	103 293	11 33
Leafy vegetable	Thiodicarb Methomyl	277 313	127 143	156 176	17 20

3. Water Resource Assessment

a. Ground Water

According to the U.S. EPA 1992 Pesticide in Ground Water Database, detections of thiodicarb in ground water have not been reported. This database shows detections of methomyl in Missouri, New York, and New Jersey at concentrations up to 20 ppb.

The final report for the methomyl small-scale prospective ground-water monitoring study conducted at a sweet corn site in Cook County, Georgia found that methomyl was sporadically detected at concentrations ranging from 0.1-0.4 ppb in ground water. This study confirms the previous findings that methomyl (the major degradate of thiodicarb) is persistent and has a potential to contaminate ground water.

b. Surface Water

Thiodicarb may reach surface water by spray drift during aerial application or by runoff after application. Substantial fractions of applied thiodicarb may be available for runoff for a few days to several weeks after application. The relatively low soil/water partitioning of thiodicarb suggests that off-site transfer will generally occur primarily via dissolution in runoff water as opposed to adsorption to eroding soil.

The rapid hydrolysis of thiodicarb under alkaline conditions and its susceptibility to biodegradation indicate that it will probably not be persistent in alkaline waters or in any waters with substantial microbiological populations. In addition susceptibility to direct aqueous photolysis should also limit to some extent its persistence in clear shallow waters. However, slower rates of hydrolysis under acidic to neutral conditions and relatively low potential for volatilization from water indicate that thiodicarb will be more persistent in deeper and/or unclear neutral to acidic waters with low microbiological populations and long hydrologic residence times. The rapid biodegradation of thiodicarb under anaerobic conditions indicates that it will not persist in typically anaerobic sediments.

The relatively low soil/water partitioning of thiodicarb suggests that it will readily partition into the water body. However, unlike in the water body, the dissolved concentrations in sediment pore water will be somewhat comparable to that in the adsorbed bottom sediment phase. A supplemental study shows a half-life of 5 days in a sediment water system.

Reported maximum bioaccumulation values for thiodicarb in the bluegill sunfish indicate that its bioaccumulation potential is negligible.

The major environmental degradate of thiodicarb under both aerobic and anaerobic conditions is methomyl. Substantial fractions of the methomyl generated may be available for runoff for several days to weeks after generation. The low soil/water partitioning of methomyl indicates that runoff will occur primarily via dissolution in runoff water as opposed to adsorption to eroding soil.

The rapid direct aqueous photolysis of methomyl should greatly limit its persistence in clear shallow waters. Its susceptibility to biodegradation should also limit the persistence of methomyl in waters with high microbiological populations. Due to its low abiotic hydrolysis rate and low potential to volatilize from water, methomyl will be more persistent in deeper waters and/or waters that are not clear with low microbiological populations and long hydrologic residence time.

The low soil/water partitioning of methomyl indicates that it will readily partition into the water body. Its dissolved concentrations in sediment pore water, and to a lesser extent the water body, will be comparable to concentrations adsorbed to suspended and bottom sediment.

The Agency does not have any data on thiodicarb concentrations in surface water, but does have some limited data on methomyl in Florida and Washington State surface waters. No information was available on applications for either State. The South Florida Water Management District (SFWMD) collected samples every two to three months from 27 surface water sites within the SFWMD and analyzed them for multiple pesticides. Approximately 810 samples (30 sampling intervals x 27 sites sampled/interval) were

collected from the 27 sites from November 1988 through November 1993. Methomyl was detected (detection limits ranging from 1.9 to 20 ppb) in only one sample at a concentration of 1.9 ppb.

In 1994, Washington State collected surface water samples in April, June, and October from 8 sites (for a total of 24 samples) and analyzed them for multiple pesticides including methomyl. Methomyl was not detected in any of the samples above an approximate quantification limit of 0.04 ppb. However, methomyl was detected at a concentration of 0.09 ppb in a 1993 sample collected from a site (Salmon Creek) which was not resampled in 1994.

The relatively low soil/water partitioning of thiodicarb indicates that it will probably not be effectively removed by the primary sediment removal treatment processes employed by many surface water supply systems. However, thiodicarb is not currently regulated under the Safe Drinking Water Act (SDWA) and the Office of Drinking Water has not issued a Maximum Contaminant Level (MCL) or a Health Advisory Level (HAL) for it.

The relatively low soil/water partitioning of methomyl indicates that it will probably not be effectively removed by the primary sediment removal treatment processes employed by most surface water supply systems. Methomyl is not regulated under the SDWA and no MCL has been established for it. However, the Office of Drinking Water has established one- and ten-day HALs of 300 ppb and a lifetime HAL of 200 ppb for methomyl.

4. Aquatic Exposure Assessment

Estimated Environmental Concentrations (EECs) in the aquatic environment were generated both for the parent thiodicarb and the major degradate methomyl. Environmental fate studies indicate that thiodicarb rapidly degrades to methomyl, with few other degradates present. For a Tier 1 assessment, an almost immediate and complete degradation of thiodicarb to methomyl was assumed. For a Tier 2 assessment (PRZM/EXAMS), an 80% conversion was used (based on results of an aerobic metabolism study) which showed that the half-life of thiodicarb was 1.5 days in the soil tested.

For a Tier 1 assessment, the Agency uses GENEEC, a screening model that provides an upper-bound estimate of environmental concentrations (EECs) on a high exposure site. The GENEEC program uses basic environmental fate values and pesticide label information to estimate the EECs in a one-hectare, two-meter deep pond following the treatment of a 10 ha field. The runoff event occurs two days after the last application. GENEEC takes into account adsorption to the soil or sediment, incorporation of the pesticide, degradation in soil before runoff, and degradation within the water body. The

model also accounts for direct deposition of spray drift onto the water body (assuming 5% of the application rate for aerial spray applications and 1% for ground spray applications).

Table 30 - Environmental fate parameters used to predict thiodicarb and methomyl EECs:

Parameter	Thiodicarb	Methomyl
water solubility (ppm)	19	58,000
Koc (avg)	485	24[1]
aerobic soil metabolism, t1/2:	1.5 day	45 day
hydrolysis t1/2, pH 7	32 day	stable
aerobic aquatic metabolism, t1/2	n/a	n/a
aqueous photolysis t1/2	8 day	1 day

[1] The Koc value for methomyl is 42. The value used in the calculations was 24 (corrected for organic matter). EPA believes that, given the variability inherent in the environmental fate parameters and the level of sensitivity of the existing models, the new value will not change the assessment.

EECs for thiodicarb alone, determined using GENEEC, ranged from 22 to 65 ppb for initial peak concentrations and from 11 to 32 ppb for 56-day average concentrations. For methomyl degrading from thiodicarb, the EECs ranged from 76 to 352 ppb for initial peak concentrations and from 65 to 301 ppb for 56-day average concentrations. Most Risk Quotients (RQs) calculated using the GENEEC EECs exceeded the LOCs. Therefore, refined aquatic concentrations (Tier 2 assessments) were calculated using PRZM/EXAMS.

The Agency uses environmental fate and transport computer models to calculate refined EECs. The Pesticide Root Zone Model (PRZM2) simulates pesticides in field runoff on daily time steps, incorporating runoff, infiltration, erosion, and evapotranspiration. The simulation is run on daily time steps where runoff is estimated daily rather than on a yearly, hourly, etc. basis. The model calculates foliar dissipation and runoff, pesticide uptake by plants, microbial transformation, volatilization, and soil dispersion and retardation. The Exposure Analysis Modeling System (EXAM II) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep). EECs are tabulated in the following table.

Table 31 - Tier 2 (PRZM/EXAMS) Simulated EECs for Thiodicarb and Methomyl

Crop/ State	Chemical	Maximum EEC *ug/L*	96 Hour EEC *ug/L*	21 Day EEC *ug/L*	60 Day EEC *ug/L*	90 Day EEC *ug/L*
Corn, IA	Thiodicarb Methomyl	23 42	22 42	18 40	12 37	10 34
Cotton, MS	Thiodicarb Methomyl	21 151	19 149	17 141	12 129	9 120
Soybeans, MS	Thiodicarb Methomyl	9 41	8 41	7 40	5 37	4 35
Leafy Veg., FL	Thiodicarb Methomyl	5 24	5 24	4 23	3 23	2 22

The refined EECs, estimated by PRZM/EXAMS, ranged from 12% (for corn) to 63% (for cotton) of the EECs estimated using GENEEC. These EECs were used to calculate the risk quotients (RQs) in the Risk Characterization section.

E. Environmental Risk Assessment

The results of exposure and ecotoxicity data are integrated using the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, for both acute and chronic effects.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk to mammalian or avian species from granular/bait formulations.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals (3) EC50

(aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the effect is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs for terrestrial animals, aquatic animals and plants are tabulated in the following tables.

Table 32 - Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft[2] or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft[2] or LD50/day	0.1
Chronic Risk	EEC/NOEC	1.0
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft[2] or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft[2] or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft[2] or LD50/day	0.1
Chronic Risk	EEC/NOEC	1.0

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{mg/ft^2}{LD50 * wt. of bird}$ [3] $\frac{mg of toxicant consumed/day}{LD50 * wt. of bird}$

Table 33 - Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1.0

[1] EEC = (ppm or ppb) in water

Table 34 - Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC25	1.0
Acute Endangered Species	EEC/EC05 or NOEC	1.0
Aquatic Plants		
Acute High Risk	EEC[2]/EC50	1.0
Acute Endangered Species	EEC/EC05 or NOEC	1.0

[1] EEC = lbs ai/A

[2] EEC = (ppb/ppm) in water

1. Exposure and Risk to Nontarget Terrestrial Animals

The following tables identify the risk quotient values for thiodicarb and methomyl for nontarget terrestrial animals for each crop or representative crop at the daily maximum application rate for that crop.

Cole Crops: The Estimated Environmental Concentrations (EEC's in ppm) are based on maximum initial values for thiodicarb from Fletcher et al., (1994) resulting from daily 1 lb ai/A applications for 6 days, which is the maximum rate for cole crops. They incorporate degradation rates of 1.5 days for thiodicarb and 30 days for methomyl (see Table 29).

Table 35 - Risk Quotients for Nontarget Terrestrial Animals From Cole Crop Use

Species, Risk	Compound	EEC (ppm)	Toxicity[1]	RQ[2]
Avian, Acute	Thiodicarb	507 (short grass)	>5620	0.09
	Methomyl	1245 (short grass) 571 (tall grass) 701 (broadleaf plant) 79 (fruit/seed)	1100	1.13 *** 0.52 *** 0.64 *** 0.07
Avian, Chronic	Thiodicarb	507 (short grass) 232 (tall grass)	500	1.01 + 0.46
	Methomyl	1245 (short grass) 571 (tall grass) 701 (broadleaf plant) 79 (fruit/seed)	50	24.9 + 11.4 + 14.0 + 1.57 +
Mammal, Acute	Thiodicarb	507 (short grass) 232 (tall grass) 285 (broadleaf plant) 32 (fruit/seed)	506.7	1.00 *** 0.46 ** 0.56 *** 0.06
	Methomyl	1245 (short grass) 571 (tall grass) 701 (broadleaf plant) 79 (fruit/seed)	340	3.7 *** 1.7 *** 2.1 *** 0.23 **
Mammal, Chronic	Thiodicarb	507 (short grass) 232 (tall grass) 285 (broadleaf plant) 32 (fruit/seed)	100	5.1 + 2.3 + 2.9 + 0.32
	Methomyl	1245 (short grass) 571 (tall grass) 701 (broadleaf plant) 79 (fruit/seed)	75	16.6 + 7.6 + 9.3 + 1.05 +

[1] Acute toxicity values are the dietary LC50, except for the acute mammal. For thiodicarb, this is based on LD50 (mg/kg) = 76 ppm / % body weight consumed (15%) for a mouse. For methomyl, this is based on LD50 (mg/kg) = 17 ppm / % Body Weight Consumed (5%) for a rat. Chronic toxicity values are based on the NOEC from the reproductive studies.

*** exceeds acute high, acute restricted and acute endangered species LOCs.

** exceeds acute restricted and acute endangered species LOCs.

\+ exceeds chronic risk LOC

Cotton: The Estimated Environmental Concentrations (EEC's in ppm) are based on maximum initial values for thiodicarb from Fletcher et al., (1994) resulting from daily 0.9 lb ai/A applications for 6 days, which is the maximum rate for cotton. They incorporate degradation rates of 1.5 days for thiodicarb and 30 days for methomyl (see Table 29).

Table 36 - Risk Quotients for Nontarget Terrestrial Animals From Cotton Use

Species, Risk	Compound	EEC (ppm)	Toxicity[1]	RQ[2]
Avian, Acute	Thiodicarb	256 (short grass)	5620	0.05
	Methomyl	1010 (short grass) 463 (tall grass) 568 (broadleaf plant) 63 (fruit/seed)	1100	0.92 *** 0.42 *** 0.52 *** 0.06
Avian, Chronic	Thiodicarb	256 (short grass)	500	0.5 +
	Methomyl	1010 (short grass) 463 (tall grass) 568 (broadleaf plant) 63 (fruit/seed)	50	20.2 + 9.26 + 11.4 + 1.3 +
Mammal, Acute	Thiodicarb	256 (short grass) 117 (tall grass) 144 (broadleaf plant) 16 (fruit/seed)	506.7	0.51 *** 0.23 ** 0.28 *** 0.03
	Methomyl	1010 (short grass) 463 (tall grass) 568 (broadleaf plant) 63 (fruit/seed)	340	3.0 *** 1.4 *** 1.7 *** 0.19 **
Mammal, Chronic	Thiodicarb	256 (short grass) 117 (tall grass) 144 (broadleaf plant) 16 (fruit/seed)	100	2.6 + 1.2 + 1.4 + 0.16
	Methomyl	1010 (short grass) 463 (tall grass) 568 (broadleaf plant) 63 (fruit/seed)	75	13.5 + 6.2 + 7.6 + 0.8

[1] Acute toxicity values are the dietary LC50, except for the acute mammal. For thiodicarb, this is based on LD50 (mg/kg) = 76 ppm / % body weight consumed (15%) for a mouse. For methomyl, this is based on LD50 (mg/kg) = 17 ppm / % Body Weight Consumed (5%) for a rat. Chronic toxicity values are based on the NOEC from the reproductive studies.

*** exceeds acute high, acute restricted and acute endangered species LOCs.
** exceeds acute restricted and acute endangered species LOCs.
+ exceeds chronic risk LOC

Corn: The Estimated Environmental Concentrations (EEC's in ppm) are based on maximum initial

values for thiodicarb from Fletcher et al., (1994) resulting from daily 0.75 lb ai/A applications for 10 days, which is the maximum rate for corn. They incorporate degradation rates of 1.5 days for thiodicarb and 30 days for methomyl (see Table 29).

Table 37 - Risk Quotients for Nontarget Terrestrial Animals From Corn Use

Species, Risk	Compound	EEC (ppm)	Toxicity[1]	RQ[2]
Avian, Acute	Thiodicarb	389 (short grass)	5620	0.07
	Methomyl	1496 (short grass) 685 (tall grass) 93 (fruit/seed)	1100	1.4 *** 0.62 *** 0.09
Avian, Chronic	Thiodicarb	389 (short grass)	500	0.78
	Methomyl	1496 (short grass) 685 (tall grass) 93 (fruit/seed)	50	29.9 + 13.7 + 1.9 +
Mammal, Acute	Thiodicarb	389 (short grass) 178 (tall grass) 24 (fruit/seed)	506.7	0.77 *** 0.35 ** 0.05
	Methomyl	1496 (short grass) 685 (tall grass) 93 (fruit/seed)	340	4.4 *** 2.0 *** 2.5 *** 0.28 **
Mammal, Chronic	Thiodicarb	389 (short grass) 178 (tall grass) 24 (fruit/seed)	100	3.9 + 1.8 + 0.24
	Methomyl	1496 (short grass) 685 (tall grass) 93 (fruit/seed)	75	19.9 + 9.1 + 11.2 + 1.3 +

[1] Acute toxicity values are the dietary LC50, except for the acute mammal. For thiodicarb, this is based on LD50 (mg/kg) = 76 ppm / % body weight consumed (15%) for a mouse. For methomyl, this is based on LD50 (mg/kg) = 17 ppm / % Body Weight Consumed (5%) for a rat. Chronic toxicity values are based on the NOEC from the reproductive studies.

*** exceeds acute high, acute restricted and acute endangered species LOCs.
** exceeds acute restricted and acute endangered species LOCs.
+ exceeds chronic risk LOC

Leafy vegetables: The Estimated Environmental Concentrations (EEC's in ppm) are based on maximum initial values for thiodicarb from Fletcher et al., (1994) resulting from daily 0.75 lb ai/A applications for 2 days, which is the maximum rate for leafy vegetables. Theyincorporate degradation rates of 1.5 days for thiodicarb and 30 days for methomyl (see Table 29).

Table 38 - Risk Quotients for Nontarget Terrestrial Animals From Leafy Vegetable Use

Species, Risk	Compound	EEC (ppm)	Toxicity[1]	RQ[2]
Avian, Acute	Thiodicarb	277 (short grass)	5620	0.05
	Methomyl	313 (short grass) 143 (tall grass) 176 (broadleaf plant) 20 (fruit/seed)	1100	0.28 ** 0.13 * 0.16 * 0.02
Avian, Chronic	Thiodicarb	277 (short grass)	500	0.55
	Methomyl	313 (short grass) 143 (tall grass) 176 (broadleaf plant) 20 (fruit/seed)	50	6.3 + 2.9 + 3.5 + 0.4
Mammal, Acute	Thiodicarb	277 (short grass) 127 (tall grass) 156 (broadleaf plant) 17 (fruit/seed)	506.7	0.55 *** 0.25 ** 0.31 ** 0.03
	Methomyl	313 (short grass) 143 (tall grass) 176 (broadleaf plant) 20 (fruit/seed)	340	0.92 *** 0.42 ** 0.52 *** 0.06
Mammal, Chronic	Thiodicarb	277 (short grass) 127 (tall grass) 156 (broadleaf plant) 17 (fruit/seed)	100	2.8 + 1.3 + 1.56 + 0.17
	Methomyl	313 (short grass) 143 (tall grass) 176 (broadleaf plant) 20 (fruit/seed)	75	4.2 + 1.9 + 2.3 + 0.27

[1] Acute toxicity values are the dietary LC50, except for the acute mammal. For thiodicarb, this is based on LD50 (mg/kg) = 76 ppm / % body weight consumed (15%) for a mouse. For methomyl, this is based on LD50 (mg/kg) = 17 ppm / % Body Weight Consumed (5%) for a rat. Chronic toxicity values are based on the NOEC from the reproductive studies.

*** exceeds acute high, acute restricted and acute endangered species LOCs.

** exceeds acute restricted and acute endangered species LOCs.

* exceeds the endangered species LOC

+ exceeds chronic risk LOC

Soybeans: The Estimated Environmental Concentrations (EEC's in ppm) are based on maximum initial values for thiodicarb from Fletcher et al., (1994) resulting from using 4 applications of 0.75 lb ai/A every 7 days, which is the maximum rate for leafy vegetables. They incorporate degradation rates of 1.5 days for thiodicarb and 30 days for methomyl over time (see Table 29).

Table 39 - Risk Quotients for Nontarget Terrestrial Animals From Soybean Use

Species, Risk	Compound	EEC (ppm)	Toxicity[1]	RQ[2]
Avian, Acute	Thiodicarb	182 (short grass)	5620	0.03
	Methomyl	521 (short grass) 239 (tall grass) 293 (broadleaf plant) 33 (fruit/seed)	1100	0.47 ** 0.22 * 0.27 * 0.03
Avian, Chronic	Thiodicarb	182 (short grass)	500	0.36
	Methomyl	521 (short grass) 239 (tall grass) 293 (broadleaf plant) 33 (fruit/seed)	50	20.4 + 4.8 + 5.9 + 0.66
Mammal, Acute	Thiodicarb	182 (short grass) 84 (tall grass) 103 (broadleaf plant) 11 (fruit/seed)	506.7	0.36 ** 0.17 * 0.20 ** 0.02
	Methomyl	521 (short grass) 239 (tall grass) 293 (broadleaf plant) 33 (fruit/seed)	340	1.5 *** 0.7 *** 0.9 *** 0.1
Mammal, Chronic	Thiodicarb	182 (short grass) 84 (tall grass) 103 (broadleaf plant) 11 (fruit/seed)	100	1.8 + 0.84 1.03 + 0.11
	Methomyl	521 (short grass) 239 (tall grass) 293 (broadleaf plant) 33 (fruit/seed)	75	7.0 + 3.2 + 3.9 + 0.44

[1] Acute toxicity values are the dietary LC50, except for the acute mammal. For thiodicarb, this is based on LD50 (mg/kg) = 76 ppm / % body weight consumed (15%) for a mouse. For methomyl, this is based on LD50 (mg/kg) = 17 ppm / % Body Weight Consumed (5%) for a rat. Chronic toxicity values are based on the NOEC from the reproductive studies.

*** exceeds acute high, acute restricted and acute endangered species LOCs.
** exceeds acute restricted and acute endangered species LOCs.
* exceeds the endangered species LOC
+ exceeds chronic risk LOC

Laboratory studies show that thiodicarb is practically non-toxic to birds but

moderately to highly toxic to small mammals on an acute oral basis. Methomyl is highly toxic to birds and mammals on an acute oral basis but only slightly toxic to birds on a subacute dietary basis. Thiodicarb may result in chronic risks to certain species that frequent short grass (e.g, ducks, geese and swans). Methomyl, as a degradate, poses acute risks to birds and mammals that feed on short and tall grasses, broadleaf plants, and small insects. Methomyl also poses potential chronic risks to birds and mammals, primarily due to the build-up of the chemical from multiple applications of thiodicarb at short intervals.

2. Exposure and Risk to Nontarget Freshwater and Marine Aquatic Animals

The following tables identify the EEC values for acute and chronic risk from the maximum PRZM/EXAMS values (see Table 31). For chronic risk, the 21-day EECs are used for invertebrates and the 60-day EECs are used for fish. Application rates are the same as those used in the terrestrial risk assessment.

Table 40 - Risk Quotients for Aquatic Animals From Corn Use

Species	compound[1]	EEC (ppm)	Toxicity	RQ[2]
Freshwater fish	T (A)	0.023	1.47	0.02
	M (A)	0.042	0.5	0.08 *
	T (C)	0.012	0.036	0.33
	M (C)	0.037	0.057	0.65
Freshwater invertebrate	T (A)	0.023	0.027	0.85 ***
	M (A)	0.042	0.008	5.3 ***
	T (C)	0.018	0.0135	1.3 +
	M (C)	0.040	0.0004	100 +
Marine fish	T (A)	0.023	0.53	0.04
	M (A)	0.042	1.16	0.04
Marine invertebrate	T (A)	0.023	0.029	0.79 ***
	M (A)	0.042	0.23	0.18 **

[1] T= Thiodicarb M= Methomyl (A)= acute (C)= chronic

[2] *** exceeds acute high, acute restricted and acute endangered species LOCs

** exceeds acute restricted and acute endangered species LOCs

* exceeds the endangered species LOC

+ exceeds chronic risk LOC

Table 41 - Risk Quotients for Aquatic Animals From Cotton Use

Species	compound[1]	EEC (ppm)	Toxicity	RQ[2]
Freshwater fish	T (A)	0.021	1.47	0.01
	M (A)	0.151	0.5	0.30 **
	T (C)	0.012	0.036	0.33
	M (C)	0.129	0.057	2.30 +
Freshwater invertebrate	T (A)	0.021	0.027	0.78 ***
	M (A)	0.151	0.008	18.9 ***
	T (C)	0.017	0.0135	1.3 +
	M (C)	0.141	0.0004	353 +
Marine fish	T (A)	0.021	0.53	0.04
	M (A)	0.151	1.16	0.13 **
Marine invertebrate	T (A)	0.021	0.029	0.72 ***
	M (A)	0.151	0.23	0.66 ***

[1] T= Thiodicarb M= Methomyl (A)= acute (C)= chronic

[2] *** exceeds acute high, acute restricted and acute endangered species LOCs

** exceeds acute restricted and acute endangered species LOCs

+ exceeds chronic risk LOC

Table 42 - Risk Quotients For Aquatic Animals From Soybean Use

Species	compound[1]	EEC (ppm)	Toxicity	RQ[2]
Freshwater fish	T (A)	0.009	1.47	0.01
	M (A)	0.041	0.5	0.08 *
	T(C)	0.005	0.036	0.14
	M (C)	0.037	0.057	0.65
Freshwater invertebrate	T (A)	0.009	0.027	0.33 **
	M (A)	0.041	0.008	5.13 ***
	T (C)	0.007	0.0135	0.52
	M (C)	0.040	0.0004	100 +
Marine fish	T (A)	0.009	0.53	0.02
	M (A)	0.041	1.16	0.04
Marine invertebrate	T (A)	0.009	0.029	0.31 **
	M (A)	0.041	0.23	0.18 **

[1] T= Thiodicarb M= Methomyl (A)= acute (C)= chronic

[2] *** exceeds acute high, acute restricted and acute endangered species LOCs

** exceeds acute restricted and acute endangered species LOCs

* exceeds the endangered species LOC

+ exceeds chronic risk LOC

Table 43 - Risk Quotients For Aquatic Animals From Leafy Vegetable Use

Species	compound[1]	EEC (ppm)	Toxicity	RQ[2]
Freshwater fish	T (A)	0.005	1.47	0.00
	M (A)	0.024	0.5	0.048
	T (C)	0.003	0.036	0.083
	M (C)	0.023	0.057	0.40
Freshwater invertebrate	T (A)	0.005	0.027	0.19 **
	M (A)	0.024	0.008	3.0 ***
	T (C)	0.004	0.0135	0.30
	M (C)	0.023	0.0004	57.5 +
Marine fish	T (A)	0.005	0.53	0.01
	M (A)	0.024	1.16	0.02
Marine invertebrate	T (A)	0.005	0.029	0.17 **
	M (A)	0.024	0.23	0.10 **

[1] T= Thiodicarb M= Methomyl (A)= acute (C)= chronic

[2] *** exceeds acute high, acute restricted and acute endangered species LOCs

** exceeds acute restricted and acute endangered species LOCs

\+ exceeds chronic risk LOC

Acute toxicity studies show that thiodicarb is moderately to highly toxic to freshwater and estuarine/marine fish, respectively, and very highly toxic to freshwater and estuarine/marine invertebrates. The degradate methomyl is moderately to highly toxic to freshwater fish and moderately toxic to estuarine fish. In a chronic early life-stage study, methomyl significantly reduced fish larvae survival under flow through conditions. Toxicity data suggest that aquatic invertebrates are much more sensitive to methomyl contamination than either fresh or salt water fish species. While thiodicarb itself appears to pose a low acute risk to freshwater or marine/estuarine fish, the degradate methomyl does pose acute risk to freshwater and marine fish. Degradation of thiodicarb into methomyl may also pose a chronic risk to freshwater fish for maximum application rates and repeated applications on cotton. Both thiodicarb and its degradate methomyl can present high acute risk to freshwater and marine invertebrates. Chronic risk to aquatic invertebrates may result from thiodicarb in corn and cotton uses and from methomyl in all uses.

Chronic risk to marine fish and marine invertebrates for thiodicarb and chronic risk to marine fish and invertebrates for methomyl could not be adequately assessed due to a lack of toxicity data.

Direct Application to Water (citrus use)

No scenarios are available to model exposure for use sites such as drainage systems. Since direct pesticide application to water can occur when these sites are treated, a scenario using the method of direct application to water was used to estimate exposure. Using the DeWitt Nomogram (1966), a direct application of thiodicarb or methomyl results in EECs of 0.551 ppm (in 6 inches of water) and 0.046 ppm (in 6 feet of water). RQs (EEC/toxicity in ppm) for the drainage system were calculated using these EECs as follows:

Acute freshwater fish
Thiodicarb (0.551 to 0.046/1.47)= 0.3 to 0.03
Methomyl (0.551 to 0.046/0.5)= 1.1 to 0.09

Acute freshwater invertebrates
Thiodicarb (0.551 to 0.046/0.027)= 20.4 to 1.7
Methomyl (0.551 to 0.046/0.008)= 68.9 to 5.75

Acute estuarine fish
Thiodicarb (0.551 to 0.046/0.53)= 1.04 to 0.09
Methomyl (0.551 to 0.046/1.16)= 0.5 to 0.04

Acute estuarine invertebrates
Thiodicarb (0.551 to 0.046/0.029)= 19 to 1.6
Methomyl (0.551 to 0.046/0.23)= 2.4 to 0.2

These RQs indicate that freshwater and estuarine invertebrates are at high risk in shallow and deeper water bodies receiving direct treatment with thiodicarb. The rapid breakdown into methomyl can significantly increase risk to aquatic invertebrates. The risks to freshwater and estuarine fish are lower than to the invertebrates. The RQs indicate that there are high risks to estuarine fish in shallow water from both parent and degradate, and high risks to freshwater fish from the presence of the degradate. However, there are only minimal risks to fish from both compounds in deeper waterways.

3. Exposure and Risk to Nontarget Plants

a. Terrestrial and Semi-aquatic

No toxicity data are available (or required) to assess risk.

b. Aquatic Plants

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from such uses as drainage systems. An aquatic plant risk assessment for acute risk for non-endangered species is usually done for aquatic vascular

plants on the surrogate duckweed *Lemna gibba*. Non-vascular aquatic plant risk assessments for acute high risk are performed on either algae or a diatom, whichever is the most sensitive species. An aquatic plant acute risk assessment for endangered species is usually done for aquatic vascular plants using the surrogate duckweed, *Lemna gibba*. To date there are no known non-vascular plant species on the endangered species list. Runoff and drift exposure is computed from GENEEC. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC50 value. Although not currently required, the registrant has submitted toxicity data for non-vascular aquatic plants. Acute risk quotients for thiodicarb for non-vascular plants based upon green alga (*K. subcapitata*) toxicity are tabulated below.

Table 44 - Acute Risk Quotients for Aquatic Plants based EC50 of >8.3 ppm.

Site/ Application Method/ Rate of Application in lbs ai/A (No. of Apps.)	Species	EC50 (ppm)	EEC (ppm)	RQ(EEC/EC50)
Corn/aerial 0.75 (10)	green alga	>8.3	0.058	0.01
Cole crop/aerial 1.0 (6)	green alga	>8.3	0.065	0.01
Cotton/aerial 0.9 (6)	green alga	>8.3	0.036	0.00
Soybeans/aerial 0.75 (4)	green alga	>8.3	0.022	0.00

The results indicate that plant acute high risk and endangered species levels of concern are not exceeded for non-vascular single-celled aquatic plants at registered maximum use rates. There are no data available (or required) to assess risk from methomyl.

4. Exposure and Risk to Endangered Species

Endangered species LOCs are exceeded for most terrestrial and aquatic (freshwater and marine) species and uses of thiodicarb and its degradate methomyl.

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

5. Environmental Risk Characterization

Fate and Exposure

Available environmental fate studies show that thiodicarb degrades rapidly into methomyl under most conditions. While the parent chemical does not appear to be very persistent or highly mobile, the degradate methomyl is more persistent, more mobile, and more toxic. Therefore, the environmental fate and exposure assessment for thiodicarb has also taken into account the fate and exposure of methomyl.

Thiodicarb rapidly degrades (half-lives on the order of a few days) primarily by metabolism and hydrolysis in alkaline conditions. It may be more persistent under drier conditions. Uncertainties exist as to how quickly thiodicarb degrades into methomyl and how much methomyl builds up in the field under actual use conditions. For the risk assessment, it was assumed that the transformation from thiodicarb to methomyl was rapid and near-complete (based on the results of a laboratory aerobic soil metabolism study, it was assumed that methomyl will reach a peak of 80% of the applied active ingredient on a weight basis within a short period after application). A slower transformation rate from thiodicarb to methomyl would delay the effects of methomyl on non-target organisms. If the peak methomyl concentration is less than 80% of the applied, then acute risks based on peak degradate concentrations will be less.

Methomyl appears to be moderately persistent and highly mobile in the environment. The dominant routes of dissipation are metabolism (biologically-mediated degradation), leaching, and photolysis in clear waters. Site-specific factors affecting the persistence of methomyl include aerobicity, organic matter and soil moisture content, exposure to sunlight, pH, climate (especially rainfall) and crop management factors that influence leaching and runoff. The rates of dissipation of methomyl in the field (dissipation half-lives ranged from less than a week to nearly two months) were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching.

The behavior of the parent and its degradate in primary use areas (i.e., in cotton and corn areas) on a variety of soil and climatic conditions is not well-known. Such uncertainties will be addressed with additional terrestrial field dissipation studies in major use areas and crops.

Ground Water Assessment:

While thiodicarb is not expected to have a high potential to contaminate ground water because of its short persistence, methomyl has fate characteristics that favor leaching, and it has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. The potential for ground water

contamination is greatest with highly permeable soils, shallow depths to ground water, and an excess of water (from precipitation and/or irrigation) moving through the soil to carry the chemical with it. While it may reach ground water under certain conditions, methomyl may not persist under many conditions.

Surface Water Assessment:

Thiodicarb may reach surface waters by drift during spray application. Both thiodicarb and methomyl may run off to surface waters for a few days to several weeks after application. Neither chemical is likely to persist in clear, shallow waters or in waters with substantial microbiological populations. However, methomyl may persist in waters where sunlight penetration is limited (such as in deeper waters or waters with a significant sediment load or populations of organisms such as algae). Neither chemical is expected to persist in anaerobic sediments.

Runoff vulnerability of thiodicarb and methomyl is likely to be greater in high rainfall areas (eastern and southeastern U.S.) than in semi-arid to arid areas (in large areas of the southwest and western U.S.). Other sources of runoff include irrigation and drainage ditches/ channels/ lines and lateral subsurface flow. In addition to site characteristics, factors such as timing of pesticide application with rainfall and irrigation, water management practices, foliar interception, crop management practices, and formulation will also affect the potential for methomyl to reach surface or ground waters.

Characterization of Risk to Non-Target Organisms:

Because thiodicarb degrades relatively rapidly into the more persistent, mobile, and toxic methomyl, the greater risk is posed by the degradate rather than the parent. The use pattern (cotton, corn, soybeans, vegetables, cole crops and other minor uses) suggests that numerous non-target birds, mammals, and beneficial insects that directly utilize these crops for nesting, feeding, cover, and other activities are likely to be exposed to thiodicarb and methomyl. In addition, indirect exposure from drift and runoff is likely to contaminate a wide variety of ecosystems and possibly adversely affect non-target organisms utilizing these habitats.

Terrestrial Risk Assessment:

Laboratory studies show that thiodicarb is practically non-toxic to birds but moderately to highly toxic to small mammals on an acute oral basis. Methomyl is highly toxic toxic to birds and mammals on an acute oral basis but only slightly toxic to birds on a subacute dietary basis. Thiodicarb may result in chronic isks to certain species that frequent short grass (e.g, ducks, geese and swans). Methomyl, as a degradate, poses acute risks to birds and mammals that feed on short and tall grasses, broadleaf plants, and small insects. Methomyl also poses potential chronic risks to birds and mammals,

primarily due to the build-up of the chemical from multiple applications of thiodicarb at short intervals.

Aquatic Risk Assessment:

Acute toxicity studies show that thiodicarb is moderately to highly toxic to freshwater and estuarine/marine fish, respectively, and very highly toxic to freshwater and estuarine/marine invertebrates. The degradate methomyl is moderately to highly toxic to freshwater fish and moderately toxic to estuarine fish. In a chronic early life-stage study, methomyl significantly reduced fish larvae survival under flow through conditions. Toxicity data suggest that aquatic invertebrates are much more sensitive to methomyl contamination than either fresh or salt water fish species. While thiodicarb itself appears to pose a low acute risk to freshwater or marine/estuarine fish, the degradate methomyl does pose acute risk to freshwater and marine fish. Degradation of thiodicarb into methomyl may also pose a chronic risk to freshwater fish for maximum application rates and repeated applications on cotton. Both thiodicarb and its degradate methomyl can present high acute risk to freshwater and marine invertebrates. Chronic risk to aquatic invertebrates may result from thiodicarb in corn and cotton uses and from methomyl in all uses.

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 thiodicarb 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 thiodicarb. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of thiodicarb, 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 thiodicarb and to determine that thiodicarb, labeled and used as specified in this Reregistration Eligibility Decision, can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing thiodicarb as the active ingredient, labeled and used as specified in this Reregistration Eligibility Decision document, 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 thiodicarb, labeled and used as specified in this Reregistration Eligibility Decision document, 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 thiodicarb, 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 thiodicarb, the Agency has sufficient information on the health effects of thiodicarb and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that thiodicarb products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks to humans or the environment. Therefore, the Agency concludes that products containing thiodicarb for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of thiodicarb labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for thiodicarb. Where label revisions are imposed, specific language is set forth in Section V. of this document. It should be noted that, because thiodicarb degrades rapidly to methomyl in the environment, wherever relevant methomyl restrictions are more stringent these will be applied to thiodicarb also.

1. Food Quality Protection Act Findings

Determination of Safety for U.S. Population

The Agency has determined that established tolerances with amendments and changes as specified in this document for thiodicarb meet the safety standards under the

FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination the Agency has considered the available information on aggregate exposures, both acute and chronic, from food and water as well as the possibility of aggregate effects from thiodicarb and methomyl since thiodicarb degrades rapidly to methomyl. There are no residential or lawn uses of thiodicarb.

For acute dietary risk assessment for thiodicarb alone, a MOE of 1000 is required. The results of the Monte Carlo acute dietary exposure analyses, for thiodicarb alone, indicate that there are adequate margins of exposure for the general U.S. population (MOE=2450).

For the acute aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the endpoint for methomyl was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application. A MOE of 300 is required. The results of the acute aggregate exposure analyses for food, demonstrate that there are adequate margins of exposure for the general U.S. population (MOE=912).

The results of the chronic dietary risk evaluation system (DRES) analyses, for thiodicarb alone, indicate that the anticipated residue contribution for the U.S. Population occupies 68% of the FQPA adjusted RfD.

Results of the chronic aggregate exposure analyses for food, for residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application, show that for the general U.S. population, only 1.9% of the RfD is occupied.

A linear methodology (Q_1*) was applied for the estimation of human cancer risk and was calculated to be 1.88×10^{-2}. Cancer exposure is estimated by multiplying the Q_1* (1.88×10^{-2}) by the chronic dietary exposure (0.000020 mg/kg/day). The upper bound cancer risk was calculated to be 3.76×10^{-7}. This upper bound risk is below the range the Agency considers neglible for excess lifetime cancer risk and is not cause for concern.

Estimated acute and chronic water exposures do not exceed the drinking water level of concern.

Determination of Safety for Infants and Children

The Agency has determined that established tolerances with amendments and changes as specified in this document for thiodicarb meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for infants and children. In reaching this determination the Agency has considered the available information on the aggregate

exposures, both acute and chronic, from food and water as well as the possibility of aggregate exposure from methomyl and thiodicarb since thiodicarb degrades rapidly to methomyl.

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and information on exposure.

For purposes of assessing the pre- and post-natal toxicity of thiodicarb, EPA has evaluated three developmental studies and one reproduction study. Based on current toxicological data requirements, the data base for thiodicarb, relative to pre- and post-natal toxicity is complete. The data provided no indication of increased sensitivity of rats or rabbits to in utero or postnatal exposure to thiodicarb. In the prenatal developmental toxicity studies in rats and rabbits, effects in the fetuses were observed only at or above treatment levels that resulted in evidence of maternal toxicity. In the two-generation reproduction toxicity study, although the effects in the offspring were observed at a calculated lower dose (calculated NOEL =1.75 mg/kg/day) than in the parental animals (NOEL =5 mg/kg/day), it was concluded that this is not a real indication of increased susceptibility for the following reasons: 1) the endpoint (decrease in pup body weight) was considered to be a systemic effect and not a developmental or reproductive effect since the decrease was seen from day 7 through 21 of lactation in male pups and from day 14 through 21 in female pups; 2) the decreased pup weight was seen only in one generation (F2b) and not in the other generations thus lacking in consistency in response; 3) the data showed that the body weight gain of pups in this litter was at a higher rate than the body weight gain of control pups; 4) the decrease (8%) in both sexes on day 0 was not statistically significant at day 4; 5) the lowest dose (5 mg/kg/day) is actually considered close to a NOEL for the offspring while the 1.75 mg/kg/day was derived using Bench Mark methodology; and 6) it is during the latter portion of lactation that pups consume approximately twice the diet per unit body weight as an adult rat and, because of the availability of the test material to the pups from both milk and the feed, the amount consumed by the pups is likely more than double the adult's.

There are, however, data gaps for acute and subchronic neurotoxicity studies in rats. These studies are considered data gaps because thiodicarb breaks down to methomyl, which has exhibited neurotoxic signs in two species (dogs and rabbits) by two different routes of exposure (oral and dermal). In addition, thiodicarb produced neurotoxic effects (tremors and inactivity in dams) in the rat developmental toxicity study as well as tremors in rats in a 9-day inhalation toxicity study. The requirement for a developmental neurotoxicity study in rats is in reserve status pending receipt of the acute and subchronic neurotoxicity studies.

Based on these considerations, the 10x Safety Factor for increased susceptibility to

infants and children (as required by FQPA) was reduced to 3x.

For acute dietary risk assessment for thiodicarb alone, a MOE of 1000 is required. The results of the Monte Carlo acute dietary exposure analyses, for thiodicarb alone, indicate that there are adequate margins of exposure for children 1 to 6 years of age (MOE=2900), and infants (MOE=1680).

For the acute aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the endpoint for methomyl was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application. A MOE of 300 is required. The results demonstrate that there are adequate margins of exposure for children 1 to 6 years of age (MOE=417) and infants (MOE=756).

The results of the chronic dietary risk evaluation system (DRES) analyses, for thiodicarb alone, indicate that the anticipated residue contribution for children (1 to 6 years old) and infants, 104% and 43%, respectively, of the FQPA adjusted RfD is occupied. Although for children (1 to 6 years old), the FQPA adjusted RfD is slightly exceeded, if more refined estimates of dietary exposure were made (e.g. residues from field trials) significantly lower chronic risk would be estimated.

Results of the chronic aggregate exposure analyses for food, for residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application, show that the most significantly exposed subpopulation is infants (<1 year old) with 6.5% of the RfD occupied. For children 1-6 years old, 2.7% of the RfD is occupied.

Estimated acute and chronic water exposures do not exceed the drinking water level of concern.

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

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

Endocrine Disruption

The Agency 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, the Agency may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Cumulative Risk

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

The Agency does not have, at this time, available data to determine whether thiodicarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, the Agency has not assumed that thiodicarb has a common mechanism of toxicity with other substances.

2. Tolerance Reassessment

Tolerances for residues of thiodicarb in or on food commodities are currently expressed in terms of thiodicarb and its metabolite methomyl [40 CFR §180.407 (a)]. As a result of FQPA, pesticide residues are no longer regulated under section 409 of FFDCA. Consequently, all tolerances are placed in 40 CFR section 180.407(a).

Tolerances Listed Under 40 CFR §180.407(a):

Sufficient data are available to ascertain the adequacy of the established tolerances on broccoli, cabbage, cauliflower, sweet corn (K+CWHR), cottonseed, cottonseed hulls, leafy vegetables (except brassica vegetables), soybean hulls, and soybeans. The cottonseed tolerance needs to be lowered from 0.4 ppm to 0.2 ppm.

New Tolerances Needed Under 40 CFR §180.407:

Sufficient data are available to determine an appropriate tolerance for sweet corn forage and fodder and aspirated grain fractions (grain dust). The available corn forage data and storage stability data support the 300 ppm tolerance that has been proposed by the registrant. This data will be translated to sweet corn fodder by using a forage-to-fodder dry-down correction factor. On this basis, the tolerance for sweet corn fodder should be set at 500 ppm.

Data from the soybean processing study indicate that the registrants should propose a tolerance of 3 ppm for residues of thiodicarb in/on aspirated grain fractions.

A tolerance is required for thiodicarb residues in/on cotton gin byproducts. An appropriate tolerance will be determined once residue data are submitted.

A summary of the thiodicarb tolerance reassessment and recommended modifications in commodity definitions are presented in the following table.

Table 45 - Tolerance Reassessment Summary for Thiodicarb.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.407 (a):			
Broccoli	7.0	7.0	
Cabbage	7.0	7.0	
Cauliflower	7.0	7.0	
Corn, sweet grain (K+CWHR)	2.0	2	*Corn, sweet (K+CWHR)*
Cottonseed	0.4	0.2	Tolerance can be lowered based upon available data. *Cottonseed, undelinted*
Cottonseed hulls	0.8	Revoke	Tolerance should be revoked as the concentration (1.1x) of residues in cottonseed hulls is not significant.
Leafy vegetables	35.0	35.0	
Soybean, hulls	0.8	0.4	Based upon a concentration factor of 3.6x and HAFT residues of 0.103 ppm, the tolerance should be lowered.
Soybeans	0.2	0.2	
Tolerances covered under 40 CFR §180.31			
Corn, forage	150.0[1]	Revoke	Once a permanent tolerance of 300 ppm is established under §180.407, the temporary tolerance listed under §180.31 should be revoked.
Tolerances needed under 40 CFR §180.407:			
Aspirated grain fractions	None	3	Tolerance required based upon data from soybeans.

Table 45 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Corn, sweet, forage (incl. cannery waste)	None	300	The available data support establishment of a permanent tolerance of 300 ppm.
Corn, sweet, fodder	None	500	Permanent tolerance can be established using a forage-to-fodder dry-down correction factor
Cotton, gin byproducts	None	TBD [1]	Residue data are required.

1. TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiodicarb residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex has combined MRLs for thiodicarb and methomyl into a single listing. Although Codex MRLs and U.S. tolerances are not presently compatible [the U.S. tolerance expression currently includes only thiodicarb and its metabolite methomyl whereas the Codex MRL residue definition includes thiodicarb, methomyl, and methomyl oxime (methyl hydroxythioacetimidate)], EPA considers them to be essentially equivalent for enforcement purposes. While the U.S. enforcement method does measure the methomyl oxime, the Agency prefers not to alter the U.S. tolerance expression to explicitly include the oxime metabolite since we have previously indicated that the metabolite does not need to be regulated.

A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in the following table.

Table 46 - Codex MRLs for thiodicarb and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL [1] (mg/kg)	Step		
Cottonseed	0.5	CXL	0.2	U.S. residue data indicate that a lower tolerance is acceptable.
Maize	0.05 (*)	CXL	None	Not registered for use in the U.S.
Maize fodder	50 fresh wt.	CXL	None	Not registered for use in the U.S.
Maize forage[2]	50 fresh wt.	CXL	300	U.S. residue data indicate that the higher tolerance is required.
Soya bean (dry)	0.2	CXL	0.2	U.S. tolerance and Codex MRL are compatible.
Sweet corn (corn-on-the-cob)	2.0	CXL	2.0	U.S. tolerance and Codex MRL are compatible.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL [1] (mg/kg)	Step		
Tomato	1.0	CXL	None	Not registered for this use in the U.S.

1. An asterisk (*) signifies that the MRL was established at or about the limit of detection.
2. CODEX does not consider sweet corn forage to be a separate commodity. This table compares the CODEX MCL for maize forage to the U.S. tolerance for sweet corn forage.

In summary, if the Codex MRL residue definition for thiodicarb were amended, U.S. tolerances and Codex MRLs for soybeans and sweet corn (K+CWHR) will be compatible.

3. Summary of Risk Management Decisions

Human Health

As determined in section IV part C, section 1, the Agency concludes that aggregate exposure to all sources of residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application does not exceed the Agency's risk concerns.

To minimize the risks of potential systemic toxicity to mixers/loaders and other handlers the Agency is requiring the use of personal protective equipment and/or the use of engineering controls (water soluble bags).

Environmental Fate and Effects

Available environmental fate studies show that thiodicarb degrades rapidly into methomyl under most conditions. While the parent chemical does not appear to be very persistent or highly mobile, the degradate methomyl is more persistent, more mobile, and more toxic.

Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions. Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis.

Thiodicarb is moderately to highly toxic to small mammals and will result in chronic risks to certain species of avians that frequent short grass (e.g, ducks, geese and swans). Methomyl, the primary degradate of thiodicarb, is highly toxic to mammals and

poses acute and chronic risks to mammals that feed on short and tall grasses, broadleaf plants, and small insects. In summary, thiodicarb poses potential chronic risks to birds and mammals, primarily due to the build-up of the degradate methomyl from multiple applications of thiodicarb at short intervals.

Acute toxicity studies show that thiodicarb is moderately to highly toxic to freshwater and estuarine/marine fish, respectively, and very highly toxic to freshwater and estuarine/marine invertebrates. The degradate methomyl is moderately to highly toxic to freshwater fish and moderately toxic to estuarine fish. In a chronic early life-stage study, methomyl significantly reduced fish larvae survival under flow through conditions. Toxicity data suggest that aquatic invertebrates are much more sensitive to methomyl contamination than either fresh or salt water fish species. While thiodicarb itself appears to pose a low acute risk to freshwater or marine/estuarine fish, the degradate methomyl does pose acute risk to freshwater and marine fish. Degradation of thiodicarb into methomyl may also pose a chronic risk to freshwater fish for maximum application rates and repeated applications on cotton. Both thiodicarb and its degradate methomyl can present high acute risk to freshwater and marine invertebrates. Chronic risk to aquatic invertebrates may result from thiodicarb in corn and cotton uses and from methomyl in all uses.

The major concerns for non-target organisms are the chronic risks posed by the use of methomyl to non-target mammalian and freshwater invertebrate organisms. Risks to aquatic invertebrates from exposure to methomyl are likely to occur wherever methomyl is used. Accumulation of methomyl from repeated applications contributes to the chronic risks.

4. Ecological Risk Mitigation for Thiodicarb

To lessen ecological and potential water risks posed by thiodicarb and its degradate methomyl, the Agency is requiring the following mitigation for thiodicarb containing products.

1) The registrant will limit the maximum number of applications of thiodicarb on cole crops to 4 per season at the maximum rate of 1.0 lbs ai/A. Currently, the maximum of 6.0 lbs ai/A equals a total of 6 applications at the maximum rate per season. The number of applications on cotton will be limited to 6 applications. These measures will result in less loading of thiodicarb and its degradate methomyl in the environment.

2) The following statement supporting the use of an Integrated Pest Management (IPM) plan must be added to the labels.

"This product should be used as part of an Integrated Pest Management (IPM)

program which can include biological, cultural, and genetic practices aimed at preventing economic pest damage. Application of this product should be based on IPM principles and practices including field scouting or other detection methods, correct target pest identification, population monitoring and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultant or other qualified authorities to determine appropriate action threshold levels for treating specific pest/crop systems in your area.

3) Based on the environmental risk assessment for methomyl, the following advisories are required for thiodicarb: a labeling statement for potential ground water contamination, a labeling statement to minimize the potential for surface water contamination and labeling statements on manufacturing use products and end use products based on the toxicity to nontarget organisms. A bee hazard statement is also required.

4) The following spray drift label requirement for products with aerial applications is required for thiodicarb: "Do not apply by ground equipment within 25 feet, or by air within 100 feet of lakes, reservoirs, rivers, estuaries, commercial fish ponds and natural, permanent streams, marshes or natural, permanent ponds. Increase the buffer zone to 450 feet from the above aquatic areas when ultra low volume application is made."

5. Restricted Use Classification

Thiodicarb meets the requirments for classification as a Restricted Use Pesticide [40 CFR 152.170(c)(1)] because: (A) the residues of thiodicarb and its degradate, methomyl, are present in the diets of exposed mammalian and bird species at levels equal to or greater than 1/5 the dietary LC50 values (the risk quotients equal or exceed the LOC of 0.2) and (B) the residues of thiodicarb and methomyl in water equal or exceed 1/10 the LC50 values for nontarget aquatic organisms (the risk quotients equal or exceed the LOC of 0.1). In addition, thiodicarb degrades rapidly to methomyl which is a restricted use chemical.

6. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures to address the adverse impacts. The program may require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program

in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Labeling Rationale

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

The Worker Protection Standard (WPS)

The Agency has issued the Worker Protection Standard for Agricultural Pesticides (WPS) affecting 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 some of the registered uses of thiodicarb are within the scope of the WPS and some uses are outside the WPS scope.

Requirements for Handlers

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 the risks to handlers posed by the active ingredient are minimal, EPA may establish no a.i. specific handler requirements.

- Based on the acute toxicity characteristics of the end-use product, EPA usually establishes handler PPE requirements for each end-use product.

- If a.i. specific requirements have been established, they must be compared to the end-use-product-specific PPE and 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 more stringent than PPE requirements.

Occupational-Use Products

The Agency is establishing a.i. specific requirements for some occupational handlers of thiodicarb. The MOE's for inhalation exposure were less than 300 for occupational mixers and loaders handling wettable powder and liquid formulations. The MOEs were greater than 300 for persons mixing and loading liquids to support aerial and chemigation applications only when a dust/mist respirator is added. The MOEs were greater than 300 for persons mixing and loading wettable powder to support aerial, chemigation, and groundboom applications only when engineering controls (i.e., water-soluble packaging) are employed. The Agency is requiring active-ingredient-based protections for handlers of thiodicarb in these exposure situations.

WPS and NonWPS Uses:

Since potential handler exposure is similar for WPS and nonWPS uses, the a.i. specific handler requirements (specified in Section V.) are the same for WPS and nonWPS occupational uses of thiodicarb end-use products.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Intervals, Early-Entry PPE, and "Double" Notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REIs) 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 prior to 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 REIs, 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 considered the exposure and cancer risk assessment for thiodicarb post-application workers and the risks indicate an REI of at least 24 hours. However, thiodicarb degrades to methomyl, and therefore, EPA has determined that the entry restrictions should be based on exposures to methomyl. Estimates of methomyl postapplication exposure and risk indicate that for certain crops, restricted-entry intervals (REIs) based on the short and intermediate term dermal toxicological endpoint are necessary. For crops and sites on which thiodicarb is registered, estimates of dermal exposure and risk indicate that MOEs exceed 100 on the day following application (i.e., 24 hours following application). However, since methomyl is in acute toxicity category 1 for primary eye irritation, at least a 48 hour REI is required.

For early entry into treated areas (i.e., during the REI) that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, early-entry workers should wear the clothing and PPE consistent with the toxicity of the active ingredient. EPA has determined that the appropriate early-entry attire for dermal protection to thiodicarb and methomyl, the major degradate of thiodicarb, is coveralls, shoes and socks, and chemical-resistant gloves. In addition, protective eyewear must be worn, since methomyl is classified as category I for eye irritation potential. EPA is adopting this early-entry PPE for thiodicarb.

EPA is not requiring double notification for uses of thiodicarb.

Occupational-Use Products (NonWPS Uses)

At this time, EPA is not establishing entry restrictions of a specific length for nonWPS occupational uses of thiodicarb end-use products, since the anticipated frequency, duration, and degree of exposure following nonWPS occupational applications do not warrant special risk mitigation measures. However, EPA will prohibit entry into treated areas until sprays have dried, such as rights-of-way, hedgerows, fencerows, and drainage areas, due to concerns about inhalation exposures immediately after application and as a prudent safety practice.

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 thiodicarb. For the specific labeling statements, refer to Section V. of this document.

8. 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.

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 thiodicarb for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required for thiodicarb.

81-8	Acute neurotoxicity study
82-7	Subchronic neurotoxicity study
72-4(a)	Estuarine/marine fish early life stage test
72-4(b)	Estuarine/marine invertebrate life-cycle tests
164-1	Field Dissipation Study (cotton and corn)
860.1500	Magnitude of residue in cotton (formerly 171-4k)
860.1900	Field Accumulation in Rotational Crops (formerly 165-2)
830.7050	UV/Visible absorption spectrum.

Although the freshwater fish life cycle test could be required according to the criteria in 40 CFR Part 158. This study is not required at this time due to low risk estimated using the fish early life stage results and the risk mitigation required in this RED.

A confirmatory cooking study to verify the 0.07x (93% reduction) cooking factor applied to a variety of leafy vegetables in the Monte Carlo acute dietary analysis is required to be submitted by June 30, 1999. The registrant must consult with the Agency concerning the conduct of these studies including the appropriate cooking methods and cooking time as well as the specific crops on which studies should be conducted.

Additional Residue Chemistry Requirements

Directions for use are acceptable except that label directions for sweet corn should be amended to remove the restriction specifying use for "Florida Fresh Market Only" and

to remove the restrictions against grazing of livestock in treated fields or the feeding of treated corn silage or fodder to livestock. Label directions for sweet corn should also specify a maximum use rate of 7.5 lb ai/A for the entire season, rather than just after silk initiation as is currently specified. Once label directions for sweet corn are amended, the 19 SLN labels for the use of thiodicarb on sweet corn can be canceled, because these uses are essentially identical to the federal registrations.

Based upon the results of the confined rotational crop study, a plant-back interval must be added to EUP labels. The registrant can choose to conduct limited field rotational crop trials at the desired plant-back interval following soil treatment at 1x the maximum registered rate (7.5 lb ai/A) at two test sites. If residues of concern are detected in rotated crops from the limited trials, extensive rotational crop field trials will be required to determine the need for tolerances for thiodicarb residues in rotated crops. Alternatively, the registrant can choose to revise their labels to impose a 1-year restriction on the planting of rotated crops not appearing on the label, and limited field trials and rotational crop tolerances would not be required. If the registrant chooses to conduct the limited field rotational trials, the labels must be changed in the interim to specify a 1 year plantback interval.

2. Labeling Requirements for Manufacturing-Use Products and End-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) and end use product (EUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies as noted in the following table.

Table 47 Summary of Required Labeling Changes for Thiodicarb Products		
Description	**Required Labeling**	**Placement**
Manufacturing Use Products		
One of these statements may be added to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by the MP registrant]."	Directions for Use
	"This product may be used to formulate product for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
	"This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	"This pesticide is toxic to fish, aquatic invertebrates, and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements Environmental Hazards

End Use Products Intended for Occupational Use (WPS and non-WPS)		
Worker Protection Requirements for Products Subject to WPS	Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)", and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.	
PPE Requirements	Default PPE is established on the basis of acute toxicity category of the end-use products in accordance with PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE Requirements for products with water soluble packaging	Mixers, loaders, others exposed to the concentrate, and cleaners/repairers of equipment must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves*, --chemical-resistant footwear plus socks, --chemical-resistant apron, --a respirator dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicators, flaggers, and others exposed to the dilute must wear: -- long-sleeve shirt and long pants, and -- shoes plus socks. In addition, applicators using handheld equipment must wear: -- chemical-resistant gloves* *For the glove statement, use the statement established for thiodicarb through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals

PPE Requirements for liquid formulations	"Mixers, loaders, and others exposed to the concentrate, and cleaners/repairers of equipment must wear: -- long-sleeve shirt and long pants, and -- shoes plus socks, -- chemical-resistant gloves*, -- chemical-resistant apron, --a respirator dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicators, flaggers, and others exposed to the dilute must wear: -- long-sleeve shirt and long pants, and -- shoes plus socks. In addition, applicators using handheld equipment must wear: -- chemical-resistant gloves* " *For the glove statement, use the statement established for thiodicarb through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals.
PPE Requirements for granular formulations	Applicators and other handlers must wear: -- long-sleeve shirt and long pants, -- shoes plus socks, and -- chemical-resistant gloves* *For the glove statement, use the statement established for thiodicarb through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals.
User Safety Requirements	“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.”	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE.
User Safety Requirements for All Products that Specify Coveralls in the PPE	“Discard clothing or other materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE.

Engineering Controls	"Engineering Controls" "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements.
Engineering Controls for Wettable Powder Formulations	The following engineering controls are required in addition to those specified above: All wettable powder applications must be formulated in water-soluble packaging the outside of which contains a pictogram depicting that users should not cut, rip, or tear the bag. "Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets are permitted to wear long-sleeved shirt, long pants, shoes and socks, chemical-resistant gloves, and chemical-resistant apron, provided the other required PPE is immediately available in case the bag is opened."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements.
User Safety Recommendations	"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."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Engineering Controls.

Environmental Hazards, Ground and Surface Water Statements	"This pesticide is toxic to fish, aquatic invertebrates, and mammals. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate." "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area." "This chemical is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination." "This chemical can contaminate surface water through spray drift. Under some conditions, it may also have a high potential for runoff into surface water for several days to weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."	Precautionary Statements Environmental Hazards
General Application Restrictions	"Do not apply by ground equipment within 25 feet, or by air within 100 feet of lakes, reservoirs, rivers, estuaries, commercial fish ponds and natural, permanent streams, marshes or natural, permanent ponds." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	General Precautions and Restrictions section in Directions for Use.
Restricted Entry Interval for WPS Uses	"Do not enter or allow worker entry into treated areas during the restricted interval of 48 hours."	Directions for Use Agricultural Use Requirements Box as specified by Supplement Three of PR Notice 93-7.

Entry restrictions for Non-WPS uses that are applied as sprays	"Do not enter or allow others to enter the treated area until sprays have dried."	**If no WPS uses are on the label** -- Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label** -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.
Early Entry PPE for WPS Uses	The PPE required for early entry is: - coveralls, - shoes and socks, - chemical resistant gloves*, - protective eyewear. *For the glove statement, use the statement established for thiodicarb through the instructions in Supplement Three of PR Notice 93-7.	Agricultural Use Requirements Box as specified by Supplement Three of PR Notice 93-7.
The following statement supporting the use of an Integrated Pest Management (IPM) plan must be added.	"This product should be used as part of an Integrated Pest Management (IPM) program which can include biological, cultural, and genetic practices aimed at preventing economic pest damage. Application of this product should be based on IPM principles and practices including field scouting or other detection methods, correct target pest identification, population monitoring and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultant or other qualified authorities to determine appropriate action threshold levels for treating specific pest/crop systems in your area."	
Limiting the number of maximum applications of thiodicarb on cole crops and cotton.	Maximum of 4 applications for a total of 4 lbs ai/A per season using a maximum rate of 1.0 lbs ai/A for cole crops and a maximum of 6 applications per season for cotton.	Directions for Application section in Directions for Use

A review of the labels and supporting residue data indicate that the following label amendments are required: You are required to clarify these discrepances in your response to the product specific DCI.	Directions for use are acceptable except that label directions for sweet corn should be amended to remove the restriction specifying use for "Florida Fresh Market Only" and to remove the restrictions against grazing of livestock in treated fields or the feeding of treated corn silage or fodder to livestock. Label directions for sweet corn should also specify a maximum use rate of 7.5 lb ai/A for the entire season, rather than just after silk initiation as is currently specified. Once label directions for sweet corn are amended, the 19 SLN labels for the use of thiodicarb on sweet corn can be canceled, because these uses are essentially identical to the Section 3 registrations. Based upon the results of the confined rotational crop study, a plant-back interval must be added to EUP labels. The registrant can choose to conduct limited field rotational crop trials at the desired plant-back interval following soil treatment at 1x the maximum registered rate (7.5 lb ai/A) at two test sites. If residues of concern are detected in rotated crops from the limited trials, extensive rotational crop field trials will be required to determine the need for tolerances for thiodicarb residues in rotated crops. Alternatively, the registrant can choose to revise their labels to impose a 1-year restriction on the planting of rotated crops not appearing on the label, and limited field trials and rotational crop tolerances would not be required. If the registrant chooses to conduct the limited field rotational trials, the labels must be changed in the interim to specify a 1 year plantback interval.	

Spray Drift Label Requirements for Product with Aerial Applications	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. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.	
Aerial Drift Reduction Advisory Information. [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 below).	

	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.	
	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).	

B. 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 thiodicarb 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 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
The uses listed in Appendix A were evaluated for reregistration. The following uses do not include any changes to use patterns, such as application rates or frequency, that may be mandated by this RED document.											
FOOD/FEED USES											
BROCCOLI				Use Group: TERRESTRIAL FOOD CROP							
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Aircraft	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Low volume ground sprayer	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
CABBAGE				Use Group: TERRESTRIAL FOOD CROP							
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Aircraft	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Low volume ground sprayer	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
CAULIFLOWER				Use Group: TERRESTRIAL FOOD CROP							
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Aircraft	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
Spray, Foliar, Low volume ground sprayer	DF	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)
	FlC	NA	1 lb A	* NS	NS	6 lb	NS	AN .5 d			C92, CAL, H01(7)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, SWEET			Use Group: TERRESTRIAL FOOD CROP										
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d			C92, CAL, G03, GD4, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	ME		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NH		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	RI		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	VT		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	12 h	MA		C92, CAL, CAV, G03, G94, H01(0)
Chemigation, Silk, Sprinkler irrigation	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	ME		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NH		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	RI		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	VT		C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	12 h	MA		C92, CAL, CAV, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	DE		G03, GE2, H01(0)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, SWEET (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	GA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	LA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	MD		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	MI		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	MS		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	NC		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	NY		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	OH		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	PA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS	VA		G03, GE2, H01(0)
	WP	NA	.75 lb A	*	NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
Directed spray, Whorl, Ground	FlC	NA	.75 lb A	*	NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	CT		G74, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	DE		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	GA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	LA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	MD		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	MI		G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	MS		G03, GE2, H01(0)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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USES EVALUATED FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CORN, SWEET (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)									
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	NC	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	NY	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	OH	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	PA	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	AN	NS	VA	G03, GE2, H01(0)
	WP	NA	.75 lb A	*	NS	NS	NS	NS	1	NS		G03, GE2, H01(0)
Low volume spray (concentrate), Foliar, Low volume ground sprayer	FlC	NA	1 lb A	*	NS	NS	7.5 lb	NS	1	.5 d		C92, CAL, G03, GD4, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	AL	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	ME	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NH	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NJ	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	PR	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	RI	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	VT	C92, G03, G94, H01(0)

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USES EVALUATED FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CORN, SWEET (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)									
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	12 h	MA	C92, CAL, CAV, G03, G94, H01(0)
Low volume spray (concentrate), Silk, Low volume ground sprayer	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	AL	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	ME	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NH	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	NJ	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	PR	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	RI	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d	VT	C92, G03, G94, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	12 h	MA	C92, CAL, CAV, G03, G94, H01(0)
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d		C92, CAL, G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d		C92, CAL, G03, GD4, H01(0)
Spray, Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	NS	NS	7.5 lb	NS	1	.5 d		C92, CAL, G03, GE2, H01(0)

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USES EVALUATED FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CORN, SWEET (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)									
Spray, Silk, Aircraft	FlC	NA	.75 lb A	* NS	NS	7.5 lb	NS	1	12 h	MA		C92, CAL, CAV, G03, G94, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	CT		G74, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	DE		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	GA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	LA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	MD		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	MI		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	MS		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	NC		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	NY		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	OH		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	PA		G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	VA		G03, GE2, H01(0)
	WP	NA	.75 lb A	* NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
Spray, Silk, Ground	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS			G03, GE2, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	CT		G74, H01(0)
	FlC	NA	.75 lb A	* NS	NS	NS	NS	1	NS	DE		G03, GE2, H01(0)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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	# Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, SWEET (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	GA	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	LA	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	MD	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	MI	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	MS	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	NC	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	NY	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	OH	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	PA	G03, GE2, H01(0)
	FlC	NA	.75 lb A	*	NS	NS		NS	NS	1	NS	VA	G03, GE2, H01(0)
	WP	NA	.75 lb A	*	NS	NS		NS	NS	1	NS		G03, GE2, H01(0)
COTTON (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD CROP										
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.9 lb A	*	NS	NS	5.4 lb	NS	NS	7	.5 d		C92, CAL, H01(28)
Spray, Foliar, Aircraft	DF	NA	.9 lb A	*	NS	NS	5.4 lb	NS	NS	7	.5 d		C92, CAL, G03, H01(28)
	FlC	NA	.75 lb A	*	NS	NS	5.4 lb	NS	NS	7	.5 d		C92, CAL, H01(28)
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	NS	NS	5.4 lb	NS	NS	7	.5 d		C92, CAL, H01(28)
Spray, Foliar, Low volume ground sprayer	DF	NA	.9 lb A	*	NS	NS	5.4 lb	NS	NS	7	.5 d		C92, CAL, G03, H01(28)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
FOOD/FEED USES (con't)													
LEAFY VEGETABLES				Use Group: TERRESTRIAL FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	NS	NS	1.5 lb	NS	AN	.5 d			C92, CAL, H01(14)
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	NS	NS	1.5 lb	NS	AN	.5 d			C92, CAL, H01(14)
	FlC	NA	.75 lb A	*	NS	NS	1.5 lb	NS	AN	.5 d			C92, CAL, H01(14)
Spray, Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	NS	NS	1.5 lb	NS	AN	.5 d			C92, CAL, H01(14)
	FlC	NA	.75 lb A	*	NS	NS	1.5 lb	NS	AN	.5 d			C92, CAL, H01(14)
SOYBEANS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d			C92, CAL, G95, H01(28)
Low volume spray (concentrate), Foliar, Aircraft	DF	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d	MD, VA, NC, DE, SC, GA, AL, MS, LA, AR, MO		C92, CAL, G94, GA7, H01(28)
	FlC	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d			C92, CAL, G95, H01(28)
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d			C92, CAL, G94, GA7, H01(28)
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d			C92, CAL, G95, H01(28)
Spray, Foliar, Sprayer	DF	NA	.75 lb A	*	NS	NS	3 lb	NS	7	.5 d			C92, CAL, G94, GA7, H01(28)

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 EVALUATED FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
AGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS			Use Group: TERRESTRIAL NON-FOOD CROP									
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, Foliar, Aircraft	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, When needed, Sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	14	.5 d		C92, CAL, G03, G95
AGRICULTURAL UNCULTIVATED AREAS			Use Group: TERRESTRIAL NON-FOOD CROP									
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, Foliar, Aircraft	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, When needed, Sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	14	.5 d		C92, CAL, G03, G95
CITRUS FRUITS			Use Group: TERRESTRIAL NON-FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Nonbearing, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP									
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d			C92, CAL, GC1, GE3
Spray, Foliar, Aircraft	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d			C92, CAL, GC1, GE3
Spray, When needed, Sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	14	.5 d			C92, CAL, G03, G95
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d			C92, CAL, GC1, GE3
Spray, Foliar, Aircraft	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d			C92, CAL, GC1, GE3
Spray, When needed, Sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	14	.5 d			C92, CAL, G03, G95
ORNAMENTAL AND/OR SHADE TREES				Use Group: GREENHOUSE NON-FOOD CROP									
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL NON-FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast, Containerized, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL AND/OR SHADE TREES (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)								
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, Early morning, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, Late evening, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, When needed, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
Spray, Foliar, Low volume sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
ORNAMENTAL HERBACEOUS PLANTS				Use Group: GREENHOUSE NON-FOOD CROP								
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
				Use Group: TERRESTRIAL NON-FOOD CROP								
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 /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 EVALUATED FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
ORNAMENTAL HERBACEOUS PLANTS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
High volume spray (dilute), Foliar, High volume ground sprayer	FlC	NA	.75 lb/100 gal	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Foliar, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP								
Broadcast, Containerized, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, Early morning, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, Late evening, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
Broadcast, When needed, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h		CAL, CAU, CAV
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL HERBACEOUS PLANTS (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)									
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
Spray, Foliar, Low volume sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
ORNAMENTAL NONFLOWERING PLANTS				Use Group: GREENHOUSE NON-FOOD CROP									
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL NON-FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	FlC	NA	.09375 gal A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast, Containerized, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
Broadcast, Early morning, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
Broadcast, Late evening, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL NONFLOWERING PLANTS (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)									
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
Broadcast, When needed, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
Spray, Foliar, Low volume sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: GREENHOUSE NON-FOOD CROP									
Spray, Foliar, Ground	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL NON-FOOD CROP									
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d			C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d			C92, CAL
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast, Containerized, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h			CAL, CAU, CAV

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)							
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
Broadcast, Early morning, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
Broadcast, Late evening, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
Broadcast, When needed, Not on label	G	NA	.02063 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
	P/T	NA	.0175 lb 1K sq.ft	*	NS	12/1 yr	NS	NS	AN	12 h	CAL, CAU, CAV
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d	C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d	C92, CAL
Spray, Foliar, Low volume sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d	C92, CAL
POME FRUITS				Use Group: TERRESTRIAL NON-FOOD CROP							
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d	C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d	C92, CAL
High volume spray (dilute), Nonbearing, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d	C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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. Dose	Max. # Apps @ Max. Rate /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 EVALUATED FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
POME FRUITS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
SHELTERBELT PLANTINGS				Use Group: FORESTRY								
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	AN	.5 d		C92, CAL, GC1, GE3
	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, Foliar, Aircraft	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	AN	.5 d		C92, CAL, GC1, GE3
	DF	NA	.76 lb A	*	NS	NS	4.56 lb	NS	NS	.5 d		C92, CAL, GC1, GE3
Spray, When needed, Not on label	FlC	NA	.76 lb A	*	6	NS	NS	NS	14	.5 d		C92, CAL, G03, G95
STONE FRUITS				Use Group: TERRESTRIAL NON-FOOD CROP								
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Nonbearing, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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 Dose	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES EVALUATED FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
STONE FRUITS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
Low volume spray (concentrate), Nonbearing, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
TREE NUTS				Use Group: TERRESTRIAL NON-FOOD CROP								
Chemigation, Foliar, Sprinkler irrigation	FlC	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Foliar, High volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
High volume spray (dilute), Nonbearing, High volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Aircraft	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Low volume spray (concentrate), Nonbearing, Low volume ground sprayer	FlC	NA	.75 lb A	*	6	NS	NS	NS	AN	.5 d		C92, CAL
Spray, Foliar, Aircraft	DF	NA	.75 lb A	*	6	NS	NS	NS	NS	.5 d		C92, CAL

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]
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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. Antimicrobial 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

DF	: WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
FlC	: FLOWABLE CONCENTRATE
G	: GRANULAR
P/T	: PELLETED/TABLETED
WP	: WETTABLE POWDER

ABBREVIATIONS

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

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]

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
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.
CAV : Do not store or use in or around the home or home garden.
G03 : Do not graze livestock in treated areas.
G74 : Do not feed treated foliage to livestock or graze treated areas.
G94 : Do not feed treated forage or hay to livestock.
G95 : Do not feed to livestock.
GA7 : Do not harvest or feed hay to livestock.
GC1 : Do not graze treated areas.
GD4 : Do not use for feed or forage.
GE2 : Do not feed treated corn silage or fodder to livestock.
GE3 : Do not use for food or feed.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AL : Alabama
AR : Arkansas
CT : Connecticut
DE : Delaware
GA : Georgia
LA : Louisiana
MA : Massachussets
MD : Maryland
ME : Maine
MI : Michigan
MO : Missouri
MS : Mississippi
NC : North Carolina
NH : New Hampshire
NJ : New Jersey
NY : New York
OH : Ohio
PA : Pennsylvania
PR : Puerto Rico
RI : Rhode Island
SC : South Carolina
VA : Virginia
VT : Vermont

APPENDIX A REPORT

Case 2675 [Thiodicarb] Chemical 114501 [Dimethyl N,N'-(thiobis((methylimino)carbonyloxy))bis(ethanimidoth]
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REENTRY INTERVAL ABBREVIATIONS
d : day(s)
h : hour(s)

UNIT DESCRIPTIONS
A : acre
gal : gallon
lb : pound
sq.ft : square foot

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Thiodicarb covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Thiodicarb 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) 605-6000.

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 Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
830.1550 (formerly 61-1)	**Product Identity and Disclosure of Ingredients**	All	41891001
830.1600 (formerly 61-2a)	**Starting Materials and Manufacturing Process**	All	41891001
830-1670 (formerly 61-2b)	**Discussion of Formation of Impurities**	All	41891001
830.1700 (formerly 62-1)	**Preliminary Analysis**	All	41891002
830.1750 (formerly 62-2)	**Certification of Ingredient Limits**	All	41891001
830.1800 (formerly 62-3)	**Analytical Methods to Verify the Certified Limits**	All	41891002
830.6302 (formerly 63-2)	**Color**	All	41891003
830.6303 (formerly 63-3)	**Physical State**	All	41891003
830.6304 (formerly 63-4)	**Odor**	All	41891003
830.6313 (formerly 63-13)	**Stability**	All	41250005, 43059701
830.7000 (formerly 63-12)	**pH**	All	41891003
830.7050	**UV/Visible Absorption**	All	Data Gap
830.7200 (formerly 63-5)	**Melting Point/Melting Range**	All	41482001
830.7300 (formerly 63-7)	**Density/Relative Density /Bulk Density**	All	41250001
830.7370 (formerly 63-10)	**Dissociation Constant in Water**	All	Waived

REQUIREMENT		USE PATTERN	CITATION(S)
830.7550 (formerly 63-11)	**Partition Coefficient Octanol/Water**	All	41250004
830.7840 (formerly 63-8)	**Water Solubility**	All	41250002, 41482002
830.7950 (formerly 63-9)	**Vapor Pressure**	All	41250003, 43198101
ECOLOGICAL EFFECTS			
71-1a	**Acute Avian Oral - Quail**	A,B,C,I,J	00044269
71-2a	**Avian Dietary - Quail**	A,B,C,I,J	00044271
71-2b	**Avian Dietary - Duck**	A,B,C,J	00044270
71-4a	**Avian Reproduction - Quail**	A,B,C,J	43313003
71-4b	**Avian Reproduction - Duck**	A,B,C,J	43313004
72-1a	**Fish Toxicity Bluegill**	A,B,C,J	41605501
72-1c	**Fish Toxicity Rainbow Trout**	A,B,C,I,J	41605502
72-2a	**Invertebrate Toxicity**	A,B,C,I,J	41605503, 43052801
72-3a	**Estuarine/Marine Toxicity - Fish**	A,B,C,J	41891005, 42738501, 42738502
72-3b	**Estuarine/Marine Toxicity - Mollusk**	A,B,C,J	41891006, 42342501, 42834001
72-3c	**Estuarine/Marine Toxicity - Shrimp**	A,B,C,J	41891007, 42738503, 42738504
72-4a	**Early Life Stage Fish - Freshwater**	A,B,C,J	44484101
72-4a	**Early Life Stage Fish - Estuarine/Marine**	A,B,C,J	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
72-4b	**Life Cycle Invertebrate - Freshwater**	A,B,C,J	00100688
72-4b	**Life Cycle Invertebrate - Estuarine/Marine**	A,B,C,J	Data Gap
123-2	**Aquatic Plant Growth**	A,B,C,J	42324801
141-1	**Honey Bee Acute Contact**	A,B,C,J	42528501
TOXICOLOGY			
81-1	**Acute Oral Toxicity** **- Rat** **- Mouse**	All	00025791, 00115604 43784501
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	All	44025501
81-3	**Acute Inhalation Toxicity - Rat**	All	00041432, 00045467
81-4	**Primary Eye Irritation - Rabbit**	All	44025502
81-5	**Primary Dermal Irritation - Rabbit**	All	44025503
81-6	**Dermal Sensitization - Guinea Pig**	All	41891004, 43373201
81-7	**Acute Delayed Neurotoxicity - Hen**	A,B,C,I,J	00044961, 00053253
81-8	**Acute Neurotoxicity - Rat**	A,B,C,I,J	Data Gap
82-1a	**90-Day Feeding - Rodent**	A,B,C,I,J	00044965, 00098292, 43611701
82-1b	**90-Day Feeding - Non-rodent**	A,B,C,I,J	00044966, 00079474
82-2	**21-Day Dermal - Rabbit**		00043737, 00043738, 00044967
	9-Day Inhalation - Rat		00045467, 00053252

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
82-7	**Subchronic Neurotoxicity - Rat**	A,B,C,I,J	Data Gap
83-1a	**Chronic Feeding Toxicity - Rodent**	A,B,C,I,J	43308201, 43405001, 43596401
83-1b	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,I,J	00159813
83-2a	**Oncogenicity - Rat**	A,B,C,I,J	43308201, 43405001, 43596401
83-2b	**Oncogenicity - Mouse**	A,B,C,I,J	00041407, 43000501, 43619301
83-3a	**Developmental Toxicity - Rat**	A,B,C,I,J	00043739, 00043740, 00043741
83-3b	**Developmental Toxicity - Rabbit**	A,B,C,I,J	00159814, 40280001
	Developmental Toxicity - Mice		00043742, 00043743, 00053257, 00053258
83-4	**2-Generation Reproduction - Rat**	A,B,C,I,J	42381301, 42381302, 42735101
84-2a	**Gene Mutation (Ames Test)**	All	00044872, 00135792
84-2b	**Structural Chromosomal Aberration**	All	00151572, 00151574
84-4	**Other Genotoxic Effects**	All	00151573
85-1	**General Metabolism**	A,B,C,I,J	41250006, 41250007, 42667601, 43228901
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1a	**Foliar Residue Dissipation**	A,B,C,I,J	43198102

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
133-3	**Dermal Passive Dosimetry Exposure**	A,B,C,I,J	Ag. Reentry Task Force
133-4	**Inhalation Passive Dosimetry Exposure**	A,B,C,I,J	Waived
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	All	41891001
161-1	**Hydrolysis**	A,B,C,I,J	42342601
161-2	**Photodegradation - Water**	A,B,C,J	41250008
161-3	**Photodegradation - Soil**	A,B,C,J	43463401
162-1	**Aerobic Soil Metabolism**	A,B,C,I,J	42142601
162-2	**Anaerobic Soil Metabolism**	A,B,C	42142602
162-3	**Anaerobic Aquatic Metabolism**	A,B,C,J	42142602
163-1	**Leaching/Adsorption/ Desorption**	A,B,C,I,J	41998501
163-2	**Volatility - Lab**	A,B,I,	43222901
164-1	**Terrestrial Field Dissipation**	A,B,C	42203901 Data Gap for cotton and corn
165-4	**Bioaccumulation in Fish**	A,B,C,J	42834002
201-1	**Droplet Size Spectrum**	A,B,C,J	Spray Drift Task Force
202-1	**Drift Field Evaluation**	A,B,C,J	Spray Drift Task Force
RESIDUE CHEMISTRY			

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
860.1300 (formerly 171-4a)	**Nature of the Residue - Plants**	A,B	00044068, 00044069, 00044070, 00044071, 00044072, 00044073, 00159815, 40116705, 40170401, 41984901
860.1300 (formerly 171-4b)	**Nature of the Residue - Livestock**	A,B	00044075, 40824801, 40824802, 40824805, 40824806, 42919601, 43418001
860.1340 (formerly 171-4c)	**Residue Analytical Method - Plants**	A,B	41250009, 42381303
860.1340 (formerly 171-4d)	**Residue Analytical Method - Animal**	A,B	00144618, 41250010, 41250011, 43499401
860.1360 (formerly 171-4m)	**Multiresidue method**	A,B	41073201
860.1380 (formerly 171-4e)	**Storage Stability**	A,B	40824101, 42142603, 42142604, 42291601, 43313005, 44100701
860.1480 (formerly 171-4j)	**Magnitude of the Residue in Meat,Milk,Poultry, and Eggs**	A,B	41250012, 43499401

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
860.1500 (formerly 171-4k)	**Crop Field Trials**	A,B	
	Leafy Vegetables (except brassica) Group		00159935, 40116706, 40824101
	Brassica Leafy Vegetables Group:		
	- broccoli		00159935
	- cabbage		00159935
	- cauliflower		00159935
	Legume Vegetables Group:		
	- soybeans		40926801, 42330902
	Cereal Grains Group:		
	- corn, sweet (K+CWHR)		00122772, 40376101, 40884304, 42827301, 43687101
	Forage, Fodder, and Straw of Cereal Grains Group:		
	- corn, sweet, forage		00122772, 40376101, 40884304, 43687101
	Miscellaneous Commodities:		
	- cottonseed		41019101, 42330901
860.1520 (formerly 171-4l)	**Magnitude of the Residues in Processed Food/Feed**	A,B	
	- corn, sweet		42827301
	- cottonseed hulls		42043702
	- cotton gin byproducts		Data Gap
	- soybeans, hulls		42043701
860.1850 (formerly 165-1)	**Confined Accumulation in Rotational Crop**	A,B,C	43248901

Data Supporting Guideline Requirements for the Reregistration of Thiodicarb

REQUIREMENT		USE PATTERN	CITATION(S)
860.1900 (formerly 165-2)	**Field Accumulation in Rotational Crop**	A,B,C	Data Gap
Special Study	**Chronic and Acute Dietary Assessment**	A,B,C	44328701, 44328702, 44343601, 44343602, 44360702

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

   d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing

parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

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

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

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

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms(Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This 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

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) 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 (Telephone number: 703-605-6000).

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form(Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form(Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's

Response Form (Insert A). Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form(Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

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

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

studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may

request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B) committing to develop and submit the data required by this Notice.

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

Option 4. Submitting an Existing Study

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

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

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

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

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

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

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

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

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

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 entitled "Standard Format for Data Submitted under FIFRA."

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

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

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

Option 6. Citing Existing Studies

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form(Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form(Insert B) 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(Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

THIODICARB DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Thiodicarb. 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 Thiodicarb 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 Thiodicarb are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Thiodicarb 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 Thiodicarb 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 Bonnie Adler at (703) 308-8523.

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

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

RE: **Thiodicarb**

Thiodicarb DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Tom Myers at (703) 308-8589.

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

Tom Myers, Chemical Review Manager
Reregistration Branch II
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Thiodicarb

This page has been inserted as a place marker and is replaced by an electronically generated PDCI sample Part A form page number 1 in the actual Printed version of the Red document

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are

registered), you may not claim a Generic Data Exemption and you may not select this item.

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B) continued

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

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

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum,

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

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

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

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

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

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

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

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must

be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

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

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

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

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

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

choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Eleven products were found which contain Thiodicarb as the active ingredient. These products have been placed into two batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Products in batch 1 may cite acute oral, acute dermal and acute inhalation data performed on EPA Reg. No. 264-343.

- Products in batch 2 may cite category 3/4 acute oral, acute dermal and acute inhalation data performed on EPA Reg. No. 264-343.

- EPA Reg. No. 264-341 may cite acute oral, acute dermal and acute inhalation data performed on EPA Reg. No. 264-343.

- EPA Reg. No. 264-407 may cite category 3/4 acute oral, acute dermal and acute inhalation data performed on EPA Reg. No. 264-343.

- EPA Reg. No. 264-411 may cite acute data performed on EPA Reg. No. 264-343.

- EPA Reg. No. 264-568 may cite category 3/4 acute data performed on EPA Reg. No. 264-343.

- EPA Reg. No. 65636-128 may cite category 3/4 acute data performed on EPA Reg. No. 264-343.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	264-378	80	Solid
	264-530	80	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	264-379	34	Liquid
	264-406	34	Liquid
	9779-352	34	Liquid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	264-341	75.2	Solid
	264-343	96.0	Solid
	264-407	23.6	Liquid
	264-411	90.0	Solid
	264-568	4.0	Solid
	65636-128	1.75	Solid

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Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.

8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   b. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   c. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   d. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   e. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:
   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following is a list of available documents that may further assist 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 are available on our website at www.epa.gov/REDs, or contact Tom Myers at (703) 308-8589.

A. PR Notice 86-5.
B. PR Notice 91-2
C. A full copy of this RED document
D. A copy of the fact sheet for Thiodicarb

The following documents are part of the Administrative Record for this RED document 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 respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.