United States
Environmental Protection
Agency

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

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February 1994

EPA

Reregistration Eligibility Decision (RED)

Methiocarb

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

OCT 30 1994

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 Methiocarb which includes the active ingredients 4-methylthio-3,5-xylylmethylcarbamate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient(s) to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Karen Jones at 703-308-8047 .

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

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

1. DATA CALL-IN (DCI) OR "90-DAY RESPONSE"--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. Complete the two response forms provided with each DCI letter by following the instructions contained in each DCI. **You must submit the response forms for each product and for each DCI within 90 days of the date you receive the RED; otherwise, your product may be suspended.**

2. TIME EXTENSIONS AND DATA WAIVER REQUESTS--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

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

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

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

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

d. Two copies of the Confidential Statement of Formula (CSF) for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration.** You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by

the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

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

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

By U.S. Mail:

Document Processing Desk **(RED-SRRD-0577)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-0577)**
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 DOCUMENT

METHIOCARB

LIST A

CASE 0577

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

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METHIOCARB REREGISTRATION ELIGIBILITY TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe as designated by FDA
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin Of Exposure (PAD)
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide methiocarb, 4-methylthio-3,5-xylylmethylcarbamate.

Methiocarb is a carbamate insecticide, acaricide, molluscicide, and avian repellent produced by Miles, Inc. Methiocarb is used to control slugs, snails, and other pests on ornamentals, lawns, turf, and ginseng. Ginseng is not considered a food use because current methiocarb end-use labels bear the 12 months' preharvest interval. The end-use formulations of methiocarb are granular and pelleted/tableted, wettable powder, and pressurized liquid. The registered products are applied by broadcast, foliar spray, and soil-incorporation (spot treatment).

Methiocarb was initially registered as a pesticide in 1972. A Registration Standard was issued in March 1987 (NTIS# PB87-190898). This Registration Standard summarized available data supporting the registration of products containing methiocarb used as a bird repellent in corn fields and fruit orchards and for slug, snail, and other types of pest control on ornamentals, lawns, turf and ginseng. The Registration Standard also required additional product chemistry, residue chemistry, ecological effects, environmental fate, toxicology and occupational/residential exposure data. The residue chemistry data requirements were waived because of the deletion of the food uses from methiocarb product registration labels in 1992. The technical producer is no longer supporting commercial turf uses and support from end-use registrants or amendment of their labels deleting the commercial turf use is required. However, this document addresses commercial turf uses because such uses are currently still on labels. The Agency has now completed its review of the methiocarb target data base including data submitted in response to the 1987 Registration Standard.

The Agency has classified methiocarb as a Group D carcinogen (insufficient information to evaluate the chemical). The Agency has determined that methiocarb is a developmental toxicant based on a dermal developmental toxicity study in rabbits. The no observed effect level (NOEL) for developmental toxicity is 50 mg/kg/day.

There may be a risk to workers tending to plants in greenhouses/nurseries, handlers (mixer/loader/applicators), commercial turf workers, and homeowners exposed to methiocarb. The margins of exposure (MOE) for the uses with the greatest potential for occupational exposure indicate a level of concern. Specifically, for handlers using the wettable powder formulation, the MOE's are estimated to be less than 100, the commonly accepted margin of exposure. In order to achieve an acceptable MOE, the Agency is imposing additional PPE. The Agency is also concerned about workers entering treated areas following application of the wettable powder and pressurized liquid formulations. In order to achieve an acceptable MOE for workers, the Agency is requiring a 25-day restricted entry interval (REI) following foliar applications with the wettable powder formulation and treatment of greenhouses with the pressurized liquid. After 10 days workers may enter treated areas to perform tasks, including hand labor tasks that involve contact with treated

surfaces provided each worker spends no more than three hours in each 24-hour period performing such tasks. PPE is not required during the 3 hour work period. The Agency has determined that the uses of the wettable powder and the pressurized liquid formulations are eligible for reregistration. Confirmatory data on estimation of dermal and inhalation exposure to handlers for the wettable powder formulation is required. The Agency is also requiring an inhalation passive dosimetry study to better define exposure to workers reentering treated greenhouses following application of the pressurized liquid.

The Agency is requiring that coveralls be added to current Personal Protective Equipment (PPE) requirements in order to provide handlers of the wettable powder formulation with adequate MOE's for all uses. This PPE with modifications also applies to early entry workers entering treated areas. The Agency is also requiring that a dust mask be worn while mixing/loading the wettable powder formulation because the wettable powder is a potentially high exposure route with respect to inhalation. In addition, the Agency is requiring that a respirator be worn by handlers during ventilation activities.

With respect to homeowner uses of methiocarb, the Agency has determined that there is insufficient exposure data for the use of methiocarb by broadcast application on residential lawns and turf and a reregistration eligibility decision cannot be made at this time. The Agency is unable to estimate the risk to homeowners and children from the broadcast treatment of methiocarb granulars on residential lawns because of the numerous uncertainties in potential exposure levels. The only registered homeowner use is for the broadcast application of the 1% or 2% granular or pellet products on ornamentals and lawns. Data relating to postapplication reentry will be derived from the turfgrass foliar dislodgeable dissipation and dermal passive dosimetry studies required at this time to support the residential lawn uses. Registrants may prohibit use on lawns and commercial turf while maintaining uses on ornamentals and avoid generation of the foliar dissipation and passive dosimetry studies. Exposure to homeowners using methiocarb for applications to building foundations is expected to be low and additional data are not required to support this use. The Agency is retaining the 24-hour REI for postapplication activities for the granular formulation use on commercial or research production of turfgrass. The commercially grown turfgrass use is eligible for reregistration. Also, the use of the self-contained granular shakers are eligible for reregistration except for the use on residential lawns and turf.

Applications to ornamentals in residential situations, including application by commercial applicators, is eligible for reregistration except for products marketed in packages larger than the 2 lb. shaker cans (e.g. 20 - 25 lb. bags) for use by homeowners. The Agency is requiring data (soil dissipation and dermal exposure) to assess the exposure to persons entering treated ornamental planting areas. These data are considered confirmatory. After the Agency reviews exposure data on ornamentals and residential lawns, the Agency will determine if further marketing in packages other than 2 lb. shaker containers for use by homeowners is appropriate.

The Agency has also determined that the use of methiocarb exceeds levels of concern for endangered species for birds, mammals, non-target insects, and freshwater invertebrates for all outdoor uses. Because of these concerns, the Agency is requiring label amendments and confirmatory data, as well as negotiating with the registrants to maintain a production cap in an effort to decrease the environmental risk of methiocarb.

In addition, the Agency has classified methiocarb as a restricted use pesticide for all outdoor uses except homeowner uses.

In summary, the Agency has determined that the following uses and formulations are eligible for reregistration: 1) granular/pelleted formulations (1 - 2% a.i.) applied to commercially grown turfgrass; to residential and commercially grown ornamentals except for 20 - 25 lb. bag products used by homeowners; in commercial greenhouses and nurseries; and around building foundations. 2) wettable powder formulation (75 % a.i.) used as a foliar spray to nursery and greenhouse grown ornamentals. 3) pressurized liquid formulation (1% a.i.) applied as a total release spray in commercial greenhouses.

Due to a lack of exposure information, a reregistration eligibility decision on the granular and pelleted formulations for use on residential lawns and turf by broadcast methods cannot be made at this time.

The Agency is requiring that additional generic data be submitted to confirm the risk assessment done on the uses declared eligible in the reregistration review. These data include the following:

Estimation of dermal exposure - for wettable powder formulation use in greenhouses and nurseries
Estimation of inhalation exposure - for wettable powder formulation use in greenhouses and nurseries
Estimation of dermal exposure and soil dissipation - for granular formulations used on ornamentals
Inhalation passive dosimetry - for pressurized liquid formulation use in greenhouses
Aquatic and estuarine organisms - fish/mollusk/shrimp - required for all lawn and turf uses
Aquatic invertebrate life cycle - required for all lawn and turf uses
Fish early life stage - required for all lawn and turf uses
Fish life cycle - required for all lawn and turf uses
Hydrolysis - required for all outdoor uses
Adsorption/desorption/leaching - required for all outdoor uses
Terrestrial field dissipation - required for all lawn and turf uses
Outdoor usage data - specify pounds used per year by site

The following data are required to support the use of granular formulations of methiocarb on residential lawns and turf:

Foliar dislodgeable dissipation
Dermal passive dosimetry

Also, data on acute and subchronic neurotoxicity, which are not part of the target data base for methiocarb, are required because methiocarb is a carbamate pesticide.

Accordingly, the Agency has determined that only the products containing methiocarb as the sole active ingredient for the uses declared eligible for reregistration will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, the Agency is requiring that product specific data (product chemistry and acute toxicity) be submitted by the registrants within eight months of the issuance of this document. Additionally, in order to remain in compliance with FIFRA, it is the Agency's position that revised labeling be submitted by the registrants within that same time period. After reviewing these data and revised labels, the Agency will determine whether the conditions and requirements of FIFRA 3(c)(5) have been met for the reregistration of these products.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of methiocarb. The document consists of six sections. Section I is the introduction. Section II describes methiocarb, 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 methiocarb. Section V discusses the reregistration requirements for methiocarb. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision document. Additional details concerning the Agency's review of applicable data are available on request.[1]

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** methiocarb
- **Chemical Name:** 4-methylthio-3,5-xylylmethylcarbamate
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 2032-65-7
- **OPP Chemical Code:** 100501
- **Empirical Formula:** $C_{11}H_{15}NO_2S$
- **Trade and Other Names:** Mercaptodimethur, Metmercapturnon, Mesurol, Methiocarbe, Bay 376344, and H-321
- **Basic Manufacturer:** Miles, Inc.

B. Use Profile

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

For methiocarb:

Type of Pesticide: Molluscicide/Avian Repellent/Insecticide/Acaricide

Use Sites: Terrestrial Non-Food Crop: ornamental and/or shade trees, ornamental herbaceous plants, ginseng, ornamental non-flowering plants, ornamental woody shrubs and vines.

Terrestrial Non-Food/Outdoor Residential: ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental non-flowering plants, ornamental woody shrubs and vines.

Greenhouse Non-Food Crop: ornamental and/or shade trees, ornamental herbaceous plants, ornamental non-flowering plants, ornamental woody shrubs and vines.

Outdoor Residential: household/domestic dwellings outdoor premises

Target Pests: snails, slugs, sowbugs, millipedes, crickets, aphids, centipedes, fall webworms, scales, spider mites, pillbugs, moths, and whiteflies.

Formulation Types Registered:

Bait - Granular
(1.0% methiocarb plus other active ingredients, 2.0 % methiocarb)

Bait - Pelleted/Tableted
(2.0% methiocarb)

Wettable Powder
(75.0% methiocarb)

Pressurized Liquid
(1.0% methiocarb)

Technical Grade
(95% methiocarb, soluble concentrate/solid)

Manufacturing Use
(75% methiocarb, form not identified/solid)

Current Method and Rates of Application:

Granular: Water area to be treated before application. Sprinkle one pound of product directly from container or with spreader over 1000 square feet (for 2% product this equals 0.87 lbs ai/A). Scatter so that granules are hardly visible in treated area. Special attention should be given to treating areas around flower beds, under greenhouse benches, and around building foundations. Use sites include ornamentals, border plantings, flower gardens (ornamental gardens), shrubs, ornamental greenhouses, ornamental nurseries, lawns, turf, ornamental ground covers, around the home, around building foundations, and ginseng gardens.

Pelleted/Tableted: Sprinkle one pound of pellets over 1000 square feet (0.87 lbs ai/A). For best results lightly water area to be treated before application. Scatter bait so that it is visible on the ground. Use sites include flower gardens, ornamental greenhouses, around the home, and around building foundations.

Wettable Powder: Apply up to two pounds product (1.5 lbs ai/A) per acre in 50 gallons water using conventional ground spray equipment. Spray plants and foliage until thoroughly wet. Maximum of four applications per season (8 pounds of product per acre equals 6.0 lbs ai/A per season). Use sites include ornamental nurseries and ornamental greenhouses for use on shrubs, flowers, and trees.

Pressurized Liquid (Total Release Aerosol): For best results, apply in early evening when foliage is dry and temperatures are between 60-80°F. Shut off all exhaust fans and close all windows, doors and ventilators. Keep greenhouse closed 2-4 hours after treatment. Maximum rate is 1 pound per 1500 square feet. Place container on ground or on bench depending on location where plants are grown. Press tab down to lock position and leave greenhouse. Entire contents will release automatically. Use site includes commercial greenhouses.

Current Limitations on Use Practices:

Granular: Do not use on or around plants grown for food. Do not put granules in piles. Do not enter treated areas for 24 hours unless protective clothing is worn. This restriction is not applicable to the homeowner use of granular formulations.

Pelleted/Tableted: Do not use on plants grown for food. Do not put bait in piles. Toxic to fish and highly toxic to birds.

Wettable Powder: Do not apply through any type of irrigation system. Do not apply with oil. Do not enter treated areas for 24 hours without protective clothing. Do not apply in conjunction with foliar fertilizer applications.

Pressurized Liquid: Do not remain in treated area and ventilate area after treatment. Container must be at room temperature before use. Test for phytotoxicity before use. Toxic to fish.

C. Data Requirements

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

D. Regulatory History

A Registration Standard was issued in March 1987 (NTIS #PB87-190898) for all pesticide products containing the active ingredient, methiocarb. This document identified the additional generic data required to support the continued registration of the use of methiocarb as a bird repellent, insecticide, acaricide and molluscicide. The use patterns registered at that time included terrestrial food and non-food, greenhouse non-food and domestic outdoor. This document also specified those product-specific product chemistry and acute toxicity data required for the manufacturing-use products.

Additionally, the Registration Standard restricted all outdoor agricultural and commercial (non-domestic) uses of methiocarb for use by certified applicators or workers under their direct supervision on an interim basis pending submittal and evaluation of the required terrestrial field, avian repellency and aquatic residue monitoring data. The Registration Standard further specified that no new permanent tolerances would be granted pending submittal and evaluation of data required to ascertain and validate an appropriate analytical method for the enforcement of tolerances for residues of methiocarb and any metabolites deemed to be of toxicological concern.

Consequently, in 1989, Miles Inc. (technical producer) dropped all terrestrial food uses of methiocarb and in 1992, the end-use registrants either voluntarily cancelled their product(s) or amended their label(s) by deleting the food uses. Therefore, no residue chemistry data requirements remain for methiocarb. The technical producer also dropped their support of all commercial turf and field grown ornamental uses. However, these uses remain on end-use product labels. A

Reregistration Eligibility Decision document reflects a reassessment of all data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical and chemical characteristics of methiocarb are described below:

TGAI	Methiocarb
Molecular weight	225.3
Color	White
Physical State	Crystalline solid
Odor	Slightly mercaptan
Melting Point	121°C
Boiling Point	N/A
Bulk Density	35-40 lb/cu. ft (0.56 - 0.64 g/cc)
Solubility	27 mg/l in water, 80 g/l in 2-propanol, 70 g/l in toluene and 2 g/l in n-hexane
Vapor Pressure	8.8×10^{-7} mbar at 25°C (6.6×10^{-7} torr)
Dissoc. Constant	N/A
Oct./Water Part. Coeff.	2200 at 20°C
pH	N/A
Stability	Half life at 22°C is >1 year at pH 4

There are no further Product Chemistry data requirements for methiocarb technical.

B. Human Health Assessment

1. Toxicology Assessment

Adequate animal toxicological data on methiocarb are available and will support reregistration eligibility as a terrestrial non-food use pesticide. The data are reported below.

a. Acute Toxicity

Acute toxicity data for methiocarb technical are listed in the table below.

Acute Toxicity

Test	Result	Category
Oral LD_{50} (rat)[1,2]	30 mg/kg (both sexes)[a] 14 mg/kg (males)[b] 16 mg/kg (females)[b]	I
Dermal LD_{50} (rabbit)[3]	> 2000 mg/kg	III
Inhalation LC_{50} (rat)[4]	0.585 mg/l (males) 0.433 mg/l (females)	II
Eye Irritation[5]	Not an irritant	IV
Dermal Irritation[6]	Not an irritant	IV
Delayed Neurotoxicity[7,c]	Negative	N/A

1-7 MRID numbers are 00036477, 00083437, 00036478, 4040420, 00055163, 00055163, and 00083438.
a Test material in ethanol and propylene glycol vehicle.
b Test material in polyethylene glycol 400 (Lutrol) vehicle.
c Study available but not required for carbamates.
N/A Not applicable

b. Subchronic Toxicity

Four dermal toxicity studies in rabbits are available. The first two, a six-day initial range-finding study and a 21-day repeated dermal toxicity study (interrupted at day 14), were performed by the same laboratory . In the range-finding study, doses of 0 (saline vehicle), 15.7, 31.3, 62.5, 125, 250, 500, 1000, or 2000 mg/kg/day of methiocarb technical were administered. Death occurred in one out of two females per group at doses of 250, 500, and 1000 mg/kg/day and in both of the high dose females. One out of two males per group died at doses of 1000 mg/kg/day and above. All deaths were ascribed to treatment since no other explanation was provided in the study report. Other clear-cut clinical signs of toxicity were noted at the two highest doses. The interrupted 21-day study, in which doses of 0 (saline vehicle), 60, 150, or 375 mg/kg/day of methiocarb technical were being administered, was stopped due to three accidental deaths at the high dose. No treatment-related effects were observed by day 14 at the lower doses.

The third and fourth dermal studies were 21-day studies which were performed at later dates by a different laboratory. The respective doses of methiocarb technical used in the two studies were 0 (saline

vehicle), 60, 150, or 375 mg/kg/day and, 0 (saline vehicle) or 500 mg/kg/day. No clear adverse findings were observed and a lowest observed effect level (LOEL) could not be established (MRIDs 40922301 and 41771701).

Although inconsistencies were noted in the data from the two laboratories and the quality of the data from the two completed 21-day dermal studies exceeded that of the earlier studies, the deaths in the dose ranging study cannot be ignored. Therefore, based on all of the available information, a no observed effect level (NOEL) for subchronic dermal toxicity could be established at 150 mg/kg/day (the next lower dose tested from amongst the studies in which no treatment-related effects were noted). The LOEL was 250 mg/kg/day based on mortality in females at doses of 250 mg/kg/day and above. (MRIDs 40922301 and 41771701).

Since a subchronic NOEL could be established from the above studies, the requirements for subchronic toxicity studies in rodents and non-rodents are formally satisfied by the availability of acceptable chronic feeding studies (MRIDs 00115226, 00128939, and 00149362).

c. Chronic toxicity

In a chronic feeding study in rodents, groups of rats (60/sex/group) were fed diets containing 0, 67, 200, or 600 ppm of methiocarb technical for two years. The systemic NOEL was determined to be 600 ppm (30 mg/kg/day). At this dose, in both sexes, body weight decreases, relative to controls, were observed which were considered to be a secondary effect of cholinesterase inhibition. Both erythrocyte and plasma cholinesterase inhibition occurred at the high dose. The LOEL for cholinesterase inhibition was judged to be 200 ppm (10 mg/kg/day), at which dose transitory erythrocyte cholinesterase inhibition was observed. The NOEL for cholinesterase inhibition was set at 67 ppm (3.35 mg/kg/day). Brain cholinesterase was not affected (MRID 00115226 and 00128723)

In a chronic feeding study in the non-rodent, groups of six-month old pure bred beagle dogs (4/sex/group) were fed diets containing 0, 5 (reduced from 15 ppm at study week three), 60, or 240 ppm of methiocarb technical in the diet for two years. Effects which appeared to be treatment-related were sporadic incidences of hind limb weakness and tremor in the high dose group animals fed 240 ppm (6 mg/kg/day) of test material and plasma cholinesterase inhibition of 30% or greater, with respect to controls, at dose levels of 15 ppm (0.375

mg/kg/day) and above. The NOEL for systemic effects was determined to be 60 ppm (1.5 mg/kg/day) and the NOEL for plasma cholinesterase inhibition was determined to be 5 ppm (0.125 mg/kg/day). RBC and brain cholinesterase were not affected (MRIDs 00128939 and 00149362).

d. Carcinogenicity

Methiocarb technical was not found to be carcinogenic in a two-year rat feeding/carcinogenicity study in which the highest dose tested was 600 ppm (30 mg/kg/day) (MRID 00115226 and 00128723).

The data presented in a two-year mouse carcinogenicity study were not sufficient to fully evaluate the carcinogenic potential of the test material in the mouse. An acceptable mouse carcinogenicity study is no longer required since the registrant dropped food-uses for the chemical (MRIDs 00128723, 00133477, and 00133480)

e. Developmental Toxicity

In a developmental toxicity study in rats, daily oral doses of vehicle, 1, 3, or 10 mg/kg/day of methiocarb technical, were administered to groups of 19 or 20 fertilized female FB-30 rats from the sixth to the fifteenth day of pregnancy inclusive. Although a decrease in weight gain was noted in the high dose group compared to controls, there was no evidence of developmental toxicity in the study. The LOEL and NOEL for maternal toxicity were 10 mg/kg/day and 3 mg/kg/day, respectively. The NOEL for developmental effects was greater than 10 mg/kg/day (MRID 00124617).

In an oral developmental toxicity study in rabbits, groups of 17 New Zealand White rabbits were dosed orally with vehicle, 1, 3 or 10 mg/kg/day of methiocarb technical from day 6 to 18 inclusive of gestation. The maternal toxicity NOEL was 3 mg/kg/day and the LOEL was 10 mg/kg/day based on cholinergic signs and body weight loss. There was no evidence of developmental toxicity in the study. The NOEL for developmental toxicity was greater than 10 mg/kg/day (MRID 00143213).

In a dermal developmental toxicity study in rabbits, methiocarb technical was administered by the dermal route to 16 Chinchilla rabbits (CHbb:CH, hybrids, SPF quality) per group during gestational days 6 through 18 at doses of 0 (1% Cremophor vehicle), 10, 50, or 250 mg/kg/day. The NOEL for developmental toxicity is 50 mg/kg/day.

The LEL for developmental toxicity is judged to be 250 mg/kg/day based on a statistically significant increase in embryonic resorptions as a percentage of implantation sites and incompletely ossified hind limb phalanx at multiple sites. The maternal NOEL/LEL was judged to be 50/250 mg/kg/day based on a slight body weight decrement in the main study, confirmed by a definitive body weight decrement in the range-finding study (MRIDs 42496401, 42931901).

f. Reproductive Toxicity

An acceptable reproduction study is not available. There is no requirement for a reproductive study since the registrant dropped food-uses for the chemical.

g. Mutagenicity

The 1987 Methiocarb Registration Standard listed data gaps for three categories of mutagenicity studies based on the 1982 Pesticide Assessment Guidelines: I. Gene Mutation; II. Structural Chromosomal Aberration; and III. Other Genotoxic Effects. Three studies, the results of which are summarized below, were submitted by the registrant to fill the data gaps:

- Gene Mutation - Methiocarb was not mutagenic in the presence or absence of metabolic activation in the Salmonella typhimurium/mammalian microsome mutagenicity assay (MRID 40508101).

- Structural Chromosomal Aberration - In a sister chromatid exchange assay in Chinese hamster ovary (CHO) cells, methiocarb was not genotoxic. The guidance given under the 1982 guidelines for mutagenicity was that a sister chromatid exchange assay could be used to satisfy the requirement for a study in either Mutagenicity Study Category II or III (MRID 40508102).

- Other Genotoxic Effects - In an in vitro unscheduled DNA synthesis assay in primary rat hepatocytes, methiocarb was not genotoxic up to and including cytotoxic concentrations (MRID 40700801).

The current mutagenicity guideline requirements (starting from 1991) for mutagenicity testing include an Ames assay, a mammalian cell gene mutation assay, and an in vivo cytogenetics assay. According

to this guidance, there would be two data gaps for methiocarb mutagenicity testing. However, since the submitted studies are acceptable and negative, and since food uses for methiocarb have been withdrawn, no additional mutagenicity testing will be required at this time.

h. Metabolism

A metabolism study was performed in rats. More than 80% of the ^{14}C-carbonyl label was eliminated in 48 hours. Radioactivity was distributed in expired CO_2, urine, feces, and body tissues. The study was considered to be inadequate due to a number of deficiencies (only one dose level was tested, an insufficient number of animals was used, and a number of metabolites was not clearly identified). There is no requirement for a metabolism study since the registrant dropped food-uses for the chemical.

i. Other Toxic Endpoints

Neurotoxicity Testing

Both an acute and a subchronic (90-day) neurotoxicity study in rodents must be performed with methiocarb technical. These studies are now required for all carbamate pesticides. They are not part of the target data set for this reregistration review, but are required for the continued registration of methiocarb.

Ocular Toxicity Testing

Ocular toxicity testing is not currently required for the carbamate class of pesticides.

Dermal Absorption

A dermal absorption study is not required at this time.

Domestic Animal Safety

A domestic animal safety study is not required at this time.

j. Other Toxicological Considerations

When food uses existed for methiocarb, an amendment to the 1987 Methiocarb Registration Standard Toxicology Chapter required

that a 30-day dog feeding study (including measurement of cholinesterase activities) be performed using methiocarb sulfoxide, a cholinesterase-inhibiting metabolite of methiocarb (Mesurol®). Methiocarb sulfoxide had been shown in some studies to be more acutely toxic than methiocarb and to comprise a much larger portion of certain post-application, non-removable residues than the parent compound. The 30-day dog study was no longer required when food uses were dropped for methiocarb.

k. Reference Dose

On February 25, 1993, the OPP RfD/Peer Review Committee recommended that the RfD for methiocarb (Mesurol®) be established at 0.005 mg/kg/day. This value was based on a NOEL of 1.5 mg/kg/day for tremors and muscle weakness observed at 6 mg/kg/day in a long-term feeding study in dogs using an uncertainty factor (UF) of 100 to account for inter-species extrapolation and intra-species variability. Even though a reproduction study is not required, the RfD Committee recommended that an additional UF of 3 be added to compensate for the lack of adequate reproduction data. Since methiocarb was shown to be a developmental toxicant in rabbits, when administered by the dermal route, the Committee also expressed a concern for acute risk from exposure to methiocarb.

On November 18, 1993, the OPP RfD/Peer Review Committee reconsidered the NOEL/LOEL in light of the additional information submitted by the registrant on the dermal developmental toxicity study. The OPP RfD/Peer Review Committee reevaluated and changed the NOEL/LOEL from 10/50 mg/kg/day to 50/250 mg/kg/day for the dermal toxicity study with methiocarb.

2. Exposure Assessment

a. Dietary

No dietary exposure is expected from use of methiocarb since there are no remaining food uses. Ginseng is not considered a food use since current methiocarb end-use labels bear a 12 month-preharvest interval.

Since all food uses for methiocarb have been cancelled, there are no Residue Chemistry data requirements and no Codex harmonization issues to be resolved. The Agency accordingly intends to revoke <u>all</u> tolerances for methiocarb (40 CFR 180.320).

b. Occupational and Residential

Post-application/reentry data and mixer/loader/applicator data are required by the Agency when both toxicity and exposure criteria are met. Methiocarb is a N-methyl carbamate pesticide used to control snails, slugs and other pests on ornamental plants and turfgrass. Methiocarb was previously used on agricultural food crops, primarily as a bird repellent. The registrants however, are not supporting the food uses and these uses have been deleted from all labels.

Methiocarb end-use products are formulated as granulars/pellets (1 - 2% a.i.), wettable powder (75% a.i.), and pressurized liquids (1% a.i.). The granular/pelleted formulations are applied to residential and commercially grown turfgrass; to residential and commercially grown ornamentals; in commercial greenhouses; and around building foundations. A 75% wettable powder formulation is used as a foliar spray to nursery and greenhouse grown ornamentals. A pressurized liquid formulation is applied as a total release spray in commercial greenhouses.

In the Methiocarb Registration Standard, the Agency imposed an interim 24-hour, reentry interval. The reentry interval was imposed for labels containing directions for applications to the then registered agricultural food crops, commercially grown turfgrass, commercially grown ornamentals, and greenhouses. The reentry interval was required until postapplication/reentry data were submitted and reviewed by the Agency.

The Worker Protection Standard (WPS) for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- converted the 24-hour <u>reentry</u> interval (where reentry with protective clothing is allowed) to a 24-hour <u>restricted</u>-entry interval (where entry is prohibited except under the limited circumstances allowed under the Worker Protection Standards such as exception for activities with no contact, 40 CFR 170.112 [b], short term activities, 40 CFR 170.112[c], exceptions for agricultural emergencies, 40 CFR 170.112[d], and exceptions for requiring Agency approval, 40 CFR 170.112[e]).

Personal protective equipment (PPE) were required while applying end use products containing 20 to 75% methiocarb. These PPE consisted of a long sleeve shirt, long pants, shoes, socks, and chemical-resistant gloves. There are no current PPE requirements or reentry intervals for the homeowner products. However, there are certain labels containing directions for applications to greenhouses as

well as residential turfgrass and building foundations that display the reentry and PPE statements regardless of percent methiocarb.

On March 2, 1993, the OPP's Toxicology Branch determined that methiocarb is a developmental toxicant based on a dermal toxicity study using rabbits. The data, which were submitted to the Agency under 6(a)(2), indicate a no observed effect level (NOEL) of 50 mg/kg/day. Because methiocarb is a developmental toxicant, it meets the Agency's toxicity criteria for requiring postapplication/reentry and mixer/loader/applicator exposure data. In addition, methiocarb, a cholinesterase inhibitor (reversible), is in Toxicity Category I for acute oral toxicity (MRID 42496401).

Mixer/Loader/Applicator Exposure (Handlers)

There is a potential for exposure to methiocarb sprays and dusts via the dermal and inhalation route, particularly during foliar applications using low pressure, hand sprayers. Applicator exposure regarding the total release aerosol applications, and self-contained granular shakers is expected to be lower.

There are no chemical-specific mixer/loader/applicator exposure data available for methiocarb. In the absence of these data, the Agency has reviewed the Pesticide Handlers Exposure Database (PHED) for application scenarios similar to those used to apply methiocarb. The one identified by PHED with the greatest potential for exposure is the application of wettable powder formulations using a low pressure hand sprayer.

Based on the available data in PHED, the exposure estimate for an individual mixing/loading and applying methiocarb (while wearing the currently labeled PPE) is as follows:

> A mixer/loader/applicator applying a wettable powder (open bag) with a low pressure hand wand, is exposed to 8.6 mg/lb ai (dermal). Inhalation exposure is estimated to be 1 mg/lb ai per acre. The Agency assumes a mixer/loader/applicator treating 6 acres per day (based on previous backpack sprayer assessment for maleic hydrazide).
>
> 6 acres x 0.75 lb ai/acre x 8.6 mg/lb. ai handled (dermal)
>
> 6 acres x 0.75 lb ai/acre x 1 mg/lb. ai handled (inhalation)

Thus, the respective dermal and inhalation exposure estimates are 38.7 mg/day and 4.5 mg/day for the wettable powder formulation.

The mixer/loader/applicator exposure assessment was estimated using surrogate data and conservative exposure assumptions. The Agency is requiring mixer/loader/applicator exposure data to support reregistration of methiocarb for the following commercial uses:

233 and 234 - For commercial application of wettable powder formulations to greenhouse/nursery grown ornamentals.

These data will be considered confirmatory for scenarios where margins of exposure (MOE) are estimated to be greater than 100 with appropriate personal protective equipment (PPE) (coveralls) and appropriate restricted entry intervals.

Postapplication/Reentry Exposure (Worker and Residential)

There is a potential for postapplication exposure following most of the methiocarb applications. These include dermal exposure to residues on treated lawns and turf, thatch and soil following the granular applications; and to the foliage of commercially grown ornamentals treated with the wettable powder and pressurized liquid formulations. There is also a potential for inhalation exposure following the application of the total release aerosols.

Postapplication exposure is expected to be low following the application of granular formulations beneath greenhouse benches, around building foundations, and in residential ornamental plantings other than lawns and turf.

Postapplication inhalation monitoring data are required to support the reregistration of the pressurized liquid formulation. These data are considered confirmatory:

- Inhalation passive dosimetry for entry into greenhouses following an application using the pressurized liquid formulation (133-4).

Postapplication/reentry data are required to support the reregistration of the granular formulations used on ornamentals. These data are considered confirmatory:

- Soil residue dissipation (132-1b)
- Dermal passive dosimetry exposure (133-3)

The following postapplication/reentry data are required to support homeowner lawn use:

- Foliar dislodgeable dissipation, lawns and turf (132-1a), and
- Dermal passive dosimetry, lawns and turf (133-3)

These studies must be conducted concurrently.

3. Risk Assessment

The data available on the toxicological effects of methiocarb are sufficient for assessing human risks.

In acute toxicity studies in laboratory animals, methiocarb is highly toxic by the oral route (Toxicity Category I), moderately toxic by the inhalation route (Toxicity Category II), slightly toxic by the dermal route (Toxicity Category III), but is not a dermal or eye irritant. In long-term studies, administration of methiocarb have been observed to inhibit RBC and/or plasma cholinesterase but not brain cholinesterase in both the rat and dog. In the latter species the enzyme inhibition was associated with signs of muscular weakness and/or tremors at the high dose. Methiocarb is not carcinogenic in rats and does not appear to have any mutagenicity potential. Methiocarb administered by the dermal route is associated with developmental toxicity in rabbits. Administered by the oral route, it is associated only with maternal toxicity in both rats and rabbits.

The OPP RfD/Peer Review Committee considered the carcinogenicity study in rats to be acceptable and the doses used to be adequate for carcinogenicity testing. There was no other carcinogenicity study available on methiocarb. On this basis the OPP RfD/Peer Review Committee classified methiocarb as a Group D carcinogen (insufficient information to evaluate chemical).

The toxicology endpoint of concern is developmental toxicity. Based on the developmental study with the most sensitive species (rabbits) and the appropriate developmental NOEL (NOEL = 50 mg/kg/day), there may be a potential for adverse developmental effects in exposed humans.

a. Dietary

Dietary risk from exposure is not expected since there are no remaining food uses for methiocarb.

b. Occupational and Residential

Workers and homeowners may be at risk for developmental effects from exposure to methiocarb. The Agency has no chemical-specific data for assessing potential exposure from the use of methiocarb. The margin of exposure (MOE) may be estimated by the following equation:

$$MOE = \frac{NOEL\ (mg/kg/day)}{Exposure\ (mg/kg/day)}$$

where the NOEL = 50 mg/kg/day based on the dermal developmental study in rabbits. The MOE from use of the granular formulations cannot be estimated at this time because we do not have actual or surrogate exposure data. The MOEs from the use of the wettable powder formulations are presented in the table below.

Margin of Exposure

Wettable Powder Formulation	Exposure Rate (mg/day)		Exposure Rate (mg/kg/day)		MOE* Dermal + Inhalation
	Dermal	Inhalation	Dermal	Inhalation	
With current PPE	38.70	4.50	0.645	0.072	70
With coveralls	7.74	2.25	0.129	0.072	250

*Assumptions:
(1) A handler weighs 60 kg,
(2) Currently labeled-PPE are used, and
(3) maximum efficiencies achieved for coverall (80%).

The MOE is less than 100 for handlers (with PPE) of wettable powder formulations. With risk mitigation steps such as coveralls, the margins of exposure are expected to be greater than 100 with a maximum efficiency of 80% for coveralls.

Restricted Entry Intervals (REIs)

The registrant submitted a foliar dissipation study measuring dislodgeable residues after a wettable powder formulation of methiocarb had been foliarly applied to grapes. The dislodgeable residues declined in a linear fashion with residue decay equation having an intercept of 2.95 and a slope of -0.064. These data are considered supplementary and have been used to calculate a reentry interval for ornamental crops foliarly treated with methiocarb. These data are not appropriate to calculate a reentry interval following the application of granular formulations to turfgrass due to the differences in formulation type and method of application (MRID 40465901).

Based on the data from MRID 40465901, an REI of 25 days is imposed following foliar applications of the wettable powder and the pressurized liquid (total release aerosol) formulations to ornamental plants. After 10 days workers may enter treated areas to perform tasks, including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than 3 hours in each 24-hour period performing such tasks. PPE is not required during the 3 hour work period.

Personal Protective Equipment (PPE)

Occupational Uses: Although methiocarb has been classified as a Toxicity Category III chemical for acute dermal toxicity and skin irritation potential, the Agency is requiring personal protective equipment (PPE) for applicators and other handlers as well as early entry workers consistent with the PPE level (as established by 40 CFR Part 156, the Worker Protection Standard) required for pesticides classified as Toxicity Category II for acute dermal toxicity. In addition, the Agency is requiring that a respirator be worn by handlers during ventilation activities. The Agency is also requiring that a dust mask be worn while mixing/loading the wettable powder formulation because this is a potentially high exposure route with respect to inhalation. These PPE requirements are due to the known toxicological concerns for methiocarb, including its identification as a developmental toxicant.

Homeowner Uses: The Agency has determined that, at this time, the personal protective equipment discussed in this section need not apply to homeowner users of methiocarb. The predicted frequency, duration, and degree of exposure by homeowners should not warrant the risk mitigation measures being required for occupationally exposed users. No data are available to support homeowner use by broadcast method.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

Based on incomplete, supplemental and acceptable environmental fate data, methiocarb appears to be moderately persistent and relatively immobile in soil. Methiocarb degradation appears to be dependent on microbial-mediated (aerobic soil metabolism - half-life = 17 to 111 days); anaerobic soil metabolism (half-life = 64 days); and abiotic processes (photodegradation metabolism in water and on soil (half-life = 88 days). These data indicate that methiocarb degrades in mineral soils and anaerobic soil environments, and should photodegrade

slowly in soil and slightly acidic aqueous environments. The major degradates are methiocarb sulfoxide, methiocarb sulfoxide phenol, methiocarb phenol, and methiocarb sulfone. Supplemental field dissipation studies suggest methiocarb residues (e.g., methiocarb, methiocarb sulfone, and methiocarb sulfoxide) are moderately persistent (half-life < 92 days) in surface soil (30 cm). Methiocarb was also detected in a single well in a New York well survey of 21,000 wells.

b. Environmental Fate Assessment

Methiocarb appears to be relatively immobile (K_d = 12.5) in loam textured soil, but methiocarb degradates as well as parent methiocarb were found to be mobile in "aged" soil column leaching studies. The mobility of methiocarb and its degradates could not be confirmed in field dissipation studies because of inadequate soil sampling and/or nonspecific analytical methodologies. Although compounds similar to methiocarb (e.g., aldicarb) are mobile in soil and have been found in groundwater, the weight of evidence from supplemental field dissipation data suggest that methiocarb, methiocarb sulfoxide, and methiocarb sulfone are retained in the surface soil(0-30 cm). The results of the screening model PATRIOT (Pesticides Assessment Tool for Rating Investigations of Transport), performed over a range of soil textures for methiocarb reinforced the conclusion that methiocarb per se is not likely to contaminate groundwater. However, a full assessment will only be possible when the following confirmatory data are provided.

These studies are required for all outdoor uses:

161-1 Hydrolysis
163-1 Adsorption-Desorption/Leaching

This study is required to support the lawns and turf uses of methiocarb:

164-1 Terrestrial Field Dissipation

The additional confirmatory data will help to define the rates and routes of methiocarb dissipation under typical use conditions. The additional hydrolysis data would provide information on abiotic degradation of methiocarb in soil and aquatic environments. Although the unaged portion of the adsorption-desorption/leaching (GL 163-1) study was previously fulfilled using a single soil type, additional batch equilibrium data on parent methiocarb would provide a more reliable

mobility classification in coarse textured soils (e.g., sand and loamy sands) with low organic matter. Fine textured soil, which was used in the study, tends to decrease estimates of mobility. In addition, parent methiocarb was detected in the leachate of aged-residue soil column studies and hence may be mobile in coarse textured soils. The additional terrestrial field dissipation data are necessary with greater sampling depths and appropriate soil sampling increments to assess leaching of methiocarb below 30 cm.

The Fish Accumulation (165-4) study is waived because methiocarb and its degradates in aquatic systems are likely to kill fish before the residues could accumulate to levels of concern in fish tissues.

2. Ecological Effects

a. Ecological Effects Data

There are enough ecotoxicological data submitted to characterize the toxicity of methiocarb to nontarget terrestrial and aquatic organisms when used primarily on ornamentals and in greenhouses. The toxicity evaluation of methiocarb for lawns and turf use is based on limited available data.

(1) Terrestrial Data

Available data indicate that methiocarb is toxic to terrestrial mammals (acute oral LD_{50} range from 14 to 30 mg/kg) for males and females rats, respectively.

The avian toxicity of methiocarb was evaluated from thirty-four studies. The data indicate that the technical grade (TGAI) of methiocarb is very highly toxic to birds on an acute oral basis. The LD_{50}s to passerine species tested ranged as low as 2.47 mg/kg, and the LD_{50} values to mallards (waterfowl) were determined to be 12.8 mg/kg. The subacute dietary data using the TGAI indicate that methiocarb is practically non-toxic to upland game birds, LC_{50} of > 5000 ppm for ring-necked pheasants and slightly toxic to waterfowl with an LC_{50} of 1071 ppm for mallard ducks. Because no feed consumption data were provided, it can not be determined if the low dietary toxicity is attributable to reduced feed consumption. Also, pen studies with 2% bait and 4% bait suggest that these formulations may produce a repellent effect in bobwhite quail and pheasants,

respectively. Avian reproduction studies indicate that no reproductive impairment is caused in the mallard duck at a dietary dose level of 100 ppm TGAI methiocarb or in bobwhite quail at a dietary dose level of 50 ppm. Pen studies with 2% bait suggest that this formulation may produce a repellency effect in the bobwhite quail (MRIDs 00036482, 00036491, 00128119, and GS0577006).

(2) Aquatic Data

The available data indicate that the TGAI of methiocarb is highly toxic to coldwater (rainbow trout LC_{50} =0.436 ppm) and warmwater (bluegill LC_{50} = 0.734 ppm) fish. The freshwater fish acute toxicity data on formulated products indicate that the 75% wettable powder formulation of methiocarb is moderately toxic to coldwater (rainbow trout LC_{50} =1.4 ppm) and warmwater (bluegill LC_{50} = 1.9 ppm) fish. Data from a fish early life stage study using rainbow trout suggest that methiocarb is highly toxic (the MATC of technical methiocarb to this species is 50 to 100 ppb). The data indicate that methiocarb is very highly toxic to freshwater aquatic invertebrates (48-hour EC_{50} for Daphnia magna was 0.019 ppm); (48-hour EC_{50} for mayflies was 0.007 ppm). Data from an aquatic invertebrate life cycle test further support the very high toxicity of methiocarb to aquatic invertebrates (test using Daphnia magna suggest that the MATC of technical methiocarb to this species is 0.10-0.17 ppb). There are no estuarine data available on methiocarb. (MRIDs 0036484, 00127638, 00150383, 00150628, 155967).

(3) Non-Target Insects Data

There are sufficient data to characterize technical methiocarb as very highly toxic to honey bees (LD_{50} for honey bees is 0.375 ug/bee) (MRIDs 00001999, 00036935).

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Organisms

Granular

The level of concern to mammalian and avian species, 1/2 the LC_{50}, is exceeded for all formulations of methiocarb for

all outdoor uses of methiocarb. The acute toxicity data of methiocarb to rats indicate that a rat weighing 0.4 kg could obtain an LD_{50} (14 to 30 mg/kg for male and females rats, respectively) eating less than 10 of the 1% (0.6mg a.i./granule) bait formulation granules. Less than one granule of the 2% (1-2 mg per granule) bait formulation or 1% bait formulation could contain the LD_{50} for blackbirds (3.2 mg/kg). Therefore, all of the granular uses represent a hazard to blackbirds or other birds of similar size and sensitivity to the toxicant. After ingesting 10 to 20 granules of the 2% and 1% granular formulations, respectively, the mallard duck would reach the LD_{50} (12.8 mg/kg). Repellency data demonstrated that it is not clear that medium to large sized birds may be repelled from treated granules; therefore, granular formulations could present a hazard to medium and larger birds.

Wettable Powder

Methiocarb 75% wettable powder is applied indirectly to avian food items as an insecticide. The chemical is applied as a spray. Therefore, residues are expected to be available to birds on a variety of food and forage items. A model, explained in the following paragraph, was used to estimate the maximum residues expected after application on several different exposed substrates, for example, leaves, long grass, short grass, and soil. For all application rates, except the lowest, residues on short grass exceeded endangered species concern levels (1/10 LC_{50} for mallard duck, 107 ppm) from 1 to 3.5 times and exceed the restricted use criteria (1/5 LC_{50} for mallard duck 214 ppm) by 1.5 times on short grass at the highest application rate.

Calculation of Exposure Levels

The majority of the labels for methiocarb do not indicate a maximum amount of active ingredient to be applied per season nor time intervals between applications. Therefore, the Agency Fate Model for Accumulated Pesticide Residues for Multiple Applications was run for a number of different scenarios. The model looked at various application intervals (7, 20, 30 days) and initial concentrations based on vegetative residue data determined from a nomograph developed by Hoerger and Kenega.

The results indicate that the lowest level of active ingredient applied per application to short grass would trigger the endangered species concern (1/10 LC_{50} for mallard duck, 107 ppm) by 1.5 times by the second application no matter if the interval was 7, 20, or 30 days. In addition, by the third application on short grass at either 7, 20, or 30 days the trigger for restricted use concern would be exceeded (1/5 LC_{50} for mallard duck 214 ppm) by < 1.5 times.

Models for long grass residue indicate that at the 0.5 lbs a.i./A application rate triggers for both endangered species and restricted use would be exceeded by the 2nd and 3rd applications, respectively, at all interval times (7, 20, and 30 days).

The last set of models looked at the residue on leaves and leafy plants with the lowest amount of active ingredient per application. These results indicate that both endangered species and restricted use triggers would be exceeded by the 3rd and 5th application, respectively, at 7 and 20 day intervals. At the 30 day interval endangered species and restricted use triggers were exceeded at the 3rd and 8th application, respectively. Special Review trigger levels were exceeded for small mammals (1 to 3 times the LD_{50}) at the two highest application rates for short grass. These models were run on the lowest amount of active ingredient per application; therefore, it is likely that the level of concern would be exceeded for endangered species and nontarget terrestrial organisms earlier for all other active ingredient application levels. In addition, the predicted EEC values exceed the NOEC levels for avian species with respect to chronic effects for short grass. Therefore, the use of methiocarb 75% wettable powder may be expected to result in hazard to exposed avian species both acutely and chronically.

(2) Risk to Aquatic Organisms

The level of concern for chronic fish and acute and chronic aquatic invertebrate exposures is exceeded for all formulations of methiocarb. Refined EEC's were modeled for two methiocarb formulations, Mesurol® 2% Bait and Mesurol® 75% Wettable Powder for 1, 2, and 4 applications per year. One application per year with an occasional second application is the typical use pattern for methiocarb. The 75% Wettable Powder may be applied up to four times a year. There are no

restrictions on the number of applications of the 2% bait, but 4 applications were modeled as the maximum number of uses for this formulation also. A New York turf farm was used for both formulations, as it is a reasonable surrogate for scenarios with significant turf coverage such as ornamentals and shade trees. (Spagnoli, 1993).

Results from the refined model on methiocarb in Mesurol® Bait 2% indicated that fish endangered species concern levels, 1/20 LC_{50}, were exceeded by 2 to 7 times and after 90 days the value was exceeded by 1 time, and restricted use levels, 1/10 LC_{50}, were exceeded by 1 to 4 times but after 90 days was not exceeded. Aquatic invertebrate endangered species concern levels, 1/20 LC_{50}, were exceeded by 50 to 168 times from the first to the fourth application and after 90 days with just one application the 1/20 LC_{50} value was still exceeded by 27 times. In addition, restricted use concerns were exceeded by 26 to 84 times and after 90 days the value was exceeded by 13 times, and special review concerns, 1/5 LC_{50}, were exceeded by 5 to 17 times and after 90 days the value was exceeded by 3 times.

Results from the refined model on methiocarb in Mesurol® 75% Wettable Powder, indicated that fish endangered species concern levels were exceeded by 3 to 8 times and after 90 days by 2 times, and restricted use levels were exceeded 1 to 4 times but not exceeded after 90 days. Aquatic invertebrate endangered species concern level were exceeded by 57 to 185 times from the first to the fourth application and after 90 days with just one application the endangered species concern level was still exceeded by 29 times. In addition, restricted use concerns were exceeded by 29 to 93 times and after 90 days 1/10 LC_{50} value exceeded by 15 times.

Conclusions

The ecological effects risk assessment for methiocarb indicates that for all the formulations used on all outdoor sites, the acute and chronic levels of concern are exceeded for avian species, and the acute level of concern is exceeded for mammalian species and aquatic invertebrates. The toxicity data used in the risk assessment suggest that the chronic level of concern also is exceeded for aquatic organisms.

Some of the factors considered in further evaluation of the risk of methiocarb to nontarget organisms include: 1) refined aquatic EEC's using typical number of applications, 2) methiocarb production volume, and 3) the estimate of the amount of methiocarb used for the use sites.

When the aquatic EEC's were refined using maximum as well as typical number of applications the level of concern was still exceeded (ex. the level of concern for aquatic invertebrates is exceeded by about nine times the typical number of applications). However, the typical number of applications decreased the risk by about a factor of two. The labels for methiocarb should reflect the typical number of applications as the maximum application rate. (2 lbs 75% a.i. wettable powder per 50 gallons of water applied up to 2, not 4, times a year, bait formulations should not be applied more than twice a year).

The environmental fate and ecological risk assessments are based on the estimate that 90% of methiocarb is used in nursery and greenhouses and the other 10% of methiocarb use includes homeowner ornamentals, as well as turf and lawn uses.

Methiocarb outdoor use is likely to have adverse effects on aquatic and terrestrial species. Although the total volume of methiocarb used is low relative to other pesticides, it still could have major impacts in localized areas if there is concentrated outdoor use. At present the Agency is unable to estimate how much of the use is outdoors.

If the lawn and turf use of methiocarb continues to be supported, the following studies are required on a confirmatory basis:

72-3 (a) Acute LC_{50} Estuarine/Marine Tox Fish

72-3 (b) Acute LC_{50} Estuarine/Marine Tox Mollusk

72-3 (c) Acute LC_{50} Estuarine/Marine Tox Shrimp

72-4 (a) Fish Early Life Stage
(Data describing water temperatures in each test tank are required to ensure that no significant variance of temperature occurred in any of these

tanks. If this data is submitted the currently available study may be upgradable.)

72-4 (b) Aquatic Invertebrate Life-Cycle. (Study was submitted, however it was deemed supplemental because raw data were not available.)

72-5 Fish Life-Cycle

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing methiocarb active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing methiocarb except for those products which are used on residential lawns and turf. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of methiocarb, 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 methiocarb and to determine that methiocarb can be used without resulting in unreasonable adverse effects to humans and the environment only for greenhouses, homeowner use around building foundations and ornamentals, commercially grown turfgrass, and ginseng uses. The Agency, therefore, finds that products containing methiocarb as the active ingredient used on ornamentals, greenhouses, homeowner use around building foundations, commercially grown turfgrass, and ginseng are eligible for reregistration. The reregistration of these particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that the greenhouse, homeowner use around building foundations and ornamentals, commercially grown turfgrass, and ginseng uses of methiocarb 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 methiocarb, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient methiocarb, the Agency has sufficient information on the health effects of methiocarb and on its potential for causing adverse effects in fish and wildlife and the environment to make a reregistration eligibility decision. The Agency has determined that granular and pelleted products containing methiocarb for use on ornamentals in greenhouses, homeowner use around building foundations and ornamentals, commercially grown turfgrass, ginseng, as well as the wettable powder and pressurized liquid products for use on ornamentals in greenhouses and nurseries are eligible for reregistration.

The Agency has determined that methiocarb granular, pelleted, wettable powder, and pressurized liquid products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks or adverse effects to humans or the environment.

There is insufficient exposure data for the use of methiocarb by broadcast application on residential lawn and turf and a reregistration eligibility decision for this use cannot be made until appropriate postapplication reentry exposure, ecological effects and environmental fate data are submitted and evaluated.

2. Eligible and Ineligible Uses

The Agency has determined that methiocarb use on ornamentals in greenhouses, homeowner use around building foundations, ornamentals, commercially grown turfgrass, and ginseng are eligible for reregistration.

The Agency has also determined that a reregistration eligibility decision for residential lawn and turf uses cannot be made at this time.

B. Regulatory Position

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

Since methiocarb is considered to be an important tool for control of slugs in nurseries and greenhouses and the total use volume is relatively low, the Agency is

declaring eligible for reregistration the nursery and greenhouse ornamental uses of granular/pellet and pressurized liquid formulations. However, in order to prevent the use volume and hence the risk of impact on aquatic and terrestrial species from increasing, the Agency is negotiating with the registrants to maintain a production cap.

1. Tolerance Reassessment

Since all food uses for methiocarb are cancelled, the Agency has determined that all existing tolerances for methiocarb will be revoked.

2. Restricted Use Classification

Based on the ecological effects risk assessment for methiocarb, a restricted use classification should be placed on all outdoor uses except homeowner uses.

3. Endangered Species Statement

Methiocarb (a molluscicide, insecticide and avian repellent) may pose a hazard to many listed birds, mammals, insects, and aquatic organisms. To date the Agency has one recorded incident, a wild bird kill, from the use of methiocarb. (Dec. 1983, Lima, Ohio -- waterfowl (NWHR 1980- 1990). The Agency requested consultation with the U.S. Fish and Wildlife Service (USFWS) in 1986 on, 1) blueberries and cherries, and 2) golf courses, cemeteries, parkways, roadways, and industrial sites for certain birds, reptiles, fish, mussels, and insects. The consultation was rejected because of lack of information.

The use of methiocarb exceeds triggers for endangered species for selected avian species, mammals, non-target insects, and freshwater organisms. These proposed outdoor uses cover the whole United States and are not restricted by boundaries. Therefore to properly identify endangered species which may utilize these areas, the U.S. Fish and Wildlife Service (USFWS) will be consulted. After identifying the endangered species inhabiting these areas a formal Section 7 consultation with the USFWS may be requested. Based on current information, a generic label statement may be required when the Agency's Endangered Species Protection program is implemented.

4. Labeling Rationale

a. Postapplication/Reentry Requirements

The Worker Protection Standard (WPS) for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- converted the 24-hour reentry interval (where reentry with protective clothing is allowed) to a 24-hour restricted-entry interval (where entry is prohibited except under the limited circumstances allowed under the Worker Protection Standards such as exception for activities with no contact, 40 CFR 170.112 [b], short term activities, 40 CFR 170.112[c], exceptions for agricultural emergencies, 40 CFR 170.112[d], and exceptions for requiring Agency approval, 40 CFR 170.112[e]).

All methiocarb end-use products within the scope of the Worker Protection Standard for Agricultural Pesticides (see PR Notice 93-7) -- must, within the timeframes listed in PR Notice 93-7 and 93-11, revise their labeling to be consistent with the WPS, as directed in those notices and the requirements of this RED. The restricted-entry interval for methiocarb end-use products are discussed below.

(1) For Wettable Powder:

For ornamental crops (nurseries and greenhouses) following foliar application, the Agency is requiring a 25-day restricted-entry interval (REI). After 10 days workers may enter treated areas to perform tasks, including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than three hours in each 24-hour period performing such tasks. **PPE is not required during the 3 hour work period.** This REI is supported by the foliar residue dissipation data presented in MRID 40465901. These restricted entry intervals provide margins of exposure of approximately 100. The Agency generally considers 100 an acceptable margin of exposure. Mixer/loader/applicator exposure data (studies on estimation of dermal exposure at indoor sites and estimation of inhalation exposure at indoor sites) are required to support reregistration of the wettable powder formulation (these data are considered confirmatory).

(2) For Granular Formulations:

The Agency has determined that the use of methiocarb on non-residential turfgrass (including turf grown for sod, turf grown to produce seed, or turf grown for research purposes) is eligible for reregistration. The Agency is retaining the 24-hour restricted entry interval for postapplication activities because of the known toxicological concerns for methiocarb.

For turfgrass in residential situations, including application by commercial applicators, the Agency determined that a reregistration eligibility decision cannot be made until postapplication exposure data (foliar dislodgeable dissipation and dermal passive dosimetry data) are submitted and reviewed.

Applications to ornamentals in residential situations, including application by commercial applicators, is eligible for reregistration except for products marketed in packages larger than the 2 lb. shaker cans (e.g. 20 - 25 lb. bags) for use by homeowners. The Agency is requiring data (soil dissipation and dermal exposure) to assess the exposure to persons entering treated ornamental planting areas. These data are considered confirmatory. After the Agency reviews exposure data on ornamentals and residential lawns, the Agency will determine if further marketing in packages other than 2 lb. shaker containers for use by homeowners is appropriate.

The Agency has determined that, at this time, the entry restrictions discussed in this section do **NOT** apply to homeowner uses.

(3) For the Pressurized Liquid Formulation:

For ornamental crops in greenhouses, the Agency is requiring a 25-day restricted-entry interval (REI). After 10 days workers may enter treated areas to perform tasks, including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than three hours in each 24-hour period performing such tasks. PPE is not required during the 3 hour work period. This REI is supported by the foliar residue dissipation data presented in MRID 40465901. These restricted entry intervals provide margins of exposure of approximately 100. The Agency generally considers 100 an acceptable margin of exposure.

Postapplication inhalation monitoring data are required to assess inhalation exposure to workers following the use of the pressurized formulation (these data are considered confirmatory).

b. Personal Protective Equipment (PPE) Requirements

Occupational Uses: Although methiocarb has been classified as a Toxicity Category III chemical for acute dermal toxicity and skin irritation potential, the Agency is requiring personal protective equipment (PPE) for applicators and other handlers as well as early entry workers consistent with the PPE level (as established by 40 CFR Part 156, the Worker Protection Standard) required for pesticides classified as Toxicity Category II for acute dermal toxicity. In addition, the Agency is requiring that a respirator be worn

by handlers during ventilation activities. The Agency is also requiring that a dust mask be worn while mixing/loading the wettable powder formulation because this is a potentially high exposure route with respect to inhalation. These PPE requirements are being imposed due to the known toxicological concerns for methiocarb, including its identification as a developmental toxicant.

Homeowner Uses: The Agency has determined that, at this time, the personal protective equipment discussed in this section need not apply to homeowner users of methiocarb.

c. Ecological Effects

The acute and chronic levels of concern are exceeded for avian species, the acute level of concern is exceeded for mammalian species and aquatic invertebrates, and the chronic level of concern is exceeded for aquatic organisms for all formulations of methiocarb. One means to further decrease the potential risk to the environment from the use of this toxic chemical would be to remove the turf and lawn site uses. The Agency is requiring label amendments and confirmatory data, as well as negotiating with registrants to maintain a production cap in an effort to decrease the environmental risk.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

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

Estimation of dermal exposure - for wettable powder formulation use in greenhouses and nurseries
Estimation of inhalation exposure - for wettable powder formulation use in greenhouses and nurseries
Inhalation passive dosimetry - for pressurized liquid formulation use in greenhouses
Estimation of dermal exposure and soil dissipation - for granular formulations used on ornamentals

Aquatic and estuarine organisms - fish/mollusk/shrimp - required for all lawn and turf uses
Aquatic invertebrate life cycle - required for all lawn and turf uses
Fish early life stage - required for all lawn and turf uses
Fish life cycle - required for all lawn and turf uses
Hydrolysis - required for all outdoor uses
Adsorption/desorption/leaching - required for all outdoor uses
Terrestrial field dissipation - required for all lawn and turf uses
Outdoor usage data - specify pounds used per year by site

The following data are required to support the use of granular formulations of methiocarb on residential lawns and turf:

Foliar dislodgeable dissipation
Dermal passive dosimetry

Also, data on acute and subchronic neurotoxicity, which are not part of the reregistration target data base for methiocarb, are required.

2. Labeling Requirements for Manufacturing-Use Products

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Compliance with the Worker Protection Standard

In order to remain in compliance with FIFRA, it is the Agency's position that any product whose labeling reasonably permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery, or greenhouse) must comply with the labeling requirements of 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 the deadlines specified in the WPS, unless official EPA guidance specifies otherwise. EPA has issued 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 contain specific instructions to registrants about how to complete the required WPS labeling changes and offer guidance and deadline-options for making those changes. Unless otherwise specifically directed in this RED, all statements required by the WPS (and reflected in PR Notices 93-7 and 93-11) are to be on the product labeling.

--In order to remain in compliance with FIFRA, after April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, or other EPA guidance, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by the registrant or any supplementally registered distributor, or any repackager under the Agency's Bulk Repackaging Policy.

--In order to remain in compliance with FIFRA, after October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11 or other EPA guidance, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by any person.

b. Entry Restrictions; Labeling

- **Products NOT Primarily Intended for Home Use**

--Uses Within the Scope of the WPS:

(1) **Wettable Powder Formulations:** In order to remain in compliance with FIFRA, a 25-day restricted entry interval (REI) as

follows is required on all methiocarb end-use products formulated as a wettable powder.

> Do not enter or allow worker entry in treated areas during the restricted entry interval (REI) of 25 days, except, after 10 days, workers may enter treated areas to perform tasks including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than 3 hours in each 24 hour period performing such tasks.

This REI should be inserted into the standardized REI statement required by PR Notice 93-7.

In order to remain in compliance with FIFRA, labels of sole-active-ingredient end-use products that contain methiocarb must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed.

(2) **Granular Formulations:** In order to remain in compliance with FIFRA, a 24-hour restricted entry interval (REI) is required for all uses within the scope of the WPS (see PR Notice 93-7) on all methiocarb end-use products formulated as a granular, except those products intended primarily for home use (see tests in PR Notice 93-7 and 93-11). This REI should be inserted into the standardized REI statement required by PR Notice 93-7.

In order to remain in compliance with FIFRA, labels of sole-active-ingredient end-use products that contain methiocarb must be revised to adopt the entry restrictions set forth in this section. Any granular homewoner product that currently has a 24 hour REI must retain that REI as specified on current labeling. Any conflicting entry restrictions on current labeling must be removed.

In order to remain in compliance with FIFRA, labels of multiple-active-ingredient end-use products that contain methiocarb must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

(3) **Pressurized Liquid Formulations:** In order to remain in compliance with FIFRA, a 25-day restricted entry interval (REI) as

follows is required on all methiocarb end-use products formulated as a pressurized liquid.

> Do not enter or allow worker entry in treated areas during the restricted entry interval (REI) of 25 days, except, after 10 days, workers may enter treated areas to perform tasks including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than 3 hours in each 24 hour period performing such tasks.

These restrictions should be inserted into the labeling section pertaining to REI's as required by PR Notice 93-7. Early entry by handlers and ventilation procedures must be in accordance with the WPS for greenhouse workers, 40 CFR 170.110(c) and this RED.

c. Personal Protective Equipment Requirements; Labeling

(1) Handlers:

■ **Products NOT Primarily Intended for Home Use:** The minimum personal protective equipment (PPE) requirement for pesticide handlers on all methiocarb end-use products, except products intended primarily for home use (see tests in PR Notices 93-7 and 93-11), is:

"Applicators and other handlers must wear:
--Coveralls over short-sleeved shirt and short pants
--Chemical-resistant or waterproof gloves (see * below)
--Chemical-resistant footwear plus socks
--Chemical-resistant headgear for overhead exposure
--Chemical-resistant apron when cleaning equipment, mixing, or loading (see ** below)

In addition to the above, handlers must wear a respirator with an organic vapor cartridge TC-23C during early entry to greenhouses following treatment with the pressurized liquid for those tasks associated with ventilating the greenhouse.

A dust mask must be worn while mixing/loading the wettable powder formulation.

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

** The words "mixing or loading" are not necessary for the granular and aerosol formulations.

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

■ **Products Primarily Intended for Home Use:** For products primarily intended for home use (see tests in PR Notice 93-7 and 93-11), do not add any additional personal protective equipment for such products, however, any personal protective equipment requirements on the current product labeling must be retained.

(2) PPE for Entry During the Restricted Period; Labeling

(i) Wettable Powder Formulations. The personal protective equipment for early entry is the PPE required for applicators of methiocarb, except the applicator requirement for an apron is waived. A dust mask must be worn while mixing/loading the wettable powder formulation. This PPE should be inserted into the standardized early entry PPE statement required by PR Notice 93-7.

(ii) Granulars Formulations. The personal protective equipment for early entry is the PPE required for applicators of methiocarb. This PPE should be inserted into the standardized early entry PPE statement required by PR Notice 93-7.

(iii) Pressurized Liquid Formulations. The personal protective equipment for early entry by workers is the PPE required for applicators of methiocarb. This PPE should be inserted into the standardized early entry PPE statement required by PR Notice 93-7.

The personal protective equipment for early entry by handlers should be the PPE required for applicators of methiocarb. Label language for reentry to perform ventilation tasks is as follows.

Handlers entering a treated greenhouse must wear a respirator with an organic vapor cartridge TC-23C during early entry to a greenhouse following treatment with the pressurized liquid for those tasks associated with ventilating the greenhouse.

This respirator requirement language must be included with the standardized early entry PPE statement required by PR Notice 93-7.

(iv) Uses Not Within the Scope of the WPS:

Do not add any additional entry restrictions for uses not within the scope of the WPS; however, any entry restrictions on the current product labeling for those uses must be retained.

- **Products Primarily Intended for Home Use:** For products primarily intended for home use (see tests in PR Notice 93-7 and 93-11), do not add any additional entry restrictions for such products; however, any entry restrictions on the current product labeling must be retained.

d. Other Labeling Requirements

(1) Labeling for Lawn and Turf Uses.

If a registrant chooses to support lawn and turf uses, he must submit the data required in this Reregistration Eligibility Decision document associated with the lawn and turf uses of methiocarb. If a registrant chooses to support the residential lawn uses only, he must add the following exclusionary statement to his labels in order to remove the use site from the scope of the WPS in accordance with PR Notice 93-11.

Exclusionary Statement: All granular end-use products that contain methiocarb must carry the following statement located (1) on the front panel of the label in association with the product name or (2) near the beginning of the Directions For Use section:

> "Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

If registrant does not support the residential lawn uses, the following statement must appear on his labels located (1) on the front panel of the label in association with the product name or (2) near the beginning of the Directions For Use section:

> "Do not use on turfgrass around residences or dwellings."

Also, if any lawn and turf uses are not being supported, the registrant must amend his labels by deleting the lawn and turf uses in accordance with the procedures in PR Notice 91-1.

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

(2) Restricted Use Labeling.

The following statement must appear on all end-use labels for all outdoor uses, except those products intended for homeowner uses. If your product is intended for use on sites that have been classified as restricted use as well as sites which have not been restricted as such, you must separate the restricted use from the other uses by splitting the one product label into two products and applying for a new registration number for one or the other product. Each of the labels must further clarify the intended site of use.

<u>Restricted Use Pesticide</u>

Due to Toxicity to Fish, Birds, and Aquatic Organisms

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

(3) Changes Relating to Label Rates and Number of Applications.

The following typical number of applications must appear as the maximum application rate on labels in the Directions for Use section for the specified uses of methiocarb in order to decrease the aquatic risks.

75% Wettable Powder

2 lbs 75% wettable powder per 50 gallons of water applied up to 2 times a year.

Granular or Pelletized Bait

Should not be applied more than twice a year.

(4) Labeling for Fish and Wildlife Hazard.

The following statements must appear on labeling for the following specified uses:

End Use -- Granular or Pelletized Bait for Molluscicide Use

This pesticide is toxic to fish and very highly toxic to birds and mammals. Do not apply directly to water, wetlands (swamps, bogs, marshes, and potholes). Runoff from treated area may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters and rinsates.

End Use -- 75% Wettable Powder

This pesticide is toxic to fish and very highly toxic to birds and mammals. Do not apply directly to water, or to areas below the mean high water mark. Runoff from treated area may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters and rinsates.

This product is very highly toxic to honey bees exposed to direct treatment or residues on blooming shrubs, flowers, weeds and trees. Do not apply this product or allow it to drift to blooming shrubs, flowers, weeds, or trees if bees are visiting the treatment area.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration

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

The Agency has determined that registrants may distribute and sell methiocarb products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

The following table includes uses eligible/ineligible for reregistration. It also includes changes (maximum number of applications and REIs) that result from the RED review.

APPENDIX A - Case 0577, [Methiocarb] Chemical 100501

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
Ornamental Herbaceous Plants Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Shaker Can	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Spreader	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24hr.			
Ornamental Herbaceous Plants Use Group: Terrestrial Non-Food Crop Only										
Bait Application, Nurserystock, Not on Label	B/S	na	.01 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Spray, Nurserystock, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Ornamental Herbaceous Plants Use Group: Greenhouse Non-Food Crop Only										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			* See Limitation at end
Bait Application, Foliar Stage, Not on Label	B/S or G	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Aerosol, fog, or fumigation Application, Foliar Stage, Aerosol generator	PRL	na	.0067 lb AI per 1,000 sq. ft.	not spec	not spec	not spec	** See REI at end			
Spray, Foliar Stage, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			

APPENDIX A - Case 0577, [Methiocarb] Chemical 100501

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
Ornamental Lawns and Turf Use Groups: Terrestrial Non-Food Crop										
Bait Application, Foliar Stage, Granule Applicator	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Shaker Can	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Spreader	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Ornamental and/or Shade Trees Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Shaker Can	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Ornamental and/or Shade Trees Use Group: Terrestrial Non-Food Crop Only										
Bait Application, Nurserystock, Not on Label	B/S	na	.01 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Spray, Nurserystock, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	**See REI at end			
Ornamental and/or Shade Trees Use Group: Greenhouse Non-Food Crop Only										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			* See Limitation at end
Bait Application, Foliar Stage, Not on Label	B/S or G	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Aerosol, fog, or fumigation Application, Foliar Stage, Aerosol generator	PRL	na	.0067 lb AI per 1,000 sq. ft.	not spec	not spec	not spec	** See REI at end			

APPENDIX A - Case 0577, [Methiocarb] Chemical 100501

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
Spray, Foliar Stage, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Ornamental Nonflowering Plants (inc. ferns) Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Shaker Can	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Ornamental Nonflowering Plants Use Group: Terrestrial Non-Food Crop Only										
Bait Application, Nurserystock, Not on Label	B/S	na	.01 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Spray, Nurserystock, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Ornamental Nonflowering Plants Use Group: Greenhouse Non-Food Crop Only										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			* See Limitation at end
Bait Application, Foliar Stage, Not on Label	B/S or G	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Aerosol, fog, or fumigation Application, Foliar Stage, Aerosol generator	PRL	na	.0067 lb AI per 1,000 sq. ft.	not spec	not spec	not spec	** See REI at end			
Spray, Foliar Stage, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Ornamental Woody Shrubs and Vines Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Bait Application, Foliar Stage, Shaker Can	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			

APPENDIX A - Case 0577, [Methiocarb] Chemical 100501

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations
Ornamental Woody Shrubs and Vines Use Group: Terrestrial Non-Food Crop Only										
Bait Application, Nurserystock, Not on Label	B/S	na	.01 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Spray, Nurserystock, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Ornamental Woody Shrubs and Vines Use Group: Greenhouse Non-Food Crop Only										
Bait Application, Foliar Stage, Not on Label	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			* See Limitation at end
Bait Application, Foliar Stage, Not on Label	B/S or G	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Aerosol, fog, or fumigation Application, Foliar Stage, Aerosol generator	PRL	na	.0067 lb AI per 1,000 sq. ft.	not spec	not spec	not spec	** See REI at end			
Spray, Foliar Stage, Ground	WP	na	1.5 lb AI per Acre	2 per yr.	2 per yr.	not spec	** See REI at end			
Household/Domestic Dwellings Outdoor Premises Use Group: Outdoor Residential Only										
Bait Application, When needed, Not on Label	B/S or G	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			
Ginseng (with 12 month Preharvest Interval) Use Group: Terrestrial Non-Food Crop										
Bait Application, Spring, Ground	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			12 month preharvest interval
Bait Application, Spring, Hand-Held	B/S	na	.02 lb AI per 1,000 sq. ft.	2 per yr.	2 per yr.	not spec	24 hr.			12 month preharvest interval

APPENDIX A - Case 0577, [Methiocarb] Chemical 100501

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
USES INELIGIBLE FOR REREGISTRATION: Includes Uses on Ornamental Lawns and Turf (Outdoor Residential Only) and all Food Crops including previously Registered Sites (Corn, Avocado, and Citrus Fruits).										

Abbreviations used

Header: max = maximum; min = minimum; apps = applications; not spec = not specified; na = not applicable

Form : G = Granular, B/S = Bait/Solid, WP = Wettable powder, PRL = Pressurized liquid

* Limitations for Greenhouse Use:

Do not enter treated areas without protective clothing until 24 hours after application.

** Restricted Entry Interval (REI):

REI for Wettable Powder and Pressurized Liquid formulations: Do not enter or allow worker entry in treated areas during the restricted entry interval (REI) of 25 days, except after 10 days, workers may enter treated areas to perform tasks including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than 3 hours in each 24 hour period performing such tasks.

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	CIK	40686901
61-2	Start. Mat. & Mnfg. Process	CIK	42389002
61-3	Formation of Impurities	CIK	42389002
62-1	Preliminary Analysis	CIK	40619301, 40619302
62-2	Certification of Limits	CIK	40619301
62-3	Analtyical Method	CIK	40619301
63-2	Color	CIK	40452101
63-3	Physical State	CIK	40452101
63-4	Odor	CIK	40452101
63-5	Melting Point	CIK	40452101
63-6	Boiling Point	CIK	N/A - TGAI is a solid at room temperature
63-7	Density	CIK	40452101, 42389001
63-8	Solubility	CIK	40452101
63-9	Vapor Pressure	CIK	40452101
63-10	Dissociation Constant	CIK	40452101
63-11	Octanol/Water Partition	CIK	40452101
63-12	pH	CIK	N/A - TGAI is not soluble enough in water
63-13	Stability	CIK	40452101, 42389001

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Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
64-1	Submittal of Samples	CIK	RESERVED - If samples are required, the Agency will request them
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	CIK	GS0577006, 00036482
71-2A	Avian Dietary (LC_{50}) - Quail	CIK	00022923
71-2B	Avian Dietary (LC_{50}) - Duck	CIK	00022923
71-3	Wild Mammal Toxicity	C	N/A
71-4A	Avian Reproduction - Quail	CK	00128119
71-4B	Avian Reproduction - Duck	CK	00128119
71-5A	Simulated Field Study	CK	40560001
71-5B	Actual Field Study	CK	40560001
72-1A	Fish Acute (LC_{50}) - Bluegill	CK	00150628
72-1B	Fish Acute (LC_{50}) - Bluegill (TEP)	CK	00036484
72-1C	Fish Acute (LC_{50}) - Rainbow Trout	CIK	00150628
72-1D	Fish Acute (LC_{50}) - Rainbow Trout (TEP)	CIK	00036484
72-2A	Aquatic Invertebrate (EC_{50})	CIK	00127638, 00150383
72-3A	Estuarine/Marine Toxicity - Fish	CK	DATA GAP
72-3B	Estuarine/Marine Toxicity - Mollusk	CK	DATA GAP

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
72-3C	Estuarine/Marine Toxicity - Shrimp	CK	DATA GAP
72-4A	Early Life Stage Fish	CK	00155967 - DATA GAP
72-4B	Life Cycle Invertebrate	CK	40628001 - DATA GAP
72-5	Life Cycle Fish	CK	DATA GAP
72-6	Aquatic Organism Accumulation		N/A
72-7A	Simulated Field - Aquatic Organisms	C	RESERVED
72-7B	Actual Field - Aquatic Organisms	C	RESERVED
70-A-SS	Special Test: Avian Repellency	CK	40560001
70-B-SS	Special Test: Aquatic Residue Monitoring	C	WAIVED
141-1	Honey Bee Acute Contact Toxicity	C	0001999, 00036935
141-2	Honey Bee Toxicity of Residues on Foliage	C	00060625
141-4	Honey Bee Subacute Feeding Study		RESERVED - pending development of test methodology.
141-5	Field Testing for Pollinators		N/A - data reviewed under RS does not indicate need for this study.
142-1	Acute Toxicity to Aquatic Insects		RESERVED - pending Agency decision as to whether data requirement should be established.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
142-2	Aquatic Insect Life Cycle Study		RESERVED - pending Agency decision as to whether data requirement should be established.
142-3	Simulated or Actual Field Testing for Aquatic Insects		RESERVED - pending Agency decision as to whether data requirement should be established.
143-1 thru 143-3	NonTarget Insect Testing - Predators and Parasites		RESERVED - pending Agency decision as to whether data requirement should be established.
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	CIK	00036477, 00083437
81-2	Acute Dermal Toxicity - Rabbit/Rat	CIK	00036478
81-3	Acute Inhalation Toxicity - Rat	CIK	40404201
81-4	Eye Irritation	CIK	0055163
81-5	Dermal Irritation	CIK	0055163
81-6	Dermal Sensitization	CIK	N/A - Not required for technical methiocarb.
81-7	Acute Delayed Neurotoxicity - Hen	CIK	N/A - Methiocarb is not an organophosphate.
82-1A	90-Day Feeding - Rodent		N/A - Adequate chronic studies are available.
82-1B	90-Day Feeding - Non-rodent		N/A - Adequate chronic studies are available.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	21-Day Dermal - Rabbit/Rat	CIK	41771701, 40922301 (Although these studies were classified as supplemental, acceptable chronic studies are available which satisfy this guideline requirement.)
82-3	90-Day Dermal - Rodent		N/A - because of existing use patterns do not result in repeated skin contact for an extended period of time.
82-4	90-Day Inhalation - Rat		N/A - not required for current use patterns.
82-5A	90-Day Neurotoxicity - Hen		N/A - not required for current use patterns.
82-5B	90-Day Neurotoxicity - Mammal		**DATA GAP**
82-A-SS	30-Day Feeding - Non - Rodent (Dog)	CIK	N/A - not required for current use patterns.
83-1A	Chronic Feeding Toxicity - Rodent	CIK	00115226
83-1B	Chronic Feeding Toxicity - Non-Rodent	CIK	00128939, 00149362
83-2A	Oncogenicity - Rat	CIK	00115226
83-2B	Oncogenicity - Mouse		N/A - Not required for current use patterns.
83-3A	Developmental Toxicity - Rat	CIK	00124617
83-3B	Developmental Toxicity - Rabbit	CIK	00143213, 42496401, 42931901
83-4	2-Generation Reproduction - Rat		N/A - Not required for current use patterns.
84-2A	Gene Mutation (Ames Test)	CIK	40508101

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration	CIK	40508102
84-4	Other Genotoxic Effects	CIK	40700801
85-1	General Metabolism		N/A - Not required for current use patterns.
85-2	Dermal Absorption		N/A - Not required for current use patterns.
86-1	Domestic Animal Safety		N/A - Not required for current use patterns.
REENTRY PROTECTION			
132-1A	Foliar Residue Dissipation	K	DATA GAP
132-1B	Soil Residue Dissipation		DATA GAP
133-3	Dermal Passive Dosimetry Exposure	K	DATA GAP
133-4	Inhalation Passive Dosimetry Exposure	I	DATA GAP
ENVIRONMENTAL FATE			
161-1	Hydrolysis	CK	DATA GAP
161-2	Photodegradation - Water	CI	40624501
161-3	Photodegradation - Soil	C	40622301

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
161-4	**Photodegradation - Air**		N/A - Not required based on low vapor pressure of methiocarb.
162-1	**Aerobic Soil Metabolism**	CIK	41194601
162-2	**Anaerobic Soil Metabolism**	CIK	41194601
162-3	**Anaerobic Aquatic Metabolism**		N/A - Not required because of current use patterns.
162-4	**Aerobic Aquatic Metabolism**		N/A - Not required because of current use patterns.
163-1	**Leaching/Adsorption/ Desorption**	CK	40342201 - **DATA GAP**
163-2	**Volatility - Lab**		N/A - Not required based on low vapor pressure.
163-3	**Volatility - Field**		N/A - Not required based on low vapor pressure.
164-1	**Terrestrial Field Dissipation**	CK	**DATA GAP**
164-2	**Aquatic Field Dissipation**		N/A - Not required because of current use patterns.
164-3	**Forest Field Dissipation**		N/A - Not required because of current use patterns.
164-4	**Combination and Tank Mixes**		N/A - Not required because of current use patterns.
164-5	**Long-Term Soil Dissipation**		RESERVED

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
165-1	Confined Rotational Crop		WAIVED
165-2	Field Rotational Crop		RESERVED
165-3	Irrigated Crops		N/A - Not required because of current use patterns.
165-4	Bioaccumulatin in Fish		WAIVED
165-5	Bioaccumulation - Aquatic Non-Target Organisms		N/A - Not required because of current use patterns.
201-1	Droplet Size Spectrum		N/A - Not required because of current use patterns.
202-1	Drift Field Evaluation		N/A - Not required because of current use patterns.

RESIDUE CHEMISTRY

***All of the Residue Chemistry data requirements are waived due to the dropped food uses. Residue Chemistry references are listed in the Bibliography (Appendix C).**

171-3	Directions for Use	*
171-4A	Nature of Residues - Plants	*
171-4B	Nature of Residues - Livestock	*
171-4C	Residue Analytical Method - Plants	*
171-4D	Residue Analytical Method - Animal	*

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Methiocarb

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	Storage Stability		*
171-4J	Magnitude of Residues - Meat/ Milk/Poultry		*
171-4K	Cropfield Trials		*
	Agricultural Crops (Preplant Application)		
	Avocados		
	Blueberries		
	Cherries		
	Corn, Field		
	Cranberries		
	Deciduous Fruit Trees (Nonbearing)		
	Grapefruit		
	Lemons		
	Oranges		
	Peaches		
	Peppers and Sunflowers Grown for Seed		
171-4L	Processed Food		*
	Citrus Group		
171-5	Reduction of Residues		*

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

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
--------	Spagnoli, J. (1993) Typical Use of Methiocarb. (Letter to Karen Farmer, U.S. EPA, dated July 22, 1993; submitted by Miles, Inc., Kansas City, Mo.)
00001999	Atkins, L., Jr.; Anderson, L.D. (1967) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. (Unpublished study received Jan 30, 1969 under 9G0802; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Hercules, Inc., Agricultural Chemicals, Wilmington, Del.; CDL:093111-D)
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00035520	Strankowski, K.J.; Stanley, C.W. (1978) Determination of Residues of Mesurol® and Its Toxic Metabolites in Crops: Report No. 45089. (Unpublished study including report nos. 53015, 53701 and 62625, received Jun 19, 1980 under 0F2362; prepared in cooperation with International Research & Development Corp. and others, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:099475-B)
00036477	Crawford, C.R.; Anderson, R.H. (1973) The Acute Oral Toxicity of Mesurol Technical to Rats: Report No. 34008. Rev. (Unpublished study received Mar 26, 1975 under 5F1607; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094391-T)
00036478	Crawford, C.R.; Anderson, R.H. (1972) The Dermal Toxicity of Mesurol Technical and Mesurol 75% Wettable Powder to Rabbits: Report No. 34477. (Unpublished study received Mar 26, 1975 under 5F1607; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094391-U)
00036482	Schafer, E.W., Jr.; Brunton, ? (1973) Toxicity and Repellency Tests of 9 Materials from Bayer and Chemagro: Report No. S-225; Report No. 36054. (Unpublished study including report nos. S-223 and 36055, received Mar 26, 1975 under 5F1607; prepared in cooperation with U.S. Fish and Wildlife Service, Denver Wildlife Research Center, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094391-Z)

BIBLIOGRAPHY

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00036484	Lamb, D.W.; Roney, D.J. (1973) Acute Toxicity of Mesurol 75% Wettable Powder to Bluegill and Rainbow Trout: Report No. 36612. (Unpublished study received Mar 26, 1975 under 5F1607; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094391-AB)
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APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

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

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

Federal publications on methiocarb are available and may be purchased from the National Technical Information Service (NTIS), 5825 Port Royal Road, Springfield, VA 22161.

1. Guidance for the Reregistration of Pesticide Products Containing Methiocarb as the Active Ingredient (The 1987 Registration Standard): NTIS Stock No. PB87-190898

2. Pesticide Fact Sheet (No. 120) for Methiocarb: NTIS Stock No. PB87-191920

APPENDIX E. PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The

certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum

level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

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

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

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

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

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

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

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

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

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

Option 1. Developing Data

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

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

developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

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

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

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

Option 4. Submitting an Existing Study

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

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

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

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

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

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

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

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

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

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

Attachment 1. Chemical Status Sheet

Generic and Product Specific Data Call-In

Chemical Status Sheet
for
Methiocarb

INTRODUCTION

You have been sent this **combined Generic and Product Specific Data Call-In Notice** because you have product(s) containing methiocarb.

This combined **Generic and Product Specific Data Call-In Chemical Status Sheet** contains an overview of data required by this combined notice, and points of contact for inquiries pertaining to the reregistration of methiocarb. This attachment is to be used in conjunction with:

- The Combined Generic and Product Specific Data Call-In Notice (Appendix E),
- The Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Attachment 2)
- The Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Attachment 3),
- EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration (Attachment 4),
- The EPA Acceptance Criteria (Attachment 5),
- List of registrants receiving this combined DCI (Attachment 6), and
- The Confidential Statement of Formulat, Cost Share and Data Compensation Forms (Attachment 7)

Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of methiocarb, please contact Ms. Karen Jones at (703) 308-8047.

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

Ms. Karen Jones, Chemical Review Manager
Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

RE: Methiocarb

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

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

Ms. Emily Mitchell
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Methiocarb

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

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

DATA CALL-IN RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0577 Methiocarb Chemical # and Name 100501 Methiocarb	GENERIC

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0577 Methiocarb	PRODUCT SPECIFIC

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active 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" for generic data.

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

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

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

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

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

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

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

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

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

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

2. Case # and Name
0577 Methiocarb
Chemical # and Name 100501
Methiocarb

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
72-3(a) *	Estu/mari tox. fish					CK	TGAI	12 mos.	
72-3(b) *	Estu/mari tox. mollusk					CK	TGAI	12 mos.	
72-3(c) *	Estu/mari tox. shrimp					CK	TGAI	12 mos.	
72-4(a) *	Early life stage fish					CK	TGAI	12 mos.	
72-4(b) *	Life cycle invertebrate					CK	TGAI	12 mos.	
72-5 *	Life cycle fish		Y			CK	TGAI	24 mos.	
82-5(b) *	90-day neurotox-mammal		Y			CIK	TGAI	24 mos.	
132-1(a) *	Foliar residue dissipation		Y			K	TEP	24 mos.	
132-1(b) *	Soil residue dissipation		Y			CIK	TEP	24 mos.	
133-3 *	Dermal passive dosimetry expo		Y			CIK	TEP	24 mos.	
133-4 *	Inhal. passive dosimetry expo		Y			I	TEP	24 mos.	
161-1 *	Hydrolysis					CK	TGAI/PAIRA	12 mos.	
163-1 *	Leach/adsorp/desorption					CK	TGAI	12 mos.	
164-1 *	Terrestrial field dissipation		Y			CK	TEP	24 mos.	
233 *	Estimation of Dermal Exposure at Indo						TEP	12 mos.	
234 *	Estimation of Inhalation Exposure at						TEP	12 mos.	
81-8-SS *	Acute Neurotoxicity - Rat					CIK	TGAI	12 mos.	
	Protocol	Y						3 mos.	

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
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2. Case # and Name
0577 Methiocarb
Chemical # and Name 100501
Methiocarb

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
90-1-SS *	Usage Data					CK	TGAI	3 mos.	

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

Date

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0577 Methiocarb
Chemical # and Name
100501 Methiocarb

GUIDELINE	COMMENT
72-3(a)	The Agency reviewed the estuarine/marine organisms data (MRIDs 155937, 155970) submitted by the registrant in response to the Registration Standard for methiocarb. These data contained summary information only and therefore are classified as unacceptable for use in the ecological risk assessment for methiocarb. Testing of technical methiocarb on estuarine/marine species is required since methiocarb is registered for use on lawns and turf in coastal counties. The 96-hour LC50 study on an estuarine/marine species of fish should be performed using technical methiocarb. These data are considered confirmatory for supporting the lawns and turf uses of methiocarb.
72-3(b)	The 48-hour EC50 study with oyster embryolarvae or a 96-hour EC50 oyster shell disposition study should be performed using technical methiocarb. See comment for guideline for 72-3(a).
72-3(c)	The 96-hour LC50 study on an estuarine/marine species of shrimp should be performed using technical methiocarb. See comment for guideline 72-3(a).
72-4(a)	The submitted data (MRID 00155967) partially satisfies this guideline requirement because of a technical problem in the control tank had occurred. The Agency is requiring data which describes the water temperature in each tank to ensure that no significant variance of temperature occurred in any of the tanks. If these data are submitted, the study (MRID 00155967) may be upgraded to fulfill this guideline requirement. These data are considered confirmatory to support the reregistration of methiocarb for lawn and turf uses.
72-4(b)	The submitted data (MRID 40628001) was deemed supplemental because raw data was not available. The Agency is requiring this study to support the reregistration of methiocarb on lawns and turf. These data are considered confirmatory.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0577 Methiocarb
Chemical # and Name
100501 Methiocarb

GUIDELINE	COMMENT
72-5	Data from fish life cycle tests are required to support the reregistration of an end-use product that is expected to be transported to water from the intended use site when any of the following conditions apply: * If the estimated EEC is > 1/10 of the no effect level in the fish early life stage or invertebrate life cycle test. * If studies of other organisms indicate that the reproductive physiology of the fish may be affected. The Agency is requiring this study based on the fish early life stage study results. These data are considered confirmatory for supporting the lawns and turf uses of methiocarb.
82-5(b)	The acute and neurotoxicity studies are now required for all carbamate pesticides. These studies are not part of the target data set for this reregistration review; however, the Agency is requiring these studies because methiocarb is a carbamate. These studies must be performed with the methiocarb technical in order to support the continued registration of methiocarb.
132-1(a)	The Agency is requiring postapplication/reentry data on foliar residue dissipation to support the homeowner use of methiocarb on lawns and turf. This study must be conducted concurrently with the dermal passive dosimetry study (GL 133-3).
132-1(b)	The Agency is requiring the soil residue dissipation study to support the granular formulation use of methiocarb on ornamentals. This study is required to assess the exposure to persons entering treated ornamental planting areas. This study is considered confirmatory.

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Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0577 Methiocarb
Chemical # and Name
100501 Methiocarb

GUIDELINE	COMMENT
133-3	The Agency is requiring postapplication/reentry data on dermal passive dosimetry exposure to support the homeowner use of methiocarb on lawns and turf. This study must be conducted concurrently with the foliar dislodgeable residue dissipation study (GL 132-1a). The dermal passive dosimetry study is also required to support the granular formulation use of methiocarb on ornamentals. This study is considered confirmatory for the granular formulation use on ornamentals.
133-4	There is a potential for inhalation exposure following the application of the pressurized liquid formulation of methiocarb. The Agency is retaining the 24-hour reentry interval and ventilation requirements for entering greenhouses following an application using the pressurized liquid formulation. The Agency is also requiring postapplication inhalation monitoring data in order to support the reregistration of the pressurized liquid formulation of methiocarb. These data are considered confirmatory.
161-1	The Agency is requiring this study because it is the baseline used to assess abiotic degradation of methiocarb in soil and aquatic environments. This study is required for all outdoor uses and it will be considered confirmatory data.
163-1	The unaged portion of this study was previously satisfied using a single loam textured soil. The Agency believes that additional batch equilibrium are necessary on 3 soils with different textures to assess more completely the mobility of methiocarb. As per Subdivision N guidelines, one of the test soils should have a sand or loamy sand texture with a low organic matter coontent (<1% OM). Also, the batch equilibrium data on any single soil (e.g., loam) may not adequately represent pesticide partitioning in other soils (e.g., sand and loamy sand). This study is required for all outdoor uses and it will be considered confirmatory data.

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*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0577 Methiocarb
Chemical # and Name
100501 Methiocarb

GUIDELINE	COMMENT
164-1	The submitted data (MRIDs 00155781, 00155782, and 40994801) were found unacceptable because sampling depth increments were too broad (or wide) across soil depth; broad sampling increments may dilute soil pesticide concentrations and hence mask possible detection of pesticide movement. At this time the field dissipation data cannot be used to assess leaching at soil depths greater than 30 cm. The Agency is requiring additional field studies with greater sampling depths and appropriate soil sampling increments to assess leaching of methiocarb below 30 cm. This study is required on a confirmatory basis to support the lawns and turf uses.
233	The Agency is requiring this study to support the reregistration of methiocarb for commercial application of the wettable powder formulation to greenhouse/nursery grown ornamentals.
234	See comment for guideline 233.
81-8-SS	See comment for guideline 82-5(b).
90-1-SS	The Agency has determined that the outdoor uses of methiocarb is likely to have adverse effects on aquatic and terrestrial species. The Agency is requiring usage data to estimate how much of methiocarb's use is outdoors and the geographical areas of the outdoor uses.

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REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0577 Methiocarb
EPA Reg. No. NNNNNN-NNNNN

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

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
61-2(b)	Discussion of formation of (1,3) impurities					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

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0577 Methiocarb

EPA Reg. No. NNNNNN-NNNNN

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

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability (50)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0577 Methiocarb

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

Use Categories Key:

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

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

Prod Chem - Regular Chemical

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

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0577 Methiocarb

Footnotes (cont.):

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

EPA'S DECISION ON BATCHING PRODUCTS CONTAINING METHIOCARB FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Methiocarb, the Agency considered batching products. This process involves grouping similar products for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is cited, the registrant must clearly identify the material tested by its EPA registration number.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response", asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response", lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5), or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table I lists 5 batches containing a total of 14 products.

Table I.

Batch No.	EPA Reg. No.	% of Methiocarb & other Active ingredients	Formulation Type
1	70-247	2.0	granular
	2393-241	2.0	pellet
	NC86000300	2.0	pellet
	WI92000400	2.0	pellet
2	3125-234	2.0	granular
	3125-387	2.0	pellet
	7401-342	2.0	granular
	56644-20	2.0	pellet
3	5481-189	2.0	granular
	5481-333	2.0	granular
4	5481-195	1.0 2.0 Meta Metaldehyde	granular
	5481-332	1.0 2.0 Meta Metaldehyde	granular
5	802-500	2.0	pellet
	802-566	2.0	granular

Table II lists the products which could not be batched. These products were not considered similar for purposes of acute toxicity. The registrants of these products are responsible for meeting the acute toxicity data requirements specified in the data matrix for end-use products.

Table II

EPA Reg. No.	% of Methiocarb	Formulation Type
239-2416	2.0	granular
499-276	1.0	liquid
3125-258	95.0	technical
7001-283	2.0	granular
769-706	2.0	pellet
769-707	2.0	granular
3125-288	75.0	wetable powder
3125-257	75.0	powder
WI92000300	2.0	pellet

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

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

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor

____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C

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

____ Data supporting reported value provided

63-12 pH

____ Measured at about 20-25° C

____ Measured following dilution or dispersion in distilled water

63-13 Stability

____ Sensitivity to metal ions and metal determined

____ Stability at normal and elevated temperatures

____ Sensitivity to sunlight determined

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
   _____ Freund's complete adjuvant test
   _____ Guinea pig maximization test
   _____ Split adjuvant technique
   _____ Buehler test
   _____ Open epicutaneous test
   _____ Mauer optimization test
   _____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

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

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0577 Methiocarb
Chemical # and Name
100501 Methylthio)-3,5-xylyl methylcarbamate

Company Number	Company Name	Additional Name	Address	City & State	Zip
000070	WILBUR-ELLIS COMPANY		BOX 16458	FRESNO CA	93755
000239	SOLARIS GROUP, THE	A DIV OF THE AGRICULTURAL GROUP OF	BOX 5006	SAN RAMON CA	94583
000499	WHITMIRE RESEARCH LABORATORIES, IN		3568 TREE CT INDUSTRIAL BLVD	ST LOUIS MO	63122
000769	H.R. MCLANE, INC.	AGENT FOR: SURECO, INC.	7210 RED ROAD, SUITE 206	MIAMI FL	33143
000802	CHAS H. LILLY CO.		7737 N.E. KILLINGSWORTH	PORTLAND OR	97218
002393	HACO, INC		BOX 7190	MADISON WI	53707
003125	MILES INC	AGRICULTURE DIVISION	8400 HAWTHORN RD BOX 4913	KANSAS CITY MO	64120
005481	AMVAC CHEMICAL CORP		4100 EAST WASHINGTON BLVD	LOS ANGELES CA	90023
007001	J.R. SIMPLOT CO.		BOX 198	LATHROPE CA	95330
007401	VOLUNTARY PURCHASING GROUP, INC.		P. O. BOX 460	BONHAM TX	75418

Attachment 7. Confidential Statement of Formula, Cost Share and Data Compensation Forms

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)

Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. RED Fact Sheet

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-F-94-002
February 1994

EPA R.E.D. FACTS

Methiocarb

Pesticide Reregistration

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

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

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

Use Profile

Methiocarb is an insecticide, acaricide and molluscicide. It is used to control snails, slugs, spider mites and insects on lawns, turf and ornamentals, around building foundations, and in ginseng gardens. Methiocarb has no remaining food uses; the use on ginseng has a 12-month preharvest interval and therefore is not considered a food use.

Methiocarb end-use products formulated as granulars and pellets/tablets are used on residential and commercially grown lawns, turfgrass and ornamentals, in commercial greenhouses and nurseries, around building foundations, and in ginseng gardens. A wettable powder formulation is used as a foliar spray for nursery and greenhouse ornamentals. A pressurized liquid is applied as a total release aerosol spray in commercial greenhouses.

Although the total volume of use is relatively low, methiocarb is considered an important tool for controlling slugs and snails in nurseries and greenhouses.

Regulatory History

Methiocarb was first registered as a pesticide in the U.S. in 1972. EPA issued a Registration Standard for methiocarb in March 1987 (NTIS #PB87-190898), requiring additional product chemistry, residue chemistry, ecological effects, environmental fate, toxicology, and occupational and residential exposure data. The methiocarb producers deleted all food uses from their product labels between 1989-92, so residue chemistry studies are no longer required. The technical producer is no longer supporting the commercial turf use of methiocarb. If end-use registrants do not support this use, it will have to be removed from product labels.

Currently, 22 pesticide products are registered which contain the active ingredient methiocarb. All methiocarb products for outdoor use except products with homeowner uses are classified as Restricted Use Pesticides, and may be applied only by or under the direct supervision of certified applicators.

Human Health Assessment

Toxicity

Methiocarb is among the carbamate family of chemicals; that is, it has the ability to inhibit the body's production of cholinesterase, an enzyme necessary for accurate transmission of nerve impulses.

In acute toxicity studies using laboratory animals, methiocarb has been shown to be highly toxic by the oral route and has been placed in Toxicity Category I (the highest of four levels) for acute oral effects. It is moderately toxic by the inhalation route and slightly toxic by the dermal route, and has been placed in Toxicity Categories II and III for these effects. Methiocarb is not an eye or skin irritant, and it does not cause delayed neurotoxicity.

Subchronic dermal toxicity studies using rabbits showed inconsistent results, but the range-finding study resulted in treatment-related deaths at the higher doses. In chronic feeding studies using rats and beagle dogs, methiocarb caused inhibition of red blood cell and plasma cholinesterase, but not brain cholinesterase. In the dog study, hind limb weakness and tremor occurred in the high dose group. Methiocarb is not carcinogenic in rats, and does not appear to have any mutagenicity potential. Administered by the dermal route, methiocarb is associated with developmental toxicity in rabbits. By the oral route, it is associated only with maternal toxicity in both rats and rabbits.

Although they are not part of the target data base for reregistration, acute and chronic neurotoxicity studies in rodents, now required for all carbamate pesticides, must be performed for methiocarb.

Dietary Exposure

Dietary exposure to methiocarb is not expected to occur since there are no remaining food uses. Ginseng is not considered a food use since current methiocarb labels require a 12-month preharvest interval. The

Agency will revoke all existing methiocarb tolerances (maximum food residue limits) set forth in 40 CFR 180.320.

Occupational and Residential Exposure

Methiocarb wettable powder products applied as foliar sprays can result in dermal and inhalation exposure to mixers, loaders and applicators. Use of the granular and total release aerosol products is expected to result in less applicator exposure than use of the foliar sprays.

Post-application exposure also may occur following most methiocarb applications. Examples include dermal exposure to residues on treated lawns, turf and soil following the granular applications, dermal exposure to foliage of commercially grown ornamentals following the wettable powder and pressurized liquid formulations, and inhalation exposure following application of total release aerosol sprays.

Methiocarb meets both the toxicity and the exposure criteria requiring mixer/loader/applicator exposure data and post-application reentry data. These studies will be required for reregistration of the commercial use of the wettable powder formulation to greenhouse- and nursery-grown ornamentals.

The Worker Protection Standard (WPS) converted the previous 24-hour worker reentry interval (where reentry with protective clothing is allowed) to a 24-hour restricted entry interval or REI (where entry is limited to performance of short term activities as defined in the WPS). Considering the toxicological concerns with methiocarb, EPA considers these additional protections essential to its decision that REIs will sufficiently mitigate risks to workers.

Human Risk Assessment

Since no food uses are registered, methiocarb poses no human dietary risks. Regarding acute toxicity, methiocarb is extremely toxic by the oral route but is moderately to slightly toxic by other routes of exposure. Methiocarb is a developmental toxicant, and workers and homeowners may be at risk for developmental effects from exposure to methiocarb during or after application.

For handlers of the wettable powder/foliar spray formulation of methiocarb using currently-required personal protective equipment (PPE), the estimated margin of exposure (MOE) for dermal and inhalation toxicity is estimated to be less than 100, the commonly accepted margin. However, with the use of additional PPE (coveralls), the MOE increases to well over 100. To achieve an acceptable MOE, therefore, EPA is requiring use of additional PPE.

EPA also is concerned about workers entering treated areas following application of methiocarb. To protect workers, the Agency is requiring a 25-day restricted entry interval (REI) following foliar applications of the wettable powder and pressurized liquid (total release aerosol) formulations

to ornamental plants. After 10 days, workers may enter treated areas to perform tasks, including hand labor tasks that involve contact with treated surfaces, provided each worker spends no more than 3 hours in each 24-hour period performing such tasks. PPE is not required during the 3-hour work period.

Because methiocarb has been identified as a developmental toxicant, EPA is requiring use of extra PPE by all applicators, handlers and early entry workers. These PPE requirements will not apply to homeowner users of methiocarb since their frequency and duration of exposure is less than that of occupationally exposed users.

Environmental Assessment

Environmental Fate

Methiocarb appears to be moderately persistent and relatively immobile in soil, and is not likely to contaminate ground water. A full assessment will be possible only when confirmatory hydrolysis, adsorption-desorption/leaching and terrestrial field dissipation studies are submitted.

Ecological Effects

Methiocarb is toxic to terrestrial mammals. It is very highly toxic to birds on an acute oral basis. In subacute studies, it is slightly toxic to waterfowl and practically non-toxic to upland game birds. Methiocarb is highly toxic to coldwater and warmwater fish, and very highly toxic to aquatic invertebrates. It also is very highly toxic to honey bees.

Ecological Effects Risk Assessment

Outdoor use of methiocarb is likely to have adverse effects on aquatic and terrestrial species. For all formulations of methiocarb used on all outdoor sites, acute and/or chronic levels of concern are exceeded for avian and mammalian species, aquatic invertebrates and other aquatic organisms. Although methiocarb is used in low volumes compared to other pesticides, it still could have major impacts in areas where there is concentrated outdoor use.

Methiocarb may pose a hazard to endangered species including many listed birds, mammals, insects, and aquatic organisms. The U.S. Fish and Wildlife Service will be consulted and a generic label statement may be required when EPA's Endangered Species Program is implemented.

EPA is requiring additional use precautions and maximum application rates on product labels, requiring additional confirmatory data, and negotiating with the registrants to maintain a production cap in an effort to decrease the environmental risks of methiocarb.

Additional Data Required

EPA is requiring the following additional generic data to confirm its risk assessment for methiocarb: estimation of dermal exposure for wettable powder formulation use in greenhouses and nurseries; estimation of inhalation exposure for wettable powder formulation use in greenhouses

and nurseries; inhalation passive dosimetry for pressurized liquid formulation use in greenhouses; estimation of dermal exposure and soil dissipation for granular formulations used on ornamentals; aquatic and estuarine organisms (fish/mollusk/shrimp) for all lawn and turf uses; aquatic invertebrate life cycle for all lawn and turf uses; fish early life stage for all lawn and turf uses; fish life cycle for all lawn and turf uses; hydrolysis for all outdoor uses; adsorption/desorption/leaching for all outdoor uses; terrestrial field dissipation for all lawn and turf uses; outdoor usage data (pounds used per year by site); foliar dislodgeable dissipation and dermal passive dosimetry for residential lawns and turf; and acute and subchronic neurotoxicity data (which are not part of the target data base for reregistration).

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

Product Labeling Changes Required

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

Worker Protection Standard (WPS) - Any product whose labeling permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery or greenhouse) must comply with the labeling requirements of EPA's Worker Protection Standard (WPS). See PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7." Unless specifically directed in the RED, all statements required by the WPS and reflected in these two PR Notices must be included on product labeling.

Entry Restrictions - [See the RED for detailed instructions.] For uses within the scope of the WPS and products not primarily intended for home use:

- Wettable Powder Formulations - A 25-day restricted entry interval (REI) is required:

  "Do not enter or allow worker entry in treated areas during the restricted entry interval (REI) of 25 days, except, after 10 days, workers may enter treated areas to perform tasks including hand labor tasks that involve contact with treated surfaces provided each worker spends no more than 3 hours in each 24 hour period performing such tasks."

- Pressurized Liquid Formulations - A 25-day REI is required: (see statement above).

- Granular Formulations - A 24-hour REI is required, except for products intended primarily for home use.

Personal Protective Equipment (PPE) Requirements

[See the RED for detailed instructions.]

- For Products Not Primarily Intended for Home Use - The minimum PPE requirement is:

> "Applicators and other handlers must wear:
>
> --Coveralls over short-sleeved shirt and short pants
>
> --Chemical-resistant or waterproof gloves...
>
> --Chemical-resistant footwear plus socks
>
> --Chemical-resistant headgear for overhead exposure
>
> --Chemical-resistant apron when cleaning equipment, mixing, or loading..."

In addition, handlers must wear a respirator with an organic vapor cartridge TC-23C during early entry to greenhouses following treatment with the pressurized liquid for those tasks associated with ventilating the greenhouse. A dust mask must be worn while mixing/loading the wettable powder formulation.

Compare the PPE requirements set forth in the RED to the PPE requirements, if any, on current labeling and retain the more protective.

- For Products Intended for Home Use - Do not add any additional PPE requirements but retain any requirements already on current product labeling.

- For Entry During the Restricted Entry Period - See the RED for detailed instructions.

- For Uses Not Within the Scope of the WPS, and For Products Primarily Intended for Home Use - Do not add any new entry restrictions but retain any on current product labeling.

Lawn and Turf Uses

- If a registrant chooses to support lawn and turf uses, he must submit the data required in the RED.

- If a registrant chooses to support the residential lawn uses only, he must add the following statement to his product labels to remove the site from the scope of the WPS:

> "Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

- If a registrant does not support the residential lawn uses, he must delete the use from the product label and add the following statement:

> "Do not use on turfgrass around residences or dwellings."

Restricted Use Pesticide - The following statement must appear on the labels of all end-use products for outdoor uses except products intended for use by homeowners:

"Restricted Use Pesticide

Due to Toxicity to Fish, Birds, and Aquatic Organisms

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

Use Rates and Number of Applications - The following number of applications must appear as the maximum application rate in the Directions for Use section of the label, to decrease aquatic risks:

- 75% Wettable Powder -

  "2 lbs 75% wettable powder per 50 gallons of water applied up to 2 times a year."

- Granular or Pelletized Bait -

  "Should not be applied more than twice a year."

Fish and Wildlife Protection - The following statements must appear on products for the following uses:

- Granular or Pelletized Bait for Snails and Slugs -

  "This product is toxic to fish and very highly toxic to birds and mammals. Do not apply directly to water, wetlands (swamps, bogs, marshes, and potholes). Runoff from treated area may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters and rinsates."

- 75% Wettable Powder Formulation -

  "This pesticide is toxic to fish and very highly toxic to birds and mammals. Do not apply directly to water, or to areas below the mean high water mark. Runoff from treated area may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters and rinsates.

  "This product is very highly toxic to honey bees exposed to direct treatment or residues on blooming shrubs, flowers, weeds and trees. Do not apply this product or allow it to drift to blooming shrubs, flowers, weeds, or trees if bees are visiting the treatment area."

Regulatory Conclusion

The use of most currently registered pesticide products containing methiocarb in accordance with approved labeling, except the use of granular and pelletized formulations on residential lawns and turf, and except products for use by homeowners on ornamentals marketed in 20-25 pound bags, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, uses of methiocarb on residential and commercial ornamentals (except large size products for use by homeowners

on ornamentals), by homeowners around building foundations, in greenhouses, on commercially grown turfgrass, and on ginseng are eligible for reregistration.

These products will be reregistered once the required confirmatory generic data, product specific data and revised labeling are received and accepted by EPA. Products which also contain other active ingredients will be reregistered after the other active ingredients are determined to be eligible for reregistration.

EPA cannot make a reregistration eligibility decision regarding the residential lawn and turf use of methiocarb until appropriate postapplication reentry exposure, ecological effects and environmental fate data are submitted and evaluated.

The Agency similarly cannot make a reregistration eligibility decision regarding large size methiocarb products for use by homeowners on ornamentals, marketed in 20-25 pound bags, until soil dissipation and dermal exposure data are received and evaluated.

For More Information

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

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

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

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