UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses 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 Edward Setren at (703) 308-8166. Address any questions on required generic data to the Special Review and Reregistration Division representative Paul Lewis at (703) 308-8018.

Sincerely yours,

Lois A. Rossi, Director
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. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); 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 date of this letter (RED issuance date).**

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

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

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

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

limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

PROPAMOCARB HYDROCHLORIDE

LIST C

CASE 3124

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

TABLE OF CONTENTS

PROPAMOCARB HYDROCHLORIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Gail Tomimatsu	Biological Analysis Branch
Steve Jarboe	Biological Analysis Branch
Jihad Alsadek	Economic Analysis Branch
Harry Gaede	Economic Analysis Branch

Environmental Fate and Effects Division

Harry Craven	Ecological Effects Branch
William R. Effland	Environmental Fate and Groundwater Branch
Mary Powell	Science Analysis and Coordination Staff
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Alberto Protzel	Toxicology Branch II
Winston Dang	Occupational and Residential Exposure Branch
Mary Clock	Risk Characterization and Analysis Branch
Olga Odiott	Rish Characterization and Analysis Branch

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Sidney Jackson	Fungicide-Herbicide Branch, Team 21
Al Smith	Registration Support Branch

Special Review and Reregistration Division

Paul Lewis	Accelerated Reregistration Branch
Mark Wilhite	Accelerated Reregistration Branch
Kathleen Depukat	Accelerated Reregistration Branch

Office of Enforcement and Compliance:

Beverly Updike

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide and Rodenticide Act, as amended in 1988, the U.S. Environmental Protection Agency (hereafter referred to as the "Agency" or "EPA") has completed its reregistration eligibility decision (RED) for the pesticide active ingredient propamocarb hydrochloride. This decision includes a comprehensive reassessment of the required target data base and use patterns of the currently registered products. The Agency compared its risk assessment to current science and regulatory policies. Where appropriate, it has imposed changes to the terms for continued registration in order to reduce human health and environmental risks.

The Agency has determined that all uses of propamocarb hydrochloride, with the exception of the field-grown ornamental use plus the high volume/low pressure and hand dipping application scenarios, are eligible for reregistration. A decision on the field-grown ornamentals use plus the high volume/low pressure and hand dipping application scenarios cannot be made at this time because insufficient data are available to conduct a risk assessment for chronic effects to the environment or to characterize the risk to handlers of propamocarb hydrochloride via high volume/low pressure and hand-dip uses. The registrant has proposed voluntarily deleting the use for field-grown ornamentals from the product registration and amending their label to reduce the maximum application rate for turf.

Because the Agency has identified toxicological endpoints for short and intermediate term exposure, it is imposing reentry restrictions of 24 hours for uses within the scope of the Worker Protection Standard (WPS) for agricultural pesticides or until after sprays have dried for other uses. Personal protective equipment (PPE) are being required for mixers and loaders for ground boom applications and for early reentry to certain sites. The Agency also is requiring exposure-related data to confirm the exposure assessments and adequacies of the PPE and reentry restrictions, as well as, confirmatory data for the assessment of the ecotoxicity and environmental fate of propamocarb hydrochloride.

Uses

Propamocarb hydrochloride is used to control the plant disease "damping-off" and has fungicidal activity against *Pythium* spp. and *Phytophthora* spp. Current use sites include ornamental lawns and turf, ornamental sod farms (turf), ornamental herbaceous plants, ornamental woody shrubs and vines.

Human Health Risk

From its review of the toxicology data, the Agency concluded that the technical grade active propamocarb hydrochloride is slightly toxic to practically non-toxic when administrated by inhalation, dermal or oral routes of acute exposure. In addition, the chemical was determined not to be a dermal sensitizer.

A battery of mutagenicity studies were negative for mutagenic effects. Propamocarb hydrochloride is classified a Group D carcinogen, that is not classifiable as to human carcinogenicity.

The toxicological endpoint selected by the Agency for both the short-term and intermediate-term occupational/residential exposure is a NOEL of 150 mg/kg/day. This is the maternal NOEL in rabbits for reduced body weight gain during days 6-18 of gestation and the developmental NOEL for increased post-implantation loss as demonstrated in a developmental toxicology study. It is also the NOEL from a 21-day dermal toxicology study with rabbits in which there was decreased body weight gain in females.

Based on the fact that the NOEL for systemic effects was 150 mg/kg/day by both the oral and the dermal routes and in the absence of dermal absorption measurements, the Agency assumes 100% dermal absorption for its occupational/residential exposure assessments.

The Agency has determined that the Reference Dose (RfD) for propamocarb hydrochloride should be 0.11 mg/kg/day based on a 2-year feeding study in dogs. This decision is based on the threshold LOEL of 1000 ppm (33.3 mg/kg/day in males and females), the lowest dose tested in that study. Body weight gain depression, decreased food efficiency and gastritis were observed in males of this dose group. The Agency applied an uncertainty factor (UF) of 100 to account for both interspecies extrapolation and intraspecies variability. An additional UF of 3 was used to account for the lack of a NOEL. The Agency believes that the NOEL is slightly lower than the lowest dose tested as explained in the summary of the 2-year chronic feeding study with dogs.

For short and intermediate term occupational exposures, the Agency calculated margins of exposure (MOE = NOEL/exposure) for propamocarb hydrochloride product handlers (mixer/loaders/applicators). These indicated acceptable margins of exposure (MOEs $\geq$ 100), where MOEs could be calculated. However, the Agency is requiring exposure data for handler activities associated with high volume/low pressure spray and hand-dipping applications since exposure data are unavailable for these use practices. For uses within the scope of the WPS, the Agency is also requiring persons entering treated areas before a 24-hour restricted-entry interval has expired to wear early-entry personal protective equipment consisting of coveralls over short-sleeve shirt and short pants, chemical-resistant footwear plus socks, chemical resistant headgear for overhead exposures, and chemical-resistant gloves. For occupational uses outside the scope of the WPS, EPA is restricting entry into treated areas until sprays have dried. In addition, the Agency is requiring confirmatory post-application exposure data for uses on turfgrass at residential sites and at sod-farm sites and for uses on ornamentals in greenhouses. The requested information has been required through issuance of a Data-Call In (DCI) prior to publication of this document.

Environmental Risk Assessment

Adequate data are available to assess the acute ecological hazard of propamocarb hydrochloride, but the Agency does not have sufficient data to assess chronic avian and aquatic

invertebrate hazards or adequately characterize the risk to terrestrial or aquatic plant growth and terrestrial plant emergence. Available data indicate propamocarb hydrochloride is slightly toxic to practically nontoxic to birds, small mammals, freshwater and estuarine/marine fish and invertebrates. Based upon the developmental and reproductive effects demonstrated in rats (including fetal death at low doses in developmental toxicological studies), chronic effects in avian organisms may be expected. From limited phytotoxicity data, the fungicide was observed to be toxic to plants. The Agency also has concerns that the use on field-grown ornamentals would exceed the acute Levels of Concern (LOC) for non-endangered and endangered birds, mammals, estuarine and marine animals. However, the registrant has proposed to amend their propamocarb hydrochloride product registration to eliminate the field-grown ornamental use from the label, thereby mitigating these concerns. Because of these remaining ecotoxicological concerns and data gaps, the Agency has required, through a DCI issued prior to publication of this document, submission of chronic avian and aquatic invertebrate data and additional terrestrial plant phytotoxicity data to confirm its conclusions about propamocarb hydrochloride's risks to the environment.

Product Reregistration

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** propamocarb hydrochloride
- **Chemical Name:** propyl[3-(dimethylamino)propyl]carbamate monohydrochloride
- **CAS Registry Number:** 25606-41-1
- **OPP Chemical Code:** 119302
- **Empirical Formula:** $C_9H_{21}ClN_2O_2$
- **Basic Manufacturer:** AgrEvo

B. Use Profile

The following is information on the currently registered uses of propamocarb hydrochloride with an overview of use sites and application methods. A detailed table of these uses is provided in Appendix A. Please note that recently proposed changes are not presented here.

Type of Pesticide: fungicide

Use Sites:

terrestrial nonfood crop: ornamental lawns and turf, ornamental sod farms (turf)

terrestrial + greenhouse non-food crop: ornamental herbaceous plants, ornamental woody shrubs and vines, cutting beds, and seedling areas

Note: the registrant has applied to eliminate the field-grown ornamental use. This

will result in the terrestrial ornamental herbaceous plants, terrestrial ornamental woody shrubs and vines, terrestrial cutting beds, and terrestrial seedling areas uses being deleted.

Target Pests: *Pythium* spp. and *Phytophthora* spp.

Formulation Types Registered: soluble concentrate/liquid of 66.5% of propamocarb hydrochloride

Method, Rate and Timing of Application:

herbaceous ornamentals - at potted stage, dip bare-rooted plants at 0.01 lb ai/gal. After potted stage or at containerized stage, drench at 0.0003 lb ai/4-in. pot or 0.015 lb ai/10 sq. ft., respectively. At seed bed or transplant stage, apply at 0.01 to 0.02 lb ai/10 sq. ft. Apply at weekly intervals.

woody ornamentals - drench at 0.12 lb ai/10 gallons water. Repeat applications at three to four month intervals.

turf - as a preventive treatment, apply 0.06 to 0.09 lb ai/1000 sq. ft. As a curative treatment, apply 0.14 to 0.19 lb ai per 1000 sq. ft. Applications are made immediately after germination or at 7 to 21 day intervals. The lower and higher rates are used for the shorter and longer application intervals, respectively.

Use Practice Limitations:

Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not feed treated clippings to animals or graze treated areas. Do not use in California or on sod farms in Arizona.

C. Estimated Usage of Pesticide

Almost all usage of propamocarb hydrochloride in the United States is concentrated on golf courses with approximately 100,000 to 200,000 lb/ai applied per year. This estimate is derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

D. Data Requirements

The Agency issued three Data Call-Ins (DCIs) to registrants for propamocarb hydrochloride products. The first DCI was issued on September 30, 1991, under Phase IV of the reregistration program. It required submission of acute avian, invertebrate toxicity, hydrolysis, photodegradation, and neurotoxicity data due to associated use patterns and the fungicide being a carbamate. On March 10, 1995, a second DCI was issued for propamocarb hydrochloride and other pesticide active ingredients registered for applications on residential turf. Under this DCI, submission of foliar residue dissipation, post-application dermal passive exposure and post-application inhalation dosimetry exposure data were required. The post-application dermal passive exposure and post-application inhalation dosimetry exposure studies may be waived pending completion of the database on agricultural and residential post-application/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Exposure Task Force, provided the registrant is a member of both Task Forces. A third DCI was issued on October 11, 1995, requiring avian reproduction, fish life cycle, aquatic plant growth, and seedling germination/seedling emergence studies due to use patterns associated with the fungicide. In addition, foliar residue dissipation, dermal passive dosimetry exposure, inhalation passive dosimetry exposure, honey bee acute contact, estimation of dermal exposure and estimation of inhalation exposure data were required for uses that were not addressed in the March 10, 1995, DCI.

E. Regulatory History

Pesticide products containing propamocarb hydrochloride were first registered in the United States to Nor-Am Chemical Company in 1984 for use as a fungicide. Currently, one product, Banol, (EPA 45639-88) is registered. The formulation of the product is an aqueous solution at 66.5% A.I. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Chemical name:	propyl[3-(dimethylamino)propyl]carbamate monohydrochloride
Common name:	propamocarb hydrochloride
Chemical formula:	$C_9H_{21}ClN_2O_2$
Molecular weight:	224.73
Color:	colorless to yellow

Physical state:	pure active ingredient - solid technical grade active ingredient - liquid
Odor:	odorless
Melting point:	64.2° C
Density:	1.083 g/mL

Solubility:

Solvent	g/L
Hexane	< 0.01
Methanol	> 656
Dichloromethane	> 256
Toluene	0.14
Acetone	560.3
Ethyl acetate	4.34

Solubility in water:	> 700 g/L
Vapor pressure:	8 x 10^{-5} Pa (Pascals) at 25°C
pH:	4.70
Stability:	stable at room and elevated temperatures (30 to 150° C)
Oxidizing or reducing action:	oxidizing agent
Storage stability:	stable stored below 28° C for > 11 years
Viscosity:	34.23 mpa at 20° C
Corrosion characteristics:	corrosive to iron, copper and brass

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for propamocarb hydrochloride adequately characterizes the potential toxicological effects from the active ingredient as it relates to the current registered use patterns. The Agency's assessment of the

relevant studies are discussed and summarized below.

a. Acute Toxicity

A variety of acute toxicity tests have been performed with propamocarb hydrochloride (as 66.5% - 70.0% aqueous solutions). The acute toxicity values for propamocarb hydrochloride are summarized in Table 1 below.

Table 1: Acute Toxicity

Test	MRID number	Results	Category
Oral LD_{50} - rat	41278115	2900 mg/kg (M); 2000 mg/kg (F)	III
Dermal LD_{50} - rat	41278116	> 3000 mg/kg	III
Acute inhalation LC_{50} - rat	93193044	> 7.9 mg/l	IV
Eye irritation - rabbit *	41278117	Irritation cleared by 72 hours	III
Dermal irritation - rabbit *	41278118	No erythema after 24 hours	IV
Dermal sensitization - guinea pig *	00083808	Non-sensitizer	Not applicable

* This study is a requirement for manufacturing-use and end-use products (40 CFR Section 158). For propamocarb hydrochloride, data have been generated on the TGAI and are presented here for informational purposes.

b. Subchronic Toxicity

A 90-day feeding study was performed in specific pathogen free albino rats at concentrations of propamocarb hydrochloride of 0, 20, 50, 100 or 500/1000 ppm in the diet (approximately 0, 1, 2.5, 5 or 25/50 mg/kg/day, using a food factor of 0.05) (MRID 00100723). This study by itself does not satisfy the reregistration requirements for a subchronic study in rodents. However, the reregistration requirement was satisfied when this study was considered together with a 2-year feeding carcinogenicity study in rats (MRID 00101638), as discussed below.

A 90-day feeding study was performed in beagle dogs at propamocarb hydrochloride concentrations of 0, 50, 100, 500 or 1000/2000 ppm in the diet (approximately 0, 1.25, 2.5, 12.5 or 25/50 mg/kg/day, using a food factor of 0.025). This study was classified as

invalid (MRID 41278119). As with the rat study above, this study by itself does not satisfy the reregistration requirement for a subchronic study in non-rodents. However, this requirement was satisfied when this study was considered together with the 2-year feeding study in dogs (MRID 43044201), as discussed below.

A 21-day dermal toxicity study was performed with propamocarb hydrochloride in Sprague Dawley rats at doses 0, 100, 500 or 1000 mg/kg/day, 6 hours/day, 5 days/week over a 21-day period (total of 15 doses). The NOEL was equal to or greater than 1000 mg/kg/day for both sexes. The LOEL was not defined by this study (MRID 42421201).

A 21-day dermal toxicity study was performed with propamocarb hydrochloride in New Zealand white rabbits at doses 0, 150, 525 or 1500 mg/kg/day, 6 hours/day, 5 days/week over a 21-day period (total of 15 doses). The LOEL was 525 mg/kg/day based on dose-related skin irritation and depressed body weight gain in mid-dose females. The NOEL was equal or greater than 150 mg/kg/day for both sexes (MRID 00071526).

c. Chronic Toxicity and Carcinogenicity

Chronic toxicity and carcinogenicity studies are not required for reregistration of propamocarb hydrochloride due to its status as a non-food use pesticide. However, the Agency is using the available chronic toxicity and carcinogenicity studies of propamocarb hydrochloride in rats and dogs, summarized below, to supplement the respective subchronic toxicity studies in rodents and non-rodents.

A 2-year feeding/carcinogenicity study was performed in Sprague-Dawley caesarean derived rats with propamocarb hydrochloride at concentrations of 0, 40, 200 or 1000 ppm (0, 1.4, 7.3 or 36.5 mg/kg/day in males and 0, 1.8, 9.3, or 45.4 mg/kg/day in females). No significant toxicological effect was observed at the highest dose (1000 ppm). The study was classified as core supplementary because the dose levels tested were not high enough for carcinogenicity testing and data on the stability of the compound in the test diet were not available for examination. Although the study was considered by the Agency to be unsatisfactory to fulfill data requirements for carcinogenicity testing in rats, the study was considered to be suitable for satisfying chronic toxicity testing in rats (MRID 00101638). This study, considered together with the above rat subchronic study, satisfies the 90-day rodent feeding study requirement.

A 2-year feeding study was performed in beagle dogs with

propamocarb hydrochloride at concentrations of 0, 1000, 3000 or 10000 ppm (0, 33.3, 103.7, or 356.3 mg/kg/day in males and 0, 33.3, 106.8, or 334.3 mg/kg/day in females). This study defined a LOEL of 1000 ppm (33.3 mg/kg/day) based on the finding of body weight gain depression, decreased food efficiency and of focal or multi-focal chronic erosive gastritis and/or acute erosions in males. No NOEL was defined by this study. However, the absence of such gastric lesions in the dog subchronic study (MRID 41278119), indicates that the LOEL of 1000 ppm should be considered a threshold effect level and the NOEL for the above effects should be only slightly lower than the threshold level. This study (MRID 43044201), considered together with the above dog subchronic study, satisfies the 90-day non-rodent feeding study requirement.

d. Carcinogenicity Classification

The Agency has assigned propamocarb hydrochloride a carcinogenicity classification of Group D, not classifiable as to human carcinogenicity. This classification is generally used for agents with inadequate human and animal evidence of carcinogenicity or for which no adequate data are available, as in the case of propamocarb hydrochloride.

e. Developmental Toxicity

New Zealand white rabbits were given gavage doses of propamocarb hydrochloride of 0, 15, 45, 150, 300, or 600 mg/kg/day on GD 6-18. The maternal toxicity NOEL was 150 mg/kg/day and the LOEL was 300 mg/kg/day, based on decreased body weight gains for GD 6-18. The developmental toxicity NOEL was 150 mg/kg/day and the LOEL was 300 mg/kg/day based on increased post-implantation loss (early resorptions and fetal death at 300 mg/kg/day, and early and late resorptions at 600 mg/kg/day). (MRID 93193043 reformat of MRID 00072574).

Wistar rats were given gavage doses of propamocarb hydrochloride of 0, 74, 221, 740 or 2210 mg/kg/day on gestation days (GD) 6-19. The maternal toxicity NOEL was 740 mg/kg/day and the LOEL was 2210 mg/kg/day, based on mortality, clinical observations (spastic gait, bloody snout, bloody vaginal discharge), and decreased body weight gains on GD 6-20. The developmental toxicity NOEL was 221 mg/kg/day and the LOEL was 740 mg/kg/day, based on increased GD 20 fetal death and increased incidence of minor skeletal anomalies (incomplete ossification of some sternebrae and vertebrae). It is noted that the developmental toxicity NOEL is less than the maternal toxicity NOEL. Due to the high dose at

which fetal toxicity was observed, no definite conclusion can be made regarding developmental toxicity (MRID 93193042 reformat of MRID 00101641).

f. Mutagenicity

Propamocarb hydrochloride was negative (at concentrations of up to 5000 μg/plate) in a *Salmonella* and *E. coli* assay for gene mutation. However, the Agency has classified the test as not acceptable because in the absence of cytotoxicity and/or mutagenic activity, analytical verification of the top dosing solution was not reported. As submitted, this study (MRID 41278121) does not satisfy gene mutation-ames requirements and constitutes a data gap for this data requirement. The Agency has required the registrant to upgrade this study by submitting acceptable verification of the top dosing solution by October 31, 1995.

Propamocarb hydrochloride was negative in two mouse micronucleus assays (MRIDs 00101642 and 00101643) at doses 5 and 2.5 mg/kg, respectively. The Agency initially classified each study as unacceptable. However, the Agency has decided that these two studies, considered together, are upgraded to acceptable.

Propamocarb hydrochloride was negative with (at concentrations of up to 1100 μ/ml) and without (at concentrations of up to 4700 μg/ml) metabolic activation in an acceptable *in vitro* mammalian cytogenetics assay in cultured human lymphocytes (MRID 41278122). The Agency concluded that mutagenicity data on propamocarb hydrochloride are adequate to satisfy the requirement for structural chromosome aberrations tests.

Propamocarb hydrochloride was negative in a mitotic gene conversion assay with (at concentrations of up to 24.6 mg/ml in a suspension assay, MRID 41278124) and without (at concentrations of up to 10 mg/plate in a plate assay, MRID 00101645) metabolic activation using *Saccharomyces cerevisiae* strain D_4. Additionally, propamocarb hydrochloride was negative in a mitotic recombination assay with and without (at concentrations of up to 10 mg/plate in a plate assay, MRID 00101645) metabolic activation using *Saccharomyces cerevisiae* strain D_5. When considered together, these studies satisfy the requirement for other genotoxic effects (e.g., mitotic recombination in eucaryotes).

g. Neurotoxicity

An oral acute neurotoxicity study was performed in Sprague-Dawley rats at dose levels of 0, 20, 200 or 2000 mg of propamocarb

hydrochloride/kg. The overall LOEL (combined neurotoxicity/systemic toxicity) was 2000 mg/kg for both sexes, based on soiled fur coat and decreased body weight gain in males and soiled fur coat and decreased motor activity in females. The overall NOEL (combined neurotoxicity/systemic toxicity) was 200 mg/kg in both sexes (MRIDs 43062301 and 43013101).

A 90-day feeding subchronic neurotoxicity study was performed in Sprague-Dawley rats with propamocarb hydrochloride concentrations of 0, 200, 2000, or 20000 ppm (0, 18.2, 189, or 1858 mg/kg/day in males and 0, 20, 209, or 2089 mg/kg/day in females). Neurobehavioral evaluation did not reveal any treatment-related functional observational battery findings or changes in motor activity. Plasma, red blood cells and brain cholinesterase activities were comparable to control values. There were no treatment-related gross or neuropathological findings. The overall LOEL (combined neurotoxicity/systemic toxicity) was 1858 mg/kg/day in males and 2089 mg/kg/day in females (based on decreased body weights and body weight gains). The overall NOEL (combined neurotoxicity/systemic toxicity) was 189 mg/kg/day in males and 209 mg/kg/day in females (MRIDs 43013102, 43440902, 43440903, and 43440904).

h. Toxicity Endpoints of Concern

The toxicological endpoint selected by the Agency for both the short-term and intermediate-term occupational/residential exposure is a NOEL of 150 mg/kg/day. This is the maternal NOEL in New Zealand white rabbits for reduced body weight gain during days 6-18 of gestation and the developmental NOEL for increased post-implantation loss as demonstrated in the developmental toxicology study (MRID 93193043) summarized above. It is also the NOEL from the 21-day dermal toxicology study with New Zealand white rabbits (MRID 00071526) in which decreased body weight gain in females was demonstrated.

Based on the fact that the NOEL for systemic effects was 150 mg/kg/day by both the oral and the dermal routes and in the absence of dermal absorption measurements, the Agency assumes 100% dermal absorption for the occupational/residential exposure assessment.

The Agency has determined that the Reference Dose (RfD) for propamocarb hydrochloride should be 0.11 mg/kg/day based on the 2-year feeding study in beagle dogs (MRID 43044201), as discussed above. This decision is based on the threshold LOEL of 1000 ppm (33.3 mg/kg/day in males and females), the lowest dose tested in that study. Body weight gain depression, decreased food efficiency and gastritis were observed in males

of this dose group. The Agency applied an uncertainty factor (UF) of 100 to account for both interspecies extrapolation and intraspecies variability. An additional UF of 3 was used to account for the lack of a NOEL. The Agency believes that the NOEL is slightly lower than the lowest dose tested as explained in the summary of the 2-year chronic feeding study with beagle dogs.

RfD = (33.3 mg/kg/day)/(100UF x 3UF) = 0.11 mg/kg/day

The Food and Agriculture Organization/World Health Organization Joint Committee on Pesticide Residues (JMPR) established an Acceptable Daily Intake (ADI) for this chemical of 0.1 mg/kg body weight/day in 1986. Two studies were considered to be important in the JMPR assessment: a chronic toxicity study in rats with a NOEL of 200 ppm in the diet (equivalent to 10 mg/kg/day), and a chronic toxicity study in dogs with a NOEL of 1000 ppm (equivalent to 25 mg/kg/day, apparently using the standard conversion factor and not the actual food intake values as in the Agency's evaluation of the same study).

As propamocarb hydrochloride is not a food use chemical, a dietary analysis is not needed. However, if the status of propamocarb hydrochloride as a non-food chemical changes, the fetotoxic NOEL of 150 mg/kg/day should be used as the toxicological endpoint for the acute dietary assessment.

2. Exposure Assessment

a. Dietary Exposure

As uses of propamocarb hydrochloride are currently limited to applications to ornamentals and turf only, no dietary exposure to residues in food/feed commodities are expected.

b. Occupational Exposure

Use patterns

Propamocarb hydrochloride is likely to be applied by occupational pesticide handlers, rather than homeowners, with tractor-drawn groundboom sprayers, backpack sprayers, high-volume/low-pressure sprayers (commercial-lawn), low-pressure hand-wand sprayers, high-pressure hand-wand sprayers, hose-end sprayers, hand-held sprinkler cans, and as a hand-dip application to transplants. Applications can be made as often as every seven days.

Handler (Mixer/Loader/Applicators) Exposure

The Agency believes there is potential exposure to occupational handlers during mixing/loading/application of propamocarb hydrochloride products using groundboom sprayers, high volume/low-pressure sprayers, low pressure handwand sprayers, high pressure handwand sprayers, backpack sprayers, water-hose-end sprayers, hand-held sprinkler cans, and transplant dip by hand.

The current product registration is used solely by occupational pesticide handlers. However, since there are no label restrictions limiting the product's use in this manner, the Agency included homeowner applications in its exposure and risk assessments.

The generic data from the Agency's Pesticide Handler Exposure Database (PHED) is used to determine the potential exposure values for the specified uses of propamocarb hydrochloride. PHED is a compilation of acceptable exposure studies conducted by registrants with different pesticide chemicals and for a variety of mixing, loading and application scenarios. Thus, the Agency can apply this data base as a surrogate, if necessary. The data base provides the Agency with low to high confidence in the estimates using the different application methods depending upon the number of replicates available for each application method. However, for certain uses, the Agency lacks data in PHED or from other sources to estimate exposures. These uses are high volume/low pressure sprays, hand-held sprinkler can, and transplant dips (by hand).

Exposure scenarios for mixer/loader/applicators using the different application methods are presented in Table 2 below.

Table 2: Summary of Exposure Values for Uses of Propamocarb Hydrochloride

Exposure Scenario	Dermal Unit Exposure[a] (mg/lb ai)	Inhalation Unit Exposure[b] (ug/lb ai)	Maximum Label Application Rate[c]	Daily Max. Treated[d]	Daily Dermal Exposure[e] (mg/day)		Daily Inhalation Exposure[f] (mg/day)	
					Homeowner	Occupational	Homeowner	Occupational
Mixer/Loader (Occupational Use Only)								
Mixing/Loading Liquids for Groundboom Application	0.04	1.2	8.2 lb ai/acre	80 acres	NA	26	NA	0.79
Applicator (Occupational Use Only)								
Groundboom Tractor	0.01	0.7	8.2 lb ai/acre	80 acres	NA	6.6	NA	0.46
Mixer/Loader/Applicator								
High Volume / Low Pressure Sprayer	No data	No data	No data	No data	NA	No data	NA	No data
Low Pressure Handwand	103	31	0.0094 lb ai/gal	4 gallons* 10 gallons**	3.9	9.7	0.0012	0.0029
High Pressure Handwand	3.4	117	0.0094 lb ai/gal	NA 1000 gallons**	NA	32	NA	1.1
Backpack Sprayer	3.4	30	0.0094 lb ai/gal	10 gallons* 40 gallons**	0.32	1.3	0.003	0.011
Garden Hose-End Sprayer	30.6	9.5	0.0094 lb ai/gal	10 gallons* 100 gallons**	2.9	29	0.00089	0.0089
Hand-held sprinkler can	No data	No data	No data	No data	No data	No data	No data	No data
Transplant Dip (by hand)	No data	No data	No data	No data	NA	No data	NA	No data

* Homeowner Use
** Occupational Use

[a] The baseline dermal unit exposure for occupational and homeowner use is based on a data set indicating the use of long pants, long sleeve shirt, and chemical resistant gloves during open pouring of liquids. The baseline dermal unit exposure for applicators is based on a data set indicating the use of long pants, long sleeve shirt, and no gloves, except chemical resistant gloves for occupational mixing/loading liquids for groundboom application. Dermal unit exposures are reported as the best fit mean.

[b] The baseline inhalation unit exposure values are based on a dataset indicating workers wearing no respirators during open pouring for mixer/loaders and open cab for tractor drawn applicators. Inhalation Exposure Values are reported as geometric means (lognormal distributions).

[c] Product label, Reg. No.45639-88

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day (8 hours) to complete treatments for each exposure scenario of concern.

[e] Daily Dermal Exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) X Max. Appl. Rate (lb ai/acre) X Daily Max. Treated (acre/day).

[f] Daily Inhalation Exposure (mg/day) = Inhalation Unit Exposure (mg/lb ai) X (1mg/1000ug) Units conversion X Max. Appl. Rate (lb ai/acre) X Daily Max. Treated (acre/day).

The Agency calculated estimates for dermal and inhalation exposures using the following formulae:

$$Daily\ Dermal\ Exposure\left(\frac{mg\ AI}{day}\right) = Dermal\ Unit\ Exposure\left(\frac{mg\ AI}{lb\ AI}\right) \cdot Max.\ Appl.\ Rate\left(\frac{lb\ AI}{Acre}\right) \cdot Max.\ Area\ Treated\left(\frac{Acres}{day}\right)$$

$$Daily\ Inhalation\ Exposure\left(\frac{mg\ AI}{day}\right) = Inhalation\ Unit\ Exposure\left(\frac{mg\ AI}{lb\ AI}\right) \cdot Max.\ Appl.\ Rate\left(\frac{lb\ AI}{Acre}\right) \cdot Max.\ Area\ Treated\left(\frac{Acres}{day}\right)$$

Post-Application Exposure

The Agency believes there is potential exposure to persons entering treated sites after application is complete. Post-application exposure may occur: (1) to agricultural workers entering areas of treated turfgrass being grown for sod or ornamentals grown in commercial or research nurseries and greenhouses; (2) to employees and the public in treated recreational areas (especially golf courses, the primary use of propamocarb hydrochloride); and (3) to homeowners following applications to turfgrass or ornamentals at residential sites.

The Agency does not have chemical-specific data available to address post application exposure for persons reentering areas treated with propamocarb hydrochloride.

3. Risk Assessment

a. Dietary

EPA did not conduct a dietary risk assessment for propamocarb hydrochloride since it is currently registered for non-food uses.

b. Occupational and Residential

Risk to Handlers (M/L/A)

To assess potential risks from the use of propamocarb hydrochloride, the Agency compared its estimates of dermal exposure in Table 2 (converted to mg/kg

body weight/day for a 60 kg person) to the toxicological endpoint NOEL of 150 mg/kg/day for intermediate term and short term exposure. These exposure estimates and this NOEL are described above. The ratio of the NOEL to the estimated exposure level is called the Margin of Exposure (MOE). MOE values of 100 or higher indicate to the Agency that the human health risks are low and are not generally a concern (when the NOELs are based on animal data).

MOEs were not calculated for the application scenarios of high volume/low pressure sprayer, handheld sprinkler can and transplant dip (by hand) due to the lack of exposure data. Also, EPA did not calculate MOEs for the inhalation exposure estimates because these values were considerably less than the dermal exposure estimates for all exposure scenarios and there was no identified toxicological inhalation endpoints of concern.

Table 3 below summarizes the corresponding risk assessment for the occupational uses of propamocarb hydrochloride.

Table 3: Summary of Risk Values for Uses of Propamocarb hydrochloride

Exposure Scenario	Daily Dermal Dose[c] (mg/kg/day)		MOE[d](dermal)	
	Homeowner[a]	Occupational[b]	Homeowner[a]	Occupational[b]
Mixer/Loader				
Mixing/Loading Liquids for Groundboom Application	NA	0.43	NA	350
Applicator				
Groundboom Tractor	NA	0.11	NA	1,400
Mixer/Loader/Applicator				
High Volume / Low Pressure Sprayer	NA	No data	NA	No data
Low Pressure Handwand	0.065	0.16	2300	930
High Pressure Handwand	NA	0.53	NA	280
Backpack Sprayer	0.0053	0.022	28,000	6,900
Garden Hose-End Sprayer	0.048	0.48	3,100	310
Hand-held sprinkler can	No data	No data	No data	No data
Transplant Dip (by hand)	NA	No data	NA	No data

Note: In comparison to the dermal route of exposure, inhalation exposure is estimated to be minimal.

[a] Long pants, long sleeve shirt, no gloves.
[b] Long pants, long sleeve shirt, no gloves, except chemical resistant gloves for mixing/loading of liquids for groundboom application.
[c] Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/60 kg body weight
[d] MOE(dermal) = NOEL (mg/kg/day) / Daily dermal dose (mg/kg/day). Endpoint and dose: 150 mg/kg/day (maternal NOEL for reduced body weight gain during days 6-18 of gestation, developmental NOEL for increased post-implantation loss in New Zealand White Rabbits and 21-day NOEL for decreased body weight gain in females. The dermal study supports the assumption of 100 percent dermal absorption.

Based on the estimate for dermal exposure, the MOE is greater than 100 for the occupational exposure scenario of mixing/loading the liquid formulation for groundboom applications. This use scenario is based on mixers/loaders wearing long sleeved shirts, long pants, and chemical resistant gloves. For all the other occupational and homeowner exposure scenarios for which MOEs could be calculated, the MOEs are greater than 100 without personal protective equipment other than long-sleeve shirt, long pants, and shoes and socks. As noted before, the Agency lacks exposure data for high volume/low pressure sprayer, sprinkler can and transplant dip (by hand) applications. The Agency is particularly concerned about the potential risk associated with the high volume/low pressure sprayer (commercial turfgrass sprayer) use and the hand-dip use, since these application methods may represent the greatest potential for propamocarb hydrochloride exposure. Details of these requirements are provided in Sections IV and V below.

Risk From Post-Application Exposures

There are no propamocarb hydrochloride chemical specific data available to the Agency to address post-application exposures for occupational and residential uses. However, the Agency believes that the risks from post-application exposures to treated turf (other than sod-farm turf) appear to be marginally acceptable. Since contact with the soil subsurface is unlikely at these sites, post-application risks should be adequately mitigated by restricting entry until the sprays have dried. Also, the risk to people from post-application exposures to treated ornamentals not being grown for research or commercial use (ornamentals in parks, ornamental gardens, interior plantscapes, etc.) should be adequately minimized by restricting entry until the treated surface has dried, since the degree of exposure of the people to residues remaining on such ornamentals should be relatively infrequent and generally of short duration.

The Agency also believes that the risks from post-application exposures to treated turf grown for sod and ornamentals (greenhouse and nursery) grown for sale may be unacceptable for entry immediately following applications. EPA assumes that post-application exposures will not pose an unreasonable risk to persons entering these treated areas, as long as entry is prohibited until 24 hours after application, as required under the Worker Protection Standard (WPS) and personal protective equipment is worn by workers who enter these treated areas before the REI has expired. Details of these requirements are provided in Sections IV and V below.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the acute hazard of propamocarb hydrochloride to nontarget terrestrial and aquatic organisms, but lacks data to assess chronic avian and aquatic invertebrate hazards. Available ecotoxicology studies suggest propamocarb hydrochloride is practically nontoxic to slightly toxic to birds, small mammals, freshwater and estuarine/marine fish and invertebrates. However, propamocarb hydrochloride is toxic to plants based on the limited terrestrial and aquatic plant studies.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

To establish the toxicity of propamocarb hydrochloride to birds, the following tests are required: one avian single-dose oral study (LD_{50}) on one species, preferably mallard or bobwhite quail; and two subacute dietary studies (LC_{50}). One study should use one species of waterfowl, preferably the mallard duck, and the other study should use one species of upland game bird, preferably bobwhite quail. Tables 4 and 5 present these study results.

Table 4: Avian Acute Oral Toxicity Findings (LD_{50})

Species	% A.I.	LD_{50} mg/kg	Toxicity Category	Fulfills Guideline Requirement
Ring-necked pheasant	70.0	2,998	Practically nontoxic	Partially
Northern Bobwhite	71.7	> 2,770	Practically nontoxic	Yes

Table 5: Avian Subacute Dietary Toxicity Findings (LC_{50})

Species	% A.I.	LC_{50} ppm	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	72.2	> 5,200	Practically nontoxic	Partially
Mallard	72.2	> 5,200	Practically nontoxic	Partially

These results suggest that propamocarb hydrochloride is practically nontoxic to avian species on an acute oral and subacute dietary basis (based on maximum dosage of 5,200 ppm). The guideline requirement for the acute oral study (LD_{50}) is fulfilled. However, the guideline requirement for the avian subacute dietary study (LC_{50}) is not fulfilled. This study is supplemental because the test material was unstable in avian test feed. Additional dietary toxicity testing with bobwhite and mallard duck may be required, pending the results of avian reproduction studies as described below. (MRIDs 93193007, 42567901, 42567902 and 42567903)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence or multiple applications. Use of propamocarb hydrochloride can result in several applications of the end-use product per growing season. Based on propamocarb hydrochloride use patterns, avian reproduction studies are being required. These studies are to be conducted at concentration levels reflecting maximum expected residue levels on turf following multiple applications (see terrestrial EEC calculations in the Exposure and Risk Characterization section).

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on several factors: results of the lower-tier studies, such as acute and subacute testing; the intended use pattern; and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} study is used to determine toxicity to mammals. Table 6 shows the lowest LD_{50} value for laboratory rats (66.5% - 70% aqueous solution) used in studies described above in the Human Health Assessment. (MRID 41278115)

Table 6: Mammalian Acute Oral Toxicity Findings

Species	LD_{50} mg/kg	Toxicity Category
Rat (male)	2,900	III
Rat (female)	2,000	III

The available mammalian data indicate that propamocarb hydrochloride is practically nontoxic to small mammals on an acute oral basis.

(4) Insects

A honey bee acute contact LD_{50} study is required if the use pattern results in honey bee exposure. No data are available to characterize propamocarb hydrochloride toxicity to bees. These data are being required because applications to field-grown ornamentals may result in honey bee exposure. However, if this use is deleted from the label, this study will not be required.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

To establish the toxicity of a pesticide to freshwater fish, the minimum data required are two freshwater fish toxicity studies. One study should use a coldwater species, preferably the rainbow trout, and the other should use a warmwater species, preferably the bluegill sunfish. Table 7 shows these test results from studies conducted with propamocarb hydrochloride.

Table 7: Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} ppm a.i.	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	72	> 99	Practically nontoxic	Yes
Bluegill sunfish	72	> 92	Practically nontoxic	Yes

The results of the 96-hour acute toxicity studies indicate that propamocarb hydrochloride is practically nontoxic to fish. The maximum dosage for the rainbow trout and bluegill sunfish was 99 ppm and 92 ppm, respectively. The guideline requirement is fulfilled. (MRIDs 42083103, 42083102)

(2) Freshwater Fish — Chronic

Fish early life-stage tests are required if the product is expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. Fish early life-stage tests also may be required if the actual or estimated environmental concentration in water resulting from pesticide use is less than 0.01 of any acute EC_{50} or LC_{50} value and the pesticide is persistent in water. Available data suggest that propamocarb hydrochloride is stable to hydrolysis. Based on the results of the fish early life-stage study, the corresponding guideline requirement is satisfied. Table 8 shows the results of the fish early life-stage tests conducted with propamocarb hydrochloride. (MRID 42083105)

Table 8: Fish Early Life-Stage Toxicity Findings

Species	% A.I.	NOEC (ppm) A.I.	LOEC (ppm) A.I.	MATC (ppm) A.I.	Endpoints Affected	Fulfills Guideline Requirements
Freshwater: Fathead minnow	72	6.3	13.0	9.0 ppm	dry weight	yes

A fish life-cycle test is required when an end-use product is expected to be transported to water from the intended use site, and/or when the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage test. The EECs for turf (following three or more applications) and ornamentals (based on a single 64 lb ai/A rate) are greater than one tenth of the NOEL in the fish early life stage (6.3 ppm). The study is required since the use of propamocarb hydrochloride is allowed for three or more applications to turf and ornamentals grown in fields of 10 acres or more. Thus, this guideline requirement has not been fulfilled under the current allowable use conditions.

(3) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate acute toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Table 9 shows the results of these tests. These data characterize propamocarb hydrochloride as practically nontoxic to aquatic invertebrates, on an acute basis. This guideline is fulfilled. (MRIDs 42567904, 93193013)

Table 9: Freshwater Invertebrate Acute Toxicity Findings

Species	% A.I.	EC_{50} (ppm)	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	72%	> 106 ppm	Practically nontoxic	Yes
Daphnia magna	70%	423 ppm	Practically nontoxic	Partially

Aquatic invertebrate life-cycle tests are required if the product is expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent, regardless of toxicity. These tests also may be required if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and the pesticide is sufficiently persistent to affect aquatic invertebrates in water (for example, if the $t_{1/2}$ is > 4 days). Available data suggest that propamocarb hydrochloride is stable to hydrolysis.

One study was conducted with *Daphnia magna*; however, several discrepancies were observed in the study which rendered the study unacceptable. These discrepancies include: 1) not all test concentrations were measured; 2) only half of the test animals were retained per concentration after day 6 (unhealthy or damaged ones were discarded); 3)

growth of the F1 daphnids was not measured and; 4) temperature was not monitored during the test. Therefore, a new invertebrate life-cycle study is needed.

(4) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is expected to reach the marine/estuarine environment in significant concentrations. The terrestrial non-food use of propamocarb hydrochloride on turf may result in exposure to the estuarine environment. The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. Table 10 presents these test results. (MRIDs 42083104, 41834604 and 41834603)

Table 10: Estuarine/Marine Acute Toxicity

Species	% A.I.	LC_{50}/EC_{50} (ppm)	Toxicity Category	Fulfills Guideline Requirement
Eastern oyster, Shell Deposition	72%	39.2	Slightly toxic	Yes
Mysid shrimp	72%	> 104.7	Practically nontoxic	Partially
Sheepshead minnow	72%	> 96.8	Practically nontoxic	Yes

There is sufficient information to characterize the acute toxicity of propamocarb hydrochloride to estuarine/marine organisms as slightly toxic to practically nontoxic. The guideline requirement for acute toxicity to mysid shrimp is not fulfilled because 3-day-old shrimp were used rather than $\underline{<}$ 24-hour old shrimp. However, the value of repeating the study is low in terms of the information to be gained. Therefore, the acute LC_{50} study with mysid shrimp does not need to be repeated.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence) is required for fungicides with terrestrial non-residential outdoor use patterns and/or those which may have endangered or threatened plant species associated with the application site. Tier 1 toxicity data on the typical end product (TEP) material (73.8% a.i. at the maximum application rate of 8.19 lb ai/A) indicate that propamocarb hydrochloride is toxic to terrestrial plants (MRID 41834606 and 41834607). Seedling emergence was affected in

45% of the wheat plants and 31.2% of the cucumber plants tested. Tier 1 testing is used as a coarse screen to determine whether a pesticide potentially poses sufficient risk to warrant higher level modelling. Tier 2 testing may be required when Tier 1 tests result in an effect. Subsequently, Tier 2 testing will provide an EC_{50} determination. The Tier 1 guideline requirements for terrestrial plants are fulfilled; however, because of the toxicity shown in the tests, Tier II emergence studies with wheat and cucumbers are required.

(2) Aquatic

Aquatic plant testing is required for any fungicide with outdoor non-residential terrestrial uses that may result in off-site movement through runoff (solubility > 10 ppm in water). No Tier 1 aquatic plant data are available. Table 11 presents results from Tier II toxicity testing using *Scenedesmus quadricauda* (green alga) and the TEP as the test material. *Scenedesmus quadricauda* is not a recommended species for Tier II testing; therefore, the guideline requirement is not fulfilled. The results indicate that at 70% ai, the 93-hour EC_{50} value is 301 mg ai/L. (MRID 41684302)

Table 11: Nontarget Aquatic Plant Toxicity

Species	% A.I.	$EC_{50\ (93\text{-hour})}$
Scenedesmus quadricauda	70	301 mg ai/L

A Tier I aquatic plant study with *Lemna gibba* is also being required. If the Tier 1 study shows effects, a Tier II study with *Lemna gibba* may be required to determine an EC_{50}.

2. Environmental Fate

The Agency has reviewed data from environmental fate studies of the persistence and mobility of propamocarb hydrochloride under laboratory and field conditions. The environmental fate data base for propamocarb hydrochloride for Terrestrial Nonfood Crop and Greenhouse Nonfood Crop use patterns is essentially complete. However, the environmental fate studies of hydrolysis, anaerobic aquatic metabolism and terrestrial field dissipation are of only supplemental quality due to deficiencies described below. The Agency has required the registrant under a separate letter to provide clarifications for these studies to confirm the findings and conclusions expressed in this document. The following environmental fate assessment is not expected to change appreciably with the confirmatory data.

a. Environmental Fate Summary

Persistence and mobility studies of propamocarb hydrochloride under laboratory and field conditions were reviewed and found to be either acceptable, partially acceptable and supplemental. The studies determining laboratory persistence (degradation and metabolism processes) indicate propamocarb hydrochloride is relatively non-persistent [half-life ($t_{1/2}$) ≈14 days], with degradation primarily through biotic processes such as microbial-mediated metabolism. Based on marginally acceptable information, abiotic hydrolysis is not a significant dissipation process; however, base-catalyzed hydrolysis may occur at extremely slow rates. From acceptable information on aqueous photolysis, propamocarb hydrochloride was reportedly stable to photodegradation in water. In an acceptable soil photolysis study, propamocarb hydrochloride was shown to photodegrade on soil with a $t_{1/2}$ of ≈35 days. Information provided by four acceptable aerobic soil metabolism studies suggests propamocarb hydrochloride degrades fairly rapidly by microbial-mediated metabolism, with a modal $t_{1/2}$ of 14 days and a range of seven to 30 days. Results of the anaerobic soil metabolism study suggest propamocarb hydrochloride is persistent to anaerobic metabolism with a $t_{1/2}$ of 459 days under the study's experimental conditions. In a supplemental anaerobic aquatic metabolism study, propamocarb hydrochloride was moderately persistent, with an experimentally determined $t_{1/2}$ of 55 days for a German sand sediment.

The mobility of propamocarb hydrochloride varies from mobile to relatively immobile. Propamocarb hydrochloride mobility appears to be a function of the pH and clay content (i.e., cation exchange capacity, or CEC) of the treated soil. According to the registrant, propamocarb hydrochloride is an organic base ($pK_a = 9.1$) that can be protonated in certain soil environments; therefore, increased adsorption may be observed with increasing clay content or CEC and decreasing soil Ph. Utilizing information in the submitted studies, no relationship with adsorption of propamocarb hydrochloride and soil organic matter content was observed. Information provided by the registrant indicate that the vapor pressure of propamocarb hydrochloride is 6.0×10^{-7} mm Hg (8.1×10^{-5} Pa; estimated Henry's Law Constant of 2.6×10^{-13}); therefore, volatilization is not considered a probable route of dissipation. Results of supplemental field dissipation studies in California and New York suggest propamocarb hydrochloride dissipates rapidly under field conditions with a DT_{50} (dissipation time of 50% of the material) ranging from 10-15 days. The bioaccumulation in fish study indicated limited potential for bioconcentration in sunfish, with BCFs of 1.5X and 3.0X for edible and nonedible tissues, respectively. Rapid, nearly complete depuration (seven to 10 days) was also observed in the bioaccumulation in fish study.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

The submitted study provides marginally acceptable data on the abiotic hydrolysis of propamocarb hydrochloride. Hydrolysis studies of [propyl-1-^{14}C]propamocarb hydrochloride suggest it is stable to abiotic hydrolytic degradation under elevated temperatures (50-90^{o} C) and pH extremes (pHs of 1, 12, 13 and 14). Although hydrolysis may occur under extremely alkaline conditions (pH 14), the rate of hydrolysis appears to be limited at ambient temperatures. Additional information using an OECD screening procedure to assess the potential for abiotic hydrolysis supports the researchers' assertion that propamocarb hydrochloride is resistant to abiotic hydrolysis in the pH 5-9 range at 25^{o} C.

The experimentally determined half-lives at pH 14 were 6,784 min (4.71 days) at 25^{o} C, 124 min at 70^{o} C, and 34 min at 90^{o} C. For the pH 13 test conditions, experimentally derived half-lives were 2,766 min (1.92 days) at 70^{o} C and 496 min (8.3 hours) at 90 C. The experimentally determined half-life at pH 12 (90^{o} C) was 4,127 min (2.87 days). Calculated half-lives for pH 5, 7, and 9 conditions at 25^{o} C were 1.26 x 10^{7}, 1.26 x 10^{5}, and 1.26 x 10^{3} years, respectively. [NOTE: Information on the accuracy of these theoretically determined half-lives is not available. Based on the experimentally determined half-life of 4.71 days for pH 14 at 25^{o} C, alkaline hydrolysis (i.e., at pH 9) may occur at a faster rate than indicated by the theoretical value.] The extrapolated half-life values were calculated using the experimentally derived activation energy and assuming "pure base catalysis" for propamocarb hydrochloride. The experiment conducted under extremely acidic conditions (pH 1) at 70^{o} C suggests propamocarb hydrochloride is stable in acidic environments. (MRID 00071297)

Photodegradation in Water

Propamocarb hydrochloride did not photodegrade in "heat sterilized" aqueous solutions maintained at ≈24^{o} C when exposed to artificial sunlight for a maximum of ≈22 days. No evidence of degradation by abiotic hydrolysis was reported for the dark controls. In a supplemental OECD Guideline study on the "Phototransformation of Chemicals in Water," propamocarb hydrochloride was presumed to be photolytically stable because measurements of the molar decadic absorption coefficients were < 3 l mol^{-1} cm^{-1} at wavelengths ≥295 nm in pH 4, 7, and 9 buffer

solutions. (MRID 00071296)

Photodegradation in Soil

Propamocarb hydrochloride photodegraded with a half-life of 35.4 days on loamy sand soil that was irradiated on a 16-hour daylight photoperiod with a dual-filtered xenon arc light for up to 31 days at 17-23° C. In contrast, propamocarb hydrochloride did not significantly degrade during 31 days of incubation in the dark. Only propamocarb hydrochloride was identified in the irradiated soil; three minor degradates were detected, each at ≤8.7% of the applied radioactivity. Material balances in the irradiated and dark control soil ranged from 82.7 to 98.7% and 93.3 to 97.5% of the applied, respectively. (MRID 41834608)

Aerobic Soil Metabolism

Propamocarb hydrochloride degraded with a graphically estimated half-life of 14 days in loamy sand soil treated at 200 mg/kg and incubated in the dark at 25° C and 75% of maximum water-holding capacity. Only propamocarb hydrochloride was identified in the soil; $^{14}CO_2$ was the major degradate which totaled > 70% of the applied at day 30 and 88.6% of the applied at 1 year post-treatment. Three minor degradates that comprised up to 1.3% (2.6 ppm), 0.4% (0.8 ppm), and 0.3% (0.6 ppm) of the applied were not identified. Unextracted [^{14}C]residues, plus [^{14}C]residues associated with the fulvic acid and humic acid soil fractions, increased to a maximum of 20.2% of the applied at 30 days post-treatment, then decreased to 11.9% at 12 months. Material balances ranged from 92.6 to 100.6% of the applied. (MRID 41278125)

Propamocarb hydrochloride degraded with an observed half-life of 14-30 days in a California loamy sand soil that was incubated in the dark at 25° C and 75% of maximum water-holding capacity. Only propamocarb hydrochloride was identified in the soil; $^{14}CO_2$ was the major degradate and totaled 88.5% of the applied at 1 year post-treatment. Three minor degradates that comprised up to 0.9% (1.8 ppm), 0.8% (1.6 ppm), and 0.2% (0.4 ppm) of the applied were not identified. Unextracted [^{14}C]residues, plus [^{14}C]residues associated with the fulvic acid and humic acid soil fractions, increased to a maximum 37.5% of the applied at 14 days post-treatment, then decreased to 11.3% at 12 months. Material balances ranged from 88.4 to 99.8% of the applied. (MRID 41278126)

Propamocarb hydrochloride degraded with a half-life of seven to 13 days in loamy sand soil that was treated at 200 mg/kg and incubated in the dark at 25° C and 75% of maximum water-holding capacity. Only

propamocarb hydrochloride was identified in the soil; $^{14}CO_2$ was the major degradate and totaled 80.0% of the applied at 46 days. Six minor degradates that comprised up to 1.40% (2.8 ppm), 1.10% (2.2 ppm), 0.86% (1.72 ppm), 0.78% (1.56 ppm), 0.37% (0.74 ppm), and 0.20% (0.4 ppm) of the applied were not identified. Unextracted [^{14}C]residues increased to a maximum 23.4% of the applied at 13 days post-treatment, then decreased to 14.55% at 46 days. Material balances ranged from 93.2 to 102.7% of the applied. (MRID 41278127)

Propamocarb hydrochloride degraded with a graphically estimated half-life of 12-13 days in loamy sand soil treated twice at 200 mg/kg (total application of 400 mg/kg) and incubated in the dark at 25° C and 75% of maximum water-holding capacity. Only Propamocarb was identified in the soil; $^{14}CO_2$ was the major degradate, which totaled ≈55% of the applied at day 31 and 66% of the applied at 87 days post-treatment. Material balances declined from 89.3% of the applied at three days post-treatment to 76.2% at 56 days. (MRID 41278128)

Anaerobic Soil Metabolism

Propamocarb hydrochloride degraded with a half-life of 459 days in anaerobic (flooded with water plus nitrogen atmosphere) loamy sand soil that was incubated in the dark at 25° C. The major degradation products were unextracted residues and evolved $^{14}CO_2$; three unidentified degradates were isolated, each at ≤2.0% of the applied. Unextracted [^{14}C]residues plus NaOH-extracted [^{14}C]residues ranged from 4.3% to 8.1% of the applied during the study. Material balances decreased from 96.5% of the applied at seven days post-treatment to 84.3% at 180 days. (MRID 41278129)

Anaerobic Aquatic Metabolism

[Propyl-1-^{14}C]propamocarb hydrochloride (radiochemical purity > 95%), at 200 ppm, degraded with a half-life of 54.8 days in anaerobic (flooding plus nitrogen atmosphere) sand sediment that was incubated in the dark at 25° C for 180 days. Propamocarb hydrochloride comprised 87.3% of the applied radioactivity (sediment plus flood water) at three days post-treatment (first sampling interval), 66.5% at 32 days, 44.8% at 60 days, 22.6% at 102 days, and 2.6% at 180 days. Four unknowns, I, II, III, and IV, were isolated. Unknowns I and II were detected at maximums of 0.80% (1.60 ppm) and 0.72% (1.44 ppm) of the applied, respectively. At 180 days post-treatment, unknowns II, III, and IV were a combined 11.22% of the applied (22.44 ppm).

Evolved $^{14}CO_2$ was the major degradate, totaling 33.1% of the applied radioactivity at 180 days post-treatment. Unextracted [^{14}C]residues plus NaOH-extracted [^{14}C]residues increased to a maximum 3.46% of the applied at 102 days post-treatment, then decreased to 2.36% at 180 days. Material balances were 91.8-95.1% of the applied at three to 14 days post-treatment, decreased to 83.2% by 60 days, and were 51.0% at 180 days. (MRID 00071465)

The study was determined to be unacceptable for the following reasons: 1) the material balances were incomplete; up to 49.0% of the applied radioactivity was unaccounted; 2) no information was provided to ascertain if the experiment was conducted under anaerobic conditions (e.g. Eh-pH measurements, Eh is the oxidation reduction potential measured in millivolts); and 3) the limited information provided suggests the experimental conditions were aerobic at the onset of the study. The guideline requirement is not fulfilled.

Photodegradation in Air

No studies were reviewed. The reported vapor pressure of propamocarb hydrochloride is 6.0×10^{-7} mm Hg (8.1×10^{-5} Pa; estimated Henry's Law Constant of 2.6×10^{-13}). Therefore, volatilization and subsequent photolysis in the atmosphere are not considered probable routes of dissipation.

(2) Mobility

Mobility (Batch Equilibrium)

Propamocarb hydrochloride is mobile to relatively immobile in sand, loamy sand, and sandy loam soils with Freundlich K_{ads} values of 0.67-5.20. Freundlich K_{ads} values were 0.67 for the sand soil (German standard soil 2.1), 0.85 for the loamy sand soil (German standard soil 2.2), and 5.20 for the sandy loam soil (Schering soil 170); respective K_{oc} values were 140, 41, and 359. The K_{des} values were 0.084-1.73 for the sand soil, 0.216-1.35 for the loamy sand soil, and 0.447-7.96 for the sandy loam soil. Material balances ranged from 91.5 to 100.3% of the applied radioactivity. According to the study authors, propamocarb hydrochloride is protonated in soil environments to form a positively charged (i.e., cationic) species. Therefore, adsorption increased with increasing soil clay content and CEC, and decreasing pH. No relationship with adsorption of propamocarb hydrochloride and soil organic matter was observed. (MRID 41278130)

Mobility (Soil Column Leaching)

Based on column leaching studies, [^{14}C]propamocarb hydrochloride was very mobile (51.9-60.5% of applied radioactivity in leachates) in 30-cm columns of German "Speyer" sand soil (soil 2.1) treated with 21 mg (107 kg ai/ha) of [propyl-1-^{14}C]propamocarb hydrochloride and leached with 60 cm of water. [^{14}C]Propamocarb hydrochloride was relatively immobile (≤0.07% in leachates and 85.8-88.0% throughout the upper 20 cm of columns) in German loamy sand soil (soil 2.2) and (≤0.11% in leachates and 74.9-80.9% in upper 6 cm of columns) in California loamy sand soil. Material balances ranged from 91.8 to 97.9% of the applied radioactivity in the German sand soil, 86.4 to 88.8% in the German loamy sand soil, and 79.9 to 81.0% in the California loamy sand soil. (MRID 41278132)

Mobility (Soil Thin Layer Chromatography)

Based on soil thin layer chromatography (TLC) studies and Helling's classification system, unaged [^{14}C]propamocarb hydrochloride had low mobility (average frontal R_f 0.20-0.33) in a sand, sandy loam, and one loamy sand soil, and was immobile (average frontal R_f 0.04) in a second loamy sand (Schering soil 165) soil that had been sieved through 0.2-mm mesh screen. However, soil TLC was not an appropriate method to determine mobility because unaged propamocarb hydrochloride did not migrate as a distinct spot, but streaked throughout a large R_f range for the sand, sandy loam, and loamy sand (German standard 2.2) soils.

This study is supplemental because the soils were sieved through a 0.2-mm mesh screen rather than the typical 2.0-mm mesh screen; therefore, it is possible that a considerable portion of the sand fraction (0.2-2.00 mm) may have been removed. According to the particle size scale used by the study authors, the coarse sand fraction (0.2-2.0 mm) was removed by sieving with a 0.2-mm screen. (MRID 41278131)

Mobility (Aged Soil Column Leaching)

Aged (30 days) residues of [propyl-1-^{14}C]propamocarb hydrochloride were very mobile (38.2-47.5% of applied radioactivity in leachates) in 30-cm columns of sandy loam soil (German Hatzenbuhl soil) that were leached with 22.5 inches (57 cm) of water. It was reported that only parent propamocarb hydrochloride was detected in the leachates and soil extracts, but analytical data were not provided to verify the identification of either parent propamocarb hydrochloride or its degradates. Recovered radioactivity was evenly distributed among the various soil column segments. Material balances ranged from 73.1 to 81.8% of the applied radioactivity. In loamy sand (German Neuhofen soil) soil columns,

aged (30 days) residues of [^{14}C]propamocarb hydrochloride appeared to be relatively immobile (0.39-1.96% of the recovered radioactivity in leachates and 8.1-10.9% in upper 4-5 cm of columns). Material balances were 10.4-15.1% of the applied radioactivity following leaching.

This study is supplemental because the experimental methodology was not sufficiently described; it was not specified if the aged samples were analyzed for propamocarb hydrochloride and degradates; and it was not clear if the material balances were calculated based on the radioactivity applied to the soil prior to aging, or based on the radioactivity remaining on the aged material that was applied to the columns.

Volatility - Laboratory and Field

No studies were reviewed. The reported vapor pressure of propamocarb hydrochloride is 6.0×10^{-7} mm Hg (8.1×10^{-5} Pa (Pascals); estimated Henry's Law Constant of 2.6×10^{-13}); therefore, volatilization is not considered a probable route of dissipation.

(3) Bioaccumulation in Fish

Propamocarb hydrochloride residues did not significantly accumulate in bluegill sunfish exposed to propamocarb hydrochloride at 1.0 ppm for 28 days. Maximum bioconcentration factors were 1.5X in edible tissues and 3.0X in nonedible tissues. During the exposure period, mean total [^{14}C]residues in the treated water ranged from 1.06 to 1.14 ppm. Depuration was rapid; propamocarb hydrochloride residues were not detected in the fish tissues by days seven to 10 of the depuration period. (MRID 41278114)

(4) Field Dissipation

Propamocarb hydrochloride dissipated with half-lives of 10.2 and 15.2 days in the upper 8 cm of turf plots (80 x 80 feet) of sandy loam soil in New York and California, respectively, following four applications (seven-day intervals) of propamocarb hydrochloride (Banol SC/L; 722 g ai/L) at 8.97 kg ai/ha/application (36 kg ai/ha total) in early August 1990. Limited detections of propamocarb hydrochloride were observed to > 91 cm at the New York site and up to 46 cm at the California site. Propamocarb hydrochloride was detected in several subsurface soil samples at various concentrations during different sampling times, which suggests sample contamination from improper sampling techniques. However, no soil sampling information was given to help evaluate this potential problem.

This study is supplemental because the soil at the New York site was not sampled deep enough to define the potential for propamocarb hydrochloride to leach under field conditions; thus, the corresponding guideline requirement is not satisfied. Therefore, the problems with the portion of this study conducted in New York cannot be resolved with the submission of additional data. To be able to use the portion of this study conducted at the California site toward fulfilling the terrestrial field dissipation data requirement, the registrant must submit acceptable freezer storage stability data demonstrating that propamocarb hydrochloride is stable in soil during the maximum storage interval that the field soil samples were stored from sampling to analysis. Also, the registrant should describe the soil sampling procedures and provide the missing field test data. This information has been requested of the registrant. (MRID 42421202)

(5) Spray Drift

These studies may be required when human or ecological toxicological considerations are indicated. The registrant is a participating member of the Spray Drift Task Force (SDTF). Information regarding spray drift of propamocarb hydrochloride should be provided upon completion of the SDTF data base. Information on spray drift of propamocarb hydrochloride from ground application may be estimated from the forthcoming results of the SDTF studies.

c. Water Resources

Based on the environmental fate assessment for propamocarb hydrochloride with consideration of the product formulation and application rates, the Agency believes use of propamocarb hydrochloride will not pose serious concerns for either groundwater or surface water media.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Agency uses the Levels of Concern (LOC) as criteria to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. To determine if an LOC has been exceeded, a risk quotient is derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate

exposure estimate by an appropriate toxicity test effect level, such as the LC_{50} for acute effects or NOEL for subchronic or chronic effects.

Typical acute effect levels are:

EC_{25} for terrestrial plants,
EC_{50} for aquatic plants and invertebrates,
LC_{50} for fish and birds, and
LD_{50} for birds and mammals.

Chronic test results are:

- for avian and mammalian reproduction studies, the no observed effect level (NOEL) or concentration (NOEC); and

- for chronic aquatic studies, either the NOEC or the maximum allowable toxicant concentration (MATC). The MATC is the geometric mean of the NOEC and the lowest observable effect concentration (LOEC).

When the risk quotient exceeds the LOC, the Agency presumes there is potential risk to that category. The Agency's risk presumptions and the corresponding LOCs are shown in Tables 12, 13 and 14.

Table 12: Levels of Concern (LOC) and Associated Risk Presumption: Mammals and Birds

If the	LOC	Presumption
acute RQ >	0.5	High acute risk
acute RQ >	0.2	Risk that may be mitigated through restricted use
acute RQ >	0.1	Endangered species may be acutely affected
chronic RQ >	1	Chronic risk - Endangered species and other non-target species may be chronically affected

Table 13: Levels of Concern (LOC) and Associated Risk Presumption: Fish and Aquatic Invertebrates

If the	LOC	Presumption
acute RQ >	0.5	High acute risk
acute RQ >	0.1	Risk that may be mitigated through restricted use
acute RQ >	0.05	Endangered species may be acutely affected
chronic RQ >	1	Chronic risk - Endangered species and other non-target species may be affected

Table 14: Levels of Concern (LOC) and Associated Risk Presumption: Plants

If the	LOC	Presumption
RQ >	1	High risk - Endangered plants and other non-target plants may be affected

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

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds -- Turf

Residues found on dietary food items following propamocarb hydrochloride application may be compared to LC_{50} values to predict hazard. The table below demonstrates for the turf use, the maximum concentration of propamocarb hydrochloride residues that may be expected on selected avian and mammalian dietary food items following both single and multiple applications. The resulting avian risk quotients are shown in Table 15.

Table 15: Estimated Environmental Concentrations (EEC) for Avian and Mammalian Dietary Food Items in ppm and Avian Risk Quotients (RQ) based on the EECs for turf/the highest test concentration in the LC_{50} studies, 5,200 ppm

Food items	EEC (ppm) (1 application of 8.19 lbs ai/acre)	EEC (ppm) (3 appls. of 8.19 lbs ai/acre or 6 appls. of 4.1 lbs ai/acre with no degradation)	RQ (single 8.19 lb ai/acre appl.)	RQ (multiple applications)
Short grass	1,966	5,898	< 0.38	< 1.1
Long grass	901	2,703	< 0.17	< 0.5
Broadleaf/ Insects	1,106	3,318	< 0.21	< 0.6
Fruit/Seeds	123	369	< 0.02	< 0.06

Precise LC_{50} values were not determined in the avian dietary studies summarized in Table 15 because concentrations were not high enough to cause 50% mortality. The highest concentration tested (5,200 ppm) was used in the risk quotient calculations. Propamocarb hydrochloride may be applied to turf at a maximum rate of 4 fluid oz per 1000 sq ft. This is equivalent to 8.2 lbs ai/acre. The EECs following three applications at 8.19 lbs ai/acre

or 6 applications at 4.1 lbs ai/acre to turf (no degradation) are calculated to reach a maximum of 5,898 ppm. This residue level exceeds the highest test concentration in the avian dietary studies. However, the risk is uncertain because of several factors, including:

- although LC_{50} values were not determined in the avian dietary toxicity studies, they were higher than the values used in the risk quotients;

- the test material was unstable in avian test feed; and

- available residues on turf in the environment may be lower than the maximum calculated EECs because of dissipation and mowing.

No avian reproduction studies are available. However, based upon developmental and reproductive effects demonstrated in rats (including fetal death at low doses in developmental toxicological studies), chronic effects in avian organism may be expected. Therefore, the effects of propamocarb hydrochloride on avian reproduction needs to be evaluated for the turf use which may involve multiple applications. The avian reproduction studies will enable the Agency to evaluate chronic risks to birds to better clarify the acute risk for birds.

(b) Birds — Ornamentals

The use of propamocarb hydrochloride on ornamentals grown in greenhouses and pots within nurseries does not pose a risk to birds since there is no expected exposure. However, propamocarb hydrochloride may be applied to field-grown ornamentals at a maximum rate of 0.0147 lbs ai/10 sq ft. This is equivalent to 64 lbs ai/acre.

Table 16 shows the maximum concentrations of propamocarb hydrochloride residues that may be expected on selected avian or mammalian dietary food items following a single application of 64 lb ai/acre to ornamentals and the resulting avian risk quotients. The risk quotients exceed high risk LOCs for birds. However, the registrant has proposed to amend their propamocarb hydrochloride label to eliminate the field-grown ornamental use. Thus, the Agency believes this action will mitigate the LOC exceedance for birds.

Table 16: Estimated Environmental Concentrations (EEC) for Avian or Mammalian Dietary Food Items in ppm and Risk Quotients (RQ) based on the EECs for ornamentals/the highest test concentration in the LC_{50} studies, 5,200 ppm

Food items	EEC (single application) (64 lbs ai/A)	RQ
Short grasses	15,360	< 3.0
Long grasses	7,040	< 1.4
Broadleaves/insects	8,640	< 1.7
Fruits/seeds	960	< 0.2

(c) Mammals

Risk to small mammals is assessed using the acute oral LD_{50} value of 2,000 mg/kg, the body weight of the animal in grams and the food consumption in grams per day. The estimated LC_{50} is derived using the following formula, and approximates the dietary toxicity for the animal:

$$LC_{50} = \frac{LD_{50} \text{ x body weight (g)}}{\text{food consumption per day (g)}}$$

Table 17 lists the estimated LC_{50}s.

Table 17: Small Mammal Food Consumption in ppm based on a laboratory rat LD_{50} value of 2,000 mg/kg *

Small Mammal	Body Weight (grams)	% of Weight Eaten/Day	Food Consumed/ Day (grams)	Estimated LC_{50}/ Day (ppm)
Meadow vole	46	61%	28.1	3,274
Oldfield mouse	13	16%	2.1	12,381
Least shrew	5	110%	5.5	1,818

* D. E. Davis and F. Golly. Principles of Mammology. Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the residues (EECs) to calculate the mammalian risk quotient (EEC/LC_{50}). Table 18 indicates the mammalian risk quotients for the turf (8.19 lb a.i./A) and field-grown ornamental uses (64 lb a.i./A).

Table 18: Mammalian Dietary Risk Quotients

Small Mammal	Dietary RQ *	
	8.19 single application (lbs. a.i./A)	64 single application (lbs. a.i./A)
Meadow vole consuming range grasses	0.6	4.7
Oldfield mouse consuming seeds	0.01	0.06
Least shrew consuming forage and insects	0.3	2.0

* Dietary RQ = EEC/lowest estimated LC_{50}

Small mammals are potentially at high acute risk for use of propamocarb hydrochloride on both turf and ornamentals. For mice, the marginally exceeded LOCs calculated assume maximum use and that propamocarb hydrochloride does not break down. The use of propamocarb hydrochloride on ornamentals grown in greenhouses and pots within nurseries does not pose a high risk to mammals.

(d) Insects

No data are available to assess the risk of propamocarb hydrochloride to non-target insects.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations

Propamocarb hydrochloride is slightly toxic to practically nontoxic to the aquatic organisms tested to date. Table 19 lists the EECs calculated using the Generic Expected Environmental Concentration Program (GENEEC). GENEEC is a program to calculate both acute and chronic generic expected environmental concentration values. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, direct deposition of spray drift into the water body, and degradation of pesticide within the water body. For turf and field-grown ornamental uses, the estimates were based on runoff from a 10 hectare field to a one hectare x two meter deep pond. These generic EECs take into account degradation in the field prior to a rain event. The following environmental fate parameters were used in the model: soil K_{OC}, 50.0; solubility, 50,000 ppm; aerobic soil metabolism half-life, 14 days; hydrolysis, 0; photolysis

in water, 0; aquatic metabolism, 0. EECs for the turf use were calculated for one application and three applications seven days apart.

Table 19: Estimated Environmental Concentrations (EECs) using GENEEC

Crop	Application Method	Application Rate (lbs a.i./A)	Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Turf: one application	ground	8.19	353	352	351	347
Turf: three applications	ground	8.19	862	861	857	849
Ornamentals: one application	ground	64	2,760	2,750	2,740	2,710

(a) Freshwater Fish

As presented above in Table 13 (Levels of Concern [LOC] Associated Risk Presumption: Fish and Aquatic Invertebrates), the Agency's acute and chronic LOC for freshwater fish are met or exceeded if the RQ $\geq$ 0.5 to 1.0, respectively. For propamocarb hydrochloride, the acute and chronic LOCs for freshwater fish are not exceeded for any current use. For reasons previously discussed, the precise LC_{50} values for freshwater fish were not determined in the studies; therefore, the highest test concentrations in the acute fish studies were used in the risk quotient calculations. These were 92.0 and 99.0 ppm for bluegill sunfish and rainbow trout, respectively. The chronic MATC is 9.0 ppm. Table 20 provides the acute and chronic risk quotients for freshwater fish.

Table 20: Risk Quotients (RQ) for Freshwater Fish

Crop/application rate	Species	Acute RQ (96-hr) (EEC/highest test concentration)	Chronic RQ (60-day) (EEC/MATC)
Turf/8.19 lbs ai/A (one application)	Bluegill Rainbow trout Fathead minnow	< 0.004 < 0.004 -	- - 0.04
Turf/8.19 lbs ai/A (three applications)	Bluegill Rainbow trout Fathead minnow	< 0.01 < 0.005 -	- - 0.07
Ornamentals/64 lbs ai/A (one application)	Bluegill Rainbow trout Fathead minnow	< 0.03 < 0.03 -	- - 0.31

(b) Freshwater Invertebrates

The use of propamocarb hydrochloride does not exceed the acute endangered species LOCs for freshwater invertebrates (RQ > 0.05), as shown in Table 21 below. No chronic toxicity data for freshwater invertebrates are available for use in a risk assessment.

Table 21: Risk Quotients (RQ) for Freshwater Invertebrates (48 hr. EC_{50} = 106 ppm)

Crop/application rate	Species	Acute RQ (48-hr) (EEC/highest test concentration)	Chronic RQ (21-day) (EEC/MATC)
Turf/8.19 lbs ai/A (one application)	*Daphnia magna*	0.003	N/A
Turf/8.19 lbs ai/A (three applications)	*Daphnia magna*	0.005	N/A
Ornamentals/64 lbs ai/A (one application)	*Daphnia magna*	0.03	N/A

(c) Estuarine and Marine Animals

For the turf use, the acute LOCs for estuarine and marine animals are not exceeded. However, following propamocarb hydrochloride applications to 10-acre plots of field grown ornamentals, the high risk LOC (Acute RQ for oyster = 0.70) is exceeded. The precise LC_{50} values for sheepshead minnow and mysid shrimp were not determined in the studies. Therefore, the highest test concentrations in the studies were used in the risk

quotient calculations. These were 96.8 and 104.7 ppm for sheepshead minnow and mysid shrimp, respectively. The EC_{50} value for the eastern oyster is 39.2 ppm.

Table 22 presents the acute risk quotients.

Table 22: Risk Quotients (RQ) for Estuarine and Marine Organisms

Crop/application rate	Species	Acute RQ (96-hr)
Turf/8.19 lbs ai/A (one application)	Sheepshead minnow Oyster Mysid	< 0.004 0.009 < 0.003
Turf/8.19 lbs ai/A (three applications)	Sheepshead minnow Oyster Mysid	< 0.005 0.015 < 0.005
Ornamentals/64 lbs ai/A (one application)	Sheepshead minnow Oyster Mysid	< 0.03 0.70 < 0.03

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-Aquatic

Tier 1 toxicity data on the typical end product (TEP) material (73.8% a.i. at the maximum application rate of 8.19 lb ai/A) indicate that propamocarb hydrochloride is toxic to terrestrial plants. Seedling emergence was affected in 45% of the wheat plants and 31.2% of the cucumber plants tested. Based on these results, movement of propamocarb hydrochloride off-target via runoff or spray drift may be expected to adversely affect non-target plants. However, risk quotients cannot be calculated for seedling emergence until Tier II studies are submitted. Such information will provide EC_{25} values to perform a plant risk assessment.

(b) Aquatic

Exposure to non-target aquatic plants may occur through runoff and drift. The Agency estimated EECs using the GENEEC program and estimated the toxicity using the 93-hour EC_{50} 301 ppm from the study with *Scenedesmus quadricauda* summarized above. Table 23 shows the resulting risk quotients for aquatic plants.

Table 23: EECs and RQ for Aquatic Plant Species

Use Site	Maximum Application Rate	Type of Plant	Type of EEC (GENEEC)	EEC (ppb)	Risk Quotient (EEC/EC_{50})
Turf	8.19 lbs ai/A (1 application)	Algae	runoff and 1% spray drift	353	0.001
Turf	8.19 lbs ai/A (3 application)	Algae	runoff and 1% spray drift	862	0.003
Ornamentals	64 lbs ai/A (1 application)	Algae	runoff and 1% spray drift	2,760	0.009

An algae risk assessment is a useful indicator to determine impact to food sources for fish, aquatic invertebrates, and waterfowl. Based on these risk quotients, there appears to be low risk to organisms relying on algae as a source of food. However, an additional Tier I aquatic plant test for *Lemna gibba* has been required (see section on toxicity to aquatic plants).

(4) Endangered Species

Endangered species LOCs have been exceeded for birds and mammals for the use of propamocarb hydrochloride on turf and field ornamentals. In addition, the LOCs for endangered marine animals (mollusks) have been exceeded for field-grown ornamentals. Application to woody ornamentals may also exceed endangered species LOCs depending on the application rate used.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing propamocarb hydrochloride active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing propamocarb hydrochloride, with modifications as specified in this document, and that the fungicide can be used without resulting in unreasonable adverse effects to humans and the environment. Therefore, the Agency concludes that products containing propamocarb hydrochloride for all uses, except the field-grown ornamental use plus the high volume/low pressure and hand dipping application scenarios, are eligible for reregistration. A reregistration decision cannot be made on the field-grown ornamental use plus the high volume/low pressure and hand dipping application scenarios due

to data deficiencies. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propamocarb hydrochloride, and lists the submitted studies that the Agency found acceptable.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of propamocarb hydrochloride are eligible for reregistration, with modifications as specified in this document, and with the exception of the field-grown ornamental use, 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 propamocarb hydrochloride, if new information comes to the Agency's attention, including the additional, required confirmatory generic data mentioned in this document, or if the data requirements for registration (or the guidelines for generating such data) change.

1. Uses Eligible or Not Eligible at This Time

The Agency has determined that all uses of propamocarb hydrochloride, with modifications specified herein, and with the exception of the field-grown ornamental use plus the high volume/low pressure and hand dipping application scenarios, are eligible for reregistration. A decision on the field-grown ornamental use plus the high volume/low pressure and hand dipping application scenarios cannot be made at this time due to data deficiencies. The registrant has requested the Agency to remove the field-grown ornamental use from its registration.

B. Regulatory Position

The Agency conducted its risk assessment of propamocarb hydrochloride based on the currently registered use patterns and available data. The following is a summary of the regulatory positions and rationales for propamocarb hydrochloride. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Use Deletion; Application Rate Reduction

During the drafting of this document, the registrant had submitted to EPA a proposal to amend their label by deleting the use of propamocarb hydrochloride for field grown ornamentals and limiting the use of the fungicide to 0.57 lb ai/1000 sq. ft. (equivalent to 25 lb ai/acre/year) of turfgrass per year. These modifications will reduce ecological exposures and risks. They also eliminate the requirements for a fish-life cycle and honey bee toxicity studies. The Agency will not require these studies for the remaining uses. However, if the propamocarb hydrochloride registration changes in the future, the Agency may impose these data requirements.

2. Generic Data Gaps

As discussed in Section III.B, the Agency sees a need for additional data. Requirements for mixer/loader/applicator (i.e., handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. Review of available exposure data for other pesticides indicates that these data still are not warranted for most scenarios. However, there are several scenarios for which there are no exposure data available, including application by high volume/low-pressure sprayers, by hand-dipping, and by sprinkling can. Therefore, EPA is requiring exposure data for the high volume/low-pressure spray equipment and for hand-dipping. For application by sprinkling can, the Agency anticipates that the amount of product handled using this technique would be less than that in the garden-hose-end scenario. Therefore, data are not required for application using a sprinkling can.

The available data on post-application exposure from pesticides are limited. Additional post-application/reentry exposure studies on propamocarb hydrochloride are required as confirmatory data to determine definitive REIs for sod-farm and greenhouse/nursery use sites. The interim REI established in the document (24 hours) will be adjusted, if necessary, upon Agency review of the additional data. In addition, confirmatory studies are required to determine the post-application exposure following applications to turfgrass at residential sites. Requirements for post-applications/reentry exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines.

Although gaps in the database as described above preclude the Agency from quantifying risk estimates for these scenarios, the Agency does not believe there are unreasonable risks during the time interval required to obtain these additional data. These data will be used to confirm its assumption of no unreasonable risks to handlers and those to enter treated sites. Data are not required for the other post-application exposure scenarios because it is anticipated that the exposure levels from these uses are lower than those in the greenhouse/nursery ornamental and two turfgrass scenarios.

Likewise, as noted in Section III.C, the missing data addressing potential chronic hazard to birds, aquatic invertebrates, plants and the environmental fate studies' deficiencies preclude conducting definitive chronic risk assessments for these non-target organisms. To address this, the Agency has directed the registrant to submit the appropriate studies. Although the Agency is anxious to address the potential for risk to these organisms, the Agency has decided that in consideration of propamocarb hydrochloride's known environmental fate and use characteristics, a finding of no unreasonable risk may be made at this time in the belief that when the missing information is evaluated it is not likely to be of a magnitude to change the basic regulatory findings expressed in this document.

3. Endangered Species

The LOCs have been exceeded for birds and mammals for the use of propamocarb hydrochloride on turf and field grown ornamentals. In addition, the LOCs for endangered marine animals (mollusks) have been exceeded for field-grown ornamentals. Application to woody ornamentals may also exceed endangered species LOC's depending on the application rate used. The registrant's proposed use deletion for field grown ornamentals and limiting the use of the fungicide to 0.57 lb ai/100 sq. ft. of turfgrass per year will mitigate these ecological exposures and risks.

4. Labeling Rationale

Scope of the Worker Protection Standards

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment [PPE], restricted entry intervals [REI], etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time, some of the registered uses of propamocarb hydrochloride are within the scope of the WPS and some uses are outside the scope of the WPS. Propamocarb hydrochloride uses within the WPS include:

- plants grown for commercial or research purposes,
- turf grown for commercial (sod farms) or research purposes.

Those that are outside the scope of the WPS include:

- plants grown for other than commercial or research purposes, which may include plants in habitations, and home greenhouses,

- plants, including turf, that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit.

Compliance With The WPS

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental

Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

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

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

Personal Protective Equipment/Engineering Controls for Handlers

At this time, there are no engineering control requirements, such as closed systems, currently required on labeling of the end-use product containing propamocarb hydrochloride. However, current labeling requires workers to wear long-sleeved shirt and long pants, waterproof gloves and shoes plus socks.

Occupational-Use Products

For each end-use product, personal protective equipment/engineering control requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the personal protective equipment (PPE) for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE or engineering-control requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Because the Agency has concluded there is a toxicity end-point for short and intermediate term occupational/residential exposure, which is beyond the acute toxicity of propamocarb hydrochloride, it is prudent to establish an active ingredient based minimum PPE/engineering control requirements for occupational handlers. Mixers/loaders for groundboom applications must wear chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes plus socks. For all other handler scenarios, PPE/engineering control requirements will be based on the acute toxicity of the end-use product.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

EPA has no basis at this time to establish a product-specific restricted-entry interval due to the lack of foliar dislodgeable residue dissipation, dermal passive dosimetry exposure, and inhalation passive dosimetry exposure data for residential or commercial use sites. These data are necessary for the Agency to definitively calculate the REIs for all use sites for which interim REIs have been established under the WPS.

Under the WPS, interim REI for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

For propamocarb hydrochloride, the Agency believes it is appropriate to set the interim REI for a longer period than that based on the acute toxicity of the chemical (12

hours). Since the Agency has identified toxicological endpoints of concern for short term and intermediated term occupational/residential exposure and post-application exposure data are not available, EPA is establishing a 24-hour REI and requiring data to confirm that the 24-hour REI will not result in unacceptable post-application exposure to persons reentering areas treated with propamocarb hydrochloride.

Early-Entry PPE:

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among the restrictions for workers entering treated areas is a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since EPA has identified toxicological endpoints of concern for short term and intermediate term occupational/residential exposure for propamocarb hydrochloride, the Agency is establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established based on the acute toxicity of the active ingredient. The PPE required for early entry is: coveralls over short-sleeve shirt and short pants, chemical-resistant footwear plus socks, chemical resistant headgear for overhead exposures, and chemical-resistant gloves. Since propamocarb hydrochloride is classified as toxicity category III for eye irritation potential, no protective eyewear is required.

NonWPS Uses

Since EPA has concerns about immediate (before sprays have dried) post-application exposures to persons from occupational uses outside the scope of WPS (turf, golf courses, residential lawns, and other recreational areas) it is establishing entry restrictions for all nonWPS uses of propamocarb hydrochloride end-use products. The Agency is requiring that such treated sites be dry before reentry. The Agency believes a 24-hour restriction, as it is imposing for the other uses, is not practical or feasible for the

sites of golf courses, other recreational areas and home lawns. When the Agency reviews the required confirmatory data specified above, it will adjust this REI as appropriate.

5. Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing propamocarb hydrochloride. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies additional data requirements, label changes, and any other modifications necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

As noted throughout this document, the Agency has identified studies for which additional information is needed and identified new studies which must be conducted. EPA believes these additional data are important for it to have a more comprehensive characterization of the potential hazards and exposures from propamocarb hydrochloride uses. In addition, the Agency will use these data to confirm the above estimated risks and its regulatory decision. Outstanding data have been required of the propamocarb hydrochloride registrant. The two required studies necessary to provide data on applicators during ground applications using high volume/low pressure spray equipment (commercial turfgrass) and for hand-dipping (ornamental) applications are a dermal exposure study, and an inhalation exposure study. These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same worker and at the same site during each trial. Foliar residue dissipation, post-application dermal passive dosimetry exposure and post-application inhalation dosimetry exposure are required. However, the post-application dermal passive dosimetry exposure and post-application inhalation dosimetry exposure studies for residential turf may be reserved at this time pending completion of the databases on agricultural and residential post-application/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Exposure Task Force, provided the registrant is a member of both Task Forces. In addition, the Agency has required avian reproduction, chronic aquatic invertebrate toxicity, aquatic plant growth, and seedling emergence.

The Agency has also identified deficiencies in studies addressing gene mutation, avian dietary, aquatic invertebrate life-cycle, hydrolysis, anaerobic metabolism, and terrestrial field dissipation. The registrant has been notified under a separate letter to upgrade these studies or to submit new studies.

2. Labeling Requirements for Manufactured Use Products

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

> "Only for formulation into a fungicide for the following use(s): ornamental sod farms (turf), ornamental lawns and turf, ornamental herbaceous plants, ornamental woody shrubs and vines, cutting beds, and seedling areas."

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

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. PPE Requirements for Pesticide Handlers

Sole active ingredient end-use products that contain propamocarb

hydrochloride must be revised to adopt the handler PPE requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

Multiple active ingredient end-use products that contain propamocarb hydrochloride must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on the current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended for Occupational Use

Minimum PPE requirements (WPS and nonWPS uses): The minimum PPE for all WPS and nonWPS uses for which groundboom applications can be employed is:

> "For groundboom applications, mixers and loaders must wear long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks".

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

PPE requirements for all other WPS and nonWPS uses: The PPE for all other WPS and nonWPS uses will be based on the acute toxicity of the end-use product. This PPE must be compared to the minimum (baseline) (PPE). The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

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

b. Reentry Requirements

Reentry Interval (REI for WPS uses): A 24-hour REI is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early reentry PPE requirements: The PPE label language required for early entry into WPS treated sites is:

"For early entry, wear coveralls over short-sleeve shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposures."

WPS Notification Statement (WPS uses): The following statement must be added to all end-use product labeling that contain directions for one or more WPS uses:

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

Placement in labeling: The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7. The double notification statement must be inserted into the Agricultural Use Requirements box in the location required by Supplement Three of PR Notice 93-7.

Entry restrictions for NonWPS uses: The Agency is establishing the following entry restrictions for all nonWPS occupational uses of propamocarb hydrochloride end-use products:

"Do not enter or allow others to enter the treated area until sprays have dried."

Placement in labeling:

If WPS uses are also on label, then follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate nonWPS entry restriction in that box. If no WPS uses are on label then add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading:

"Entry Restrictions:"

c. Engineering controls

The following engineering control statement is required on product labeling:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-

6), the handler PPE requirements may be reduced or modified as specified in the WPS."

d. Application restrictions

These additional use restrictions are required for propamocarb hydrochloride labels:

"Do not apply this product in a way that will contact workers, other people or pets, either directly or from drift. Keep people and pets out of the area during application. Only protected handlers may be in the area during application"

"Do not apply more than a total of 12 fl. oz. (equivalent to 0.57 lb/ai) of propamocarb hydrochloride per 1000 sq. ft. (25 lbs ai/acre/year) of turfgrass per year."

"Do not use for field-grown ornamentals."

e. User safety requirements

Add the following user safety requirement to the end-use product labeling ONLY if PPE (other than long-sleeve shirt, long pants, shoes, and socks) are required on the label due to the acute toxicity of the end-use product:

"Follow manufacturer's instructions for cleaning/maintaining protective clothing and equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash protective clothing and equipment separate from other laundry."

f. User safety recommendations

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

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

Add the following user safety recommendation to the end-use product labeling ONLY if PPE (other than long-sleeve shirt, long pants, shoes, and socks) are required on the label due to the acute toxicity of the end-use product:

- "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of

gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

C. Existing Stocks

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

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

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	# Apps Max. cycle	Min. Interv (days)	Restr. Entry Interv	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED										
ORNAMENTAL HERBACEOUS PLANTS							Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP			
Dip treatment., Potted., Not on label.	SC/L	NA	UC	*	NS	NS	NS / NS / NS / 0.5	CA		C46, C92, G82
Drench., Potted., Not on label.	SC/L	NA	6.409E-05 lb 1	*	NS	NS	NS / NS / 21 / 0.5 in. pot	CA		C46, C92, G82
Drench., Transplant bed., Not on label.	SC/L	NA	.001875 lb 1	*	NS	NS	NS / NS / NS / 0.5 sq.ft	CA		C46, C92, G82
Spray., Seed bed., Not on label.	SC/L	NA	.001055 lb 1	*	NS	NS	NS / NS / NS / 0.5 sq.ft	CA		C46, C92, G82
Spray., Transplant bed., Not on label.	SC/L	NA	.001055 lb 1	*	NS	NS	NS / NS / NS / 0.5 sq.ft	CA		C46, C92, G82
ORNAMENTAL LAWNS AND TURF							Use Group: TERRESTRIAL NON-FOOD CROP			
Spray., Foliar., Not on label.	SC/L	NA	.188 lb 1K sq.ft	*	NS	NS	NS / NS / NS / 0.5	CA		C46, C92, G82
ORNAMENTAL SOD FARM (TURF)							Use Group: TERRESTRIAL NON-FOOD CROP			
Spray., Foliar., Not on label.	SC/L	NA	.188 lb 1K sq.ft	*	NS	NS	NS / NS / NS / 0.5	CA, AZ		C46, C92, G82
USES NOT ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED										
ORNAMENTAL WOODY SHRUBS AND VINES							Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP			
Drench., Containerized., Not on label.	SC/L	NA	.001465 lb 1	*	NS	NS	NS / NS / 90 / 0.5 sq.ft	CA		C46, C92, G82

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

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

FORMULATION CODES
SC/L : SOLUBLE CONCENTRATE/LIQUID

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

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

USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
G82 : Do not feed treated clippings to domestic animals or graze treated areas.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AZ : Arizona
CA : California

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	Satisfied
61-2A	**Start. Mat. & Mnfg. Process**	All	41834601
61-2B	**Formation of Impurities**	All	41834601
62-1	**Preliminary Analysis**	All	41834601
62-2	**Certification of limits**	All	41834601
62-3	**Analytical Method**	All	41834601
63-2	**Color**	All	41834601
63-3	**Physical State**	All	41834601
63-4	**Odor**	All	41834601
63-5	**Melting Point**	All	41834601
63-6	**Boiling Point**	All	41834601
63-7	**Density**	All	41834601
63-8	**Solubility**	All	41834601
63-9	**Vapor Pressure**	All	41834601
63-10	**Dissociation Constant**	All	41834601
63-11	**Octanol/Water Partition**	All	41834601
63-12	**pH**	All	41834601
63-13	**Stability**	All	41834601
63-17	**Storage stability**	All	41834601

REQUIREMENT		USE PATTERN	CITATION(S)
63-18	**Viscosity**	All	41834601
63-19	**Miscibility**	All	41834601
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	C, I	42567901
71-1B	**Acute Avian Oral - Quail/Duck TEP**	C, I	42567901
71-2A	**Avian Dietary - Quail**	C, I	Data gap
71-2B	**Avian Dietary - Duck**	C, I	Data gap
71-4A	**Avian Reproduction - Quail**	C, I	Data gap
71-4B	**Avian Reproduction - Duck**	C, I	Data gap
72-1A	**Fish Toxicity Bluegill**	C, I	42083102
72-1B	**Fish Toxicity Bluegill - TEP**	C, I	42083102
72-1C	**Fish Toxicity Rainbow Trout**	C, I	42083103
72-2A	**Invertebrate Toxicity**	C, I	42567904
72-2B	**Invertebrate Toxicity - TEP**	C, I	42567904
72-3A	**Estuarine/Marine Toxicity - Fish**	C, I	42567904
72-3B	**Estuarine/Marine Toxicity - Mollusk**	C, I	42083104
72-3C	**Estuarine/Marine Toxicity - Shrimp**	C, I	41834604
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	C, I	42567904
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	C, I	42083104
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	C, I	41834604

Data Supporting Guideline Requirements for the Reregistration of Propamocarb Hydrochloride

REQUIREMENT		USE PATTERN	CITATION(S)
72-4A	**Early Life Stage Fish**	C, I	42083105
72-4B	**Life Cycle Invertebrate**	C, I	Data Gap
72-5	**Life Cycle Fish**	C, I	Data Gap
72-6	**Aquatic Organism Accumulation**	C, I	Waived
72-7A	**Simulated Field - Aquatic Organisms**	C, I	Waived
72-7B	**Actual Field - Aquatic Organisms**	C, I	Waived
122-1A	**Seed Germination/Seedling Emergence**	C, I	Data Gap
122-1B	**Vegetative Vigor**	C, I	41834607
122-2	**Aquatic Plant Growth**	C, I	Data gap
123-1A	**Seed Germination/Seedling Emergence**	C, I	Data gap
123-1B	**Vegetative Vigor**	C, I	Data gap
123-2	**Aquatic Plant Growth**	C, I	Data gap
124-1	**Terrestrial Field**	C, I	Waived
124-2	**Aquatic Field**	C, I	Waived
141-1	**Honey Bee Acute Contact**	C, I	Data gap
141-2	**Honey Bee Residue on Foliage**	C, I	Waived
141-5	**Field Test for Pollinators**	C, I	Waived
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	C, I	**41278115**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	C, I	**41278116**
81-3	**Acute Inhalation Toxicity - Rat**	C, I	**93193044**

Data Supporting Guideline Requirements for the Reregistration of Propamocarb Hydrochloride

REQUIREMENT		USE PATTERN	CITATION(S)
81-4	**Primary Eye Irritation - Rabbit**	C, I	**41278117**
81-5	**Primary Dermal Irritation - Rabbit**	C, I	**41278118**
81-6	**Dermal Sensitization - Guinea Pig**	C, I	**00083808**
81-8	**Acute Neurotoxicity - Rat**	C, I	**43103101**
82-1A	**90-Day Feeding - Rodent**	C, I	**00101638**
82-1B	**90-Day Feeding - Non-rodent**	C, I	**43044201**
82-2	**21-Day Dermal - Rabbit/Rat**	C, I	**42421201**
82-7	**90-Day Neurotoxicity - Rats**	C, I	**43013102, 43440902, 43440903, 43440904**
83-1A	**Chronic Feeding Toxicity - Rodent**	C, I	**00101638**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	C, I	**Waived**
83-3A	**Developmental Toxicity - Rat**	C, I	**93193042**
83-3B	**Developmental Toxicity - Rabbit**	C, I	**93103043**
83-4	**2-Generation Reproduction - Rat**	C, I	**Waived**
84-2A	**Gene Mutation (Ames Test)**	C, I	**Data gap**
84-2B	**Structural Chromosomal Aberration**	C, I	**41278122**
84-4	**Other Genotoxic Effects**	C, I	**41278124**
85-1	**General Metabolism**	C, I	**Waived**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	C, I	**Data gap**
133-3	**Dermal Passive Dosimetry Exposure**	C, I	**Data gap**
133-4	**Inhalation Passive Dosimetry Exposure**	C, I	**Data gap**

REQUIREMENT		USE PATTERN	CITATION(S)
231	**Estimation of Dermal Exposure at Outdoor Sites**		**Data gap**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	C, I	**Data gap**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	C, I	00071297
161-2	**Photodegradation - Water**	C, I	00071296
161-3	**Photodegradation - Soil**	C, I	41834608
162-1	**Aerobic Soil Metabolism**	C, I	41278125, 41278126 41278127, 41278128
162-2	**Anaerobic Soil Metabolism**	C, I	41278129
162-3	**Anaerobic Aquatic Metabolism**	C, I	00071465
163-1	**Leaching/Adsorption/Desorption**	C, I	41278130, 41278132, 41278131, 00071472
164-1	**Terrestrial Field Dissipation**	C, I	42421202

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of

your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

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

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data

requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions

will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

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

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

you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70

which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited

to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

PROPAMOCARB HYDROCHLORIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Propamocarb Hydrochloride. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Propamocarb Hydrochloride Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Ed Setren at (703) 308-8166.

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

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

RE: **Propamocarb Hydrochloride**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

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

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

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

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons

or provide information in support of my request. If the Agency approves my waiver request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

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

No toxicology batching is required.

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

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

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

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