United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA738-R-97-009 August 1997

Reregistration Eligibility Decision (RED)

PROPOXUR

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

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of receipt 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 Bonnie Adler (703) 308-8523.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

PROPOXUR

LIST B

CASE 2555

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

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PROPOXUR REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Dave Brassard	Biological Analysis Branch
Ed Brandt	Economic Analysis Branch
Wilfred Burr	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Kathy Monk	Science Analysis and Coordination Branch
Joanne Edwards	Ecological Effects Branch
Nelson Thurman	Environmental Fate and Groundwater Branch

Health Effects Risk Assessment

Tom Myers	Risk Characterization and Analysis Branch
Christine Olinger	Reregistration Support Chemistry Branch
Byron Backus	Toxicology Branch II
David Jacquith	Occupational and Residential Exposure Branch

Registration Support

Dennis Edwards	Insecticide-Rodenticide Branch
Meredith Johnson	Insecticide-Rodenticide Branch
Tina Levine	Registration Support Branch

Risk Management

Kathy Davis	Accelerated Reregistration Branch
Bonnie Adler	Accelerated Reregistration Branch
Margaret Rice	Reregistration Branch III

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

ABSTRACT

EPA has completed its reregistration eligibility decision for the pesticide propoxur and determined that all uses, when labeled and used as specified in this document, are eligible for reregistration. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. This decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3, 1996 are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

Propoxur is a carbamate insecticide used by homeowners and pest control operators (PCOs) to control ants, roaches, hornets and other pests in and around residences, commercial, industrial and institutional buildings, and in food handling establishments. Propoxur is also used on pets as a spray and in flea and tick collars. Product formulations include aerosols, baits, emulsifiable concentrates, wettable powders, ready-to-use solutions, impregnated shelf paper, and insecticidal strips and tapes.

Health Effects

Propoxur has been classified as a Group B_2, a probable human carcinogen. The Agency has calculated a unit risk, Q_1*, of 3.7×10^{-3} based on male rat bladder tumors. The RfD for propoxur has been established at 0.005 mg/kg/day. Because studies with propoxur indicate very low potential for dermal absorption, risk assessments for dermal exposures of any duration have not been conducted.

The available developmental and reproductive toxicity studies do not suggest any increased sensitivity of infants and children to propoxur from pre- and post-natal exposures. Based on reliable data, the Agency has determined that an additional safety factor is not warranted.

Residential/Occupational Exposure and Risk

In assessing the risk of cancer to the general population, EPA has assumed that some limited exposure to propoxur residues is possible from the diet, because propoxur is used in food

handling establishments. Exposure is also anticipated from propoxur use to control insects in and around the home. Drinking water exposure is not expected from current propoxur use patterns. When the dietary and residential uses are combined the aggregate cancer risk is 7.9×10^{-7}.

For non-cancer chronic dietary risk, exposures were calculated based on the proposed tolerance of 0.2 ppm for food that may be exposed to propoxur applied in food handling establishments and an assumption that 2% of these establishments were treated with propoxur. Calculated risk for both the general population (< 2% of the RfD) and the sub-population with the highest exposure, non-nursing infants, (< 8% of the RfD) are well within acceptable limits.

The only occupational endpoint of concern for propoxur is cancer. All occupational uses of propoxur have negligible cancer risks, except PCOs applying crack and crevice treatments which has an estimated cancer risk of 7.7×10^{-6}.

Environmental Fate, Ecological Effects and Risk

Although supplemental data indicated that propoxur is moderately persistent and highly mobile, current outdoor uses are limited, and exposure to the environment is expected to be minimal. Calculated risk quotients for the granular bait use exceed the Agency's acute level of concern (LOC) for avian species. However, the overall potential for avian exposure has been reduced by the 1992 deletion of the broadcast use on lawns and turf. Current use is limited to building perimeter applications. Minimal risk is expected to aquatic organisms from propoxur use on boat mooring lines.

Risk Mitigation

EPA is requiring the following personal protective equipment for PCOs applying propoxur to cracks and crevices: long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. The Agency believes that there are no other reasonable protective clothing requirements to further reduce risk to workers. EPA is restricting by-stander entry during application and re-entry until sprays have dried.

Under FIFRA, the Agency has concluded that the uses of propoxur, labeled and used as specified in this document, will not cause unreasonable risk to humans or the environment.

The Agency has assessed the pending tolerance for propoxur use in food handling establishments under the standards of FQPA and determined, based on available information, that there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to propoxur residues.

The Agency has not made a determination on whether propoxur and any other compounds have a common mechanism of toxicity for either cancer or non-cancer effects and require a cumulative risk assessment. Therefore, for the purposes of this Reregistration Eligibility Decision document, the Agency has considered only risks from propoxur. If required, cumulative risks

will be assessed when methodologies for determining common mechanism of toxicity and for performing cumulative risk assessment are finalized.

Before reregistering the products containing propoxur, the Agency is requiring that product specific data, revised Confidential Statement 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 multiple 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.

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of propoxur including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes propoxur, 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 propoxur. Section V discusses the reregistration requirements for propoxur. 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:** Propoxur
- **Chemical Name:** o-isopropoxyphenyl methylcarbamate
- **Chemical Family:** Carbamates
- **CAS Registry Number:** 114-26-1
- **OPP Chemical Code:** 47802
- **Empirical Formula:** $C_{11}H_{15}NO_3$
- **Trade and Other Names:** Baygon
- **Basic Manufacturer:** Bayer, AG

B. Use Profile

Propoxur is a residual carbamate insecticide registered for indoor applications and very limited outdoor applications. Indoor uses include residential, institutional, industrial, and commercial buildings, with uses permitted in food handling establishments and food processing plants as crack and crevice treatments only. Outdoor uses include structural perimeter applications, spot treatments to wasp nests and ant hills and insecticidal tape for boat mooring lines. Propoxur occurs in products as a single active ingredient as well as in combination with other pesticides.

An overview of the use sites and application methods for currently registered uses follows. Further details on these uses of propoxur are available in the table in Appendix A.

Type of Pesticide: Insecticide

Target Pests: Ants, cockroaches, fleas, bees, hornets, wasps, ticks, mosquitos, yellowjackets, and spiders.

Use Sites: Indoor non-food applications:

within homes, apartments, dwellings, on pets (flea collars and aerosol pet sprays); commercial, industrial, and institutional buildings

Indoor food areas:

limited to crack and crevice treatment in food areas of commercial, industrial, and institutional buildings and in food handling, storage, and processing facilities

Outdoors:

residential uses around home foundations, sidewalks, patios, and driveways; also spot treatments to wasps nests and ant hills. On building surfaces of commercial, industrial, and institutional structures. Insecticidal tape is used on boat mooring lines and in gypsy moth and medfly traps.

Formulation types and (range of percent of propoxur in formulation):

Ready to use liquid (0.5 - 1.1%), aerosol-liquid under pressure (0.25 - 2%), oil-soluble liquid, liquid concentrate (8 - 19.6%); pastes (2%), wettable powders (70%), solid baits (0.25 - 2%); pet flea collars (impregnated plastic) (0.4 - 10%), impregnated shelf papers (1%) and insecticidal tapes (10%).

Method of Application:

aerosol can: using actuator and injection tube; concentrated liquid: using compressed air sprayer, hand- or power-operated sprayer; wettable powder: using sprayer liquid - ready to use; using power operated or hand-pressurized sprayer; low-pressure sprayer oil-soluble liquid; sprayer

C. Estimated Usage of Pesticide

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

The following table summarizes the pesticide's use by market sector:

Estimates of Annual Propoxur Use (in lbs/ai)

Total use:	170,000 to 400,000

Professional Markets: 20,000 to 50,000

Consumer Markets: 150,000 to 350,000

D. Data Requirements

The reregistration Phase IV Data Call-Ins (DCIs) dated 12/13/91 and 4/21/92 included requirements for product chemistry, ecological effects, environmental fate, and residue chemistry. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Propoxur (Baygon) was first registered in the United States in 1963 for use as an insecticide by Chemagro (now known as Bayer). There are currently two registered technical products and several manufacturing-use only products. There are currently 173 products that contain propoxur registered by 67 companies.

Regarding the use of propoxur in food handling establishments, the Agency published definitions and a policy statement (38 FR 21685) in August, 1973. This FR Notice allowed the use of propoxur as well as other insecticides to continue in food areas of food handling establishments, with the provision that a petition to establish a tolerance for the use be submitted in the near future. In 1979, Bayer submitted a petition requesting a tolerance for use of propoxur in food areas of food handling establishments. In several reviews the Agency determined that additional data were needed to support the proposed tolerance. While much of these data have been submitted, the Agency was, at that time, unable to establish the tolerance (in Section 409) for food processing plants and food handling establishments under the Delaney Clause, because propoxur had been determined to be a carcinogen.

In December, 1987, the Agency issued a DCI to call in data needed to support the continued registration of propoxur products. The DCI required data to support the outdoor uses of propoxur as well as studies to examine potential risks to applicators and persons living in treated buildings. This notice was sent only to companies with manufacturing use products. None of the companies, including Bayer, the basic producer of propoxur, committed to support all of the uses registered at that time. At that time propoxur was registered for outdoor use as a premise spray, on turf, and for adult mosquito control. These uses were not supported and were deleted from labels.

In 1988, the Agency issued a preliminary notification (Grassley-Allen) letter to Bayer informing the company that propoxur was being considered for Special Review because of concerns about the potential carcinogenic risks to pest control operators and the

general public during indoor and outdoor applications of propoxur and risks to occupants of buildings treated with propoxur products.

In 1989, a DCI was issued to end-use producers after Bayer decided not to support the outdoor uses. These outdoor uses included ornamentals, lawns/turf, and mosquito control. None of the end-use producers elected to support these outdoor uses and the pertinent uses have been deleted from the labels. The remaining outdoor uses include residential uses around home foundations, sidewalks, patios, and driveways, spot treatments to wasp nests and ant hills, insecticidal tape on boat mooring lines and in gypsy moth and med fly traps.

In 1990, a Notice of Intent To Suspend (NOITS) was issued for certain propoxur registrations of indoor and outdoor aerosol spray, non-pressurized outdoor spray, granular bait and total-release fogger end-use products. Bayer failed to provide acceptable data after committing to provide exposure data for all uses except the fogger, which they declined to support. These exposure data were eventually provided and the suspensions lifted.

In January, 1995, the Agency issued a notice (60 FR 3210) proposing not to initiate a Special Review of the insecticide propoxur. The Agency had received and evaluated new exposure and carcinogenicity data on propoxur and determined that the uses which posed the greatest concern (flea dips and shampoos for pets, and total-release fogger products) had been eliminated through voluntary cancellation or label amendment. Therefore, the Agency believed that the estimated risks did not warrant initiation of a Special Review. The Agency issued a final decision not to initiate a Special Review in February, 1996 (61 FR 7508).

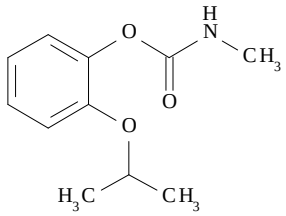
As discussed previously, the Food Quality Protection Act was signed into law on August 3, 1996. One of the components of the law set new standards for health-based risk assessments, in effect, replacing the Delaney Clause. Currently all tolerances, which had not been previously set due to the restrictions under the Delaney Clause, will need to be established.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Propoxur is a colorless crystalline solid with a melting point of ~90°C. It is readily soluble in methanol, acetone, dichloromethane, 2-propanol, toluene, and many organic solvents, but is only slightly soluble in cold hydrocarbons such as n-hexane. Propoxur is only slightly soluble in water (0.2% at 20°C) and is unstable under highly alkaline conditions. The vapor pressure is 1.29 mPa at 20°C.

Figure A. Propoxur [o-isopropoxyphenyl methylcarbamate]



Empirical Formula:	$C_{11}H_{15}NO_3$
Molecular Weight:	209.24
CAS Registry No.:	114-26-1
OPP Chemical Code:	047802

The Propoxur Phase IV Review determined that Bayer product chemistry data submissions for the 99.6% technicals met the acceptance criteria for Phase V review for GLNs 61-1, 62-3, 63-2, 63-3, 63-4, 63-9, and 63-11. Additional data were required for GLNs 61-2, 61-3, 62-1, 62-2, 63-5, 63-7, 63-8, and 63-13. These data have been submitted and are acceptable. No additional product chemistry data are required to support the technical and manufacturing-use products of propoxur.

B. Human Health Assessment

1. Toxicology Assessment

At present, the available toxicological database for propoxur is adequate and will support a reregistration eligibility determination.

a. Acute Toxicity

Results of the acute toxicity studies conducted with technical propoxur are summarized below in Table 1:

Table 1. Acute Toxicity Values of Technical Propoxur

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50} (♂) = 94 mg/kg LD_{50} (♀) = 68 mg/kg	II
Dermal	Rabbit	LD_{50} > 2000 mg/kg	III
Inhalation	Rat	LC_{50} > 0.5 mg/L	III
Eye Irritation[a]	Rabbit	Mild Irritant	III
Skin Irritation[a]	Rabbit	No Irritation	IV
Dermal Sensitization[a]	Guinea Pig	Non-sensitizer	N/A

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

In an oral LD_{50} study with rats, symptoms of muscle spasms and salivation, accompanied by dyspnea and apathy, occurred starting 1-10 minutes after administration at doses ≥ 50 mg/kg. These effects were not observed at the lowest dose of 10 mg/kg. The muscle spasms and salivation were consistent with cholinesterase inhibition. These symptoms cleared within 1-2 days, although the animals were, in some cases, "apathetic" for 5-6 days after dosage. Mortality occurred at the 50 mg/kg dose where 2/10 females died and 75 mg/kg dose where 2/10 males died. The LD_{50} is calculated to be 94 mg/kg for males and 68 mg/kg for females. These results place propoxur in Toxicity Category II (MRID 00152443).

In a dermal LD_{50} study with rabbits there were no mortalities among the 5 male and 5 female animals which received a 24-hour occluded dermal exposure of 2000 mg/kg. The test material was moistened with tap water before being applied to the rabbits. All 10 rabbits had muscular fasciculations suggestive of cholinesterase inhibition and there was decreased motor activity in 3 males and all females. These symptoms were observed on Day 0 but had resolved by Day 3 (MRID 40836401).

In an inhalation LC_{50} study in rats there were no mortalities among the 5 male and 5 female animals which were exposed for 4 hours to concentrations of 28.7, 110.1, 330.4 or 497.5 mg/m^3 propoxur. Test material was delivered in a vehicle composed of 50% polyethylene glycol 400 and 50% ethanol. Rats exposed to the two highest concentrations (330.4 or 497.5 mg/m^3) showed symptoms, which included tremors, reduced activity, piloerection and unpreened hair coat. Symptoms lasted through the day after exposure. The LC_{50} ≥ 0.498 mg/L since no mortality occurred following exposure to this concentration. Therefore, propoxur has an inhalation LC_{50} of greater than 0.5 mg/L, and is in Toxicity Category III (MRID 40836402).

Propoxur is a Toxicity Category III primary eye irritant in rabbits. Instillation resulted in minor eye irritation (redness and discharge) which cleared within 48 hours (MRID 41737801).

Propoxur is a Toxicity Category IV primary dermal irritant in rabbits (MRID 41870801) and propoxur is not a skin sensitizer in guinea pigs (MRID 41652401).

In an acute neurotoxicity study in rats, propoxur (99.4%) was administered by single dose oral gavage to 12 Wistar rats/sex/dose at 0, 2, 10 or 25 mg/kg with polyethylene glycol 400 (5 ml/kg) as the vehicle. Functional Observational Batteries (FOB) and Motor and Locomotor

Activity measurements were conducted on days -7, 0, 7 and 14. Treatment-related effects were observed in the FOB on day 0 in all treated groups, but effects were minimal at the low dose. For low-dose males, there was a significantly increased incidence of sitting or lying (rather than standing) during open field observation, a marginally decreased incidence of rearing, and a slightly decreased tail pinch response. Two low-dose females exhibited slight repetitive chewing and the incidence of rearing was marginally decreased in this group. Low-dose animals also had slightly (not significantly) lower mean body temperatures (males: 37.8°C vs. 38.0°C for controls; females 38.3°C vs. 38.6°C) which were part of dose-related trends. On day 0 in the 10 and 25 mg/kg groups there were gait abnormalities, involuntary clonic motor movements, labored breathing, decreased activity, impaired righting reflex, decreased responses to auditory and tail pinch stimuli, and decreased grip strength. Mean body temperatures were significantly reduced in both sexes (males: controls: 38.0°C; 10 mg/kg: 37.4°C; 25 mg/kg: 35.8°C; females: controls: 38.6°C; 10 mg/kg: 37.9°C; 25 mg/kg: 36.6°C). Satellite groups of 6 rats/sex received 0, 2, 10 or 25 mg/kg (4/6 high-dose males received 35 mg/kg) propoxur, with sacrifice about 45 minutes after dosing. Low-dose males and females had significant ($p \leq 0.01$) brain cholinesterase (ChE) inhibition (-18% and -21% respectively); at 10 mg/kg both sexes had significant ($p \leq 0.01$) RBC (males: -72%; females: -63%) and brain (males: -47%; females: -49%) ChE inhibition.

A neurotoxic NOEL was not determined. The neurotoxic LOEL is 2 mg/kg, based on significant ($p \leq 0.01$) brain ChE inhibition in both sexes 45 minutes after dosage.

There were no significant differences between groups with respect to mean body and/or brain weights at termination. There were no indications of any dose-related gross or microscopic findings in high-dose animals at termination.

A NOEL could not be determined for this study. This study satisfies the guideline requirement (81-8) for an acute neurotoxicity screening study (MRID 43445701).

b. Subchronic Toxicity

In a 13-week subchronic dermal toxicity study in rabbits, groups of 10 male and 10 female New Zealand rabbits received dermal applications of 0, 50, 250, or 1000 mg/kg propoxur suspended in cremophor (2% v/v). Dosing was administered for 6 hours/day, 5 days/week for a total of 65 treatments over a 90-day period. No dermal irritation was observed, and

no treatment-related effects were observed in body weight, food consumption, hematology, clinical chemistry parameters (including plasma, erythrocyte and/or brain cholinesterase activities), liver enzymes, and gross or histopathology. The NOEL is 1000 mg/kg/day which was the highest dose tested (MRID 41066001). This study satisfies the guideline requirement (82-3) for a subchronic dermal toxicity study for propoxur.

In a 13-week subchronic neurotoxicity study in rats groups of 12 male and 12 female SPF-bred Wistar rats were fed diets containing 0, 500, 2000 or 8000 ppm propoxur (99.5%) for 13 weeks. These exposure levels were equivalent to 0, 33, 132 or 543 mg/kg/day of for males, and 0, 39, 163, or 703 mg/kg/day for females. Additional groups of 12 male and 12 female rats were fed diets containing 0 or 8000 ppm propoxur for 13 weeks, followed by a 4-week recovery period.

There were Functional Observation Battery (FOB) and Motor and Locomotor observations at pretreatment and weeks 4, 8, and 13. Epileptoid seizures were observed in 5/24 8000 ppm females during FOB-testing. It is hypothesized that these were due to acetylcholine accumulation in the brain and a genetic disposition of these rats. In males, 1/12 at the 2000 ppm (but 0/24 at 8000 ppm) showed epileptoid seizures during FOB-testing; this one occurrence was not considered to be related to treatment. Slightly decreased grip strength and foot splay in males and females at 2000 and 8000 were considered to correlate with body weight retardation at these dietary exposure levels. Motor and locomotor activity were not affected in males of any dose level or in females exposed to 500 or 2000 ppm; activity was extremely low in individual females at 8000 ppm that had epileptoid seizures during FOB testing which was immediately prior to motor and locomotor activity measurements. There were no other indications of neurological effects observed in testing.

Week 13 ophthalmic examination showed a reduced pupillary reflex in 4/24 males and 2/24 females exposed to 8000 ppm, presumably due to cholinesterase (ChE) inhibition. There were no significant differences between groups with respect to mean brain weights. There were no significant differences between controls and 8000 ppm rats (6/sex/group examined) with respect to microscopic neurology findings. At week 13, 2000 ppm and 8000 ppm males had significantly lower mean body weights (-12% and -21% respectively); as did 2000 and 8000 ppm females (-7% and -20%) than controls.

Plasma and Red Blood Cell (RBC) cholinesterase measurements were taken from 6/sex/group of the non-recovery rats at weeks 4 and 14, and brain ChE was measured at week 14. For males, RBC ChE was

significantly reduced at 2000 and 8000 ppm for week 4, and at 8000 ppm for week 14. For females, plasma ChE was significantly reduced at 8000 ppm for week 4. Brain ChE was significantly reduced at week 14 in 2000 and 8000 ppm males and females (2000 ppm: males: -24%; females: -18%; 8000 ppm: males: -28%; females: -19%), and "marginally" (but with $p \leq 0.01$) in 500 ppm males (-14%). Cholinesterase inhibition associated with exposure to carbamates is reversible, and so these measured cholinesterase activities may not fully indicate the maximum levels of inhibition that occurred, as presumably some time elapsed between blood or brain collection and measurement of ChE activities.

The NOEL for FOB and motor and locomotor activity changes is 163 mg/kg/day for females, with a LOEL of 703 mg/kg/day; the NOEL in males is 543 mg/kg/day (HDT). The NOEL for ophthalmic changes is 132 mg/kg/day for males and 164 mg/kg/day for females, with a LOEL (reduced pupillary reflex in some rats) of 543 mg/kg/day for males and 703 mg/kg/day for females. The NOEL for reduced ChE in females was 39 mg/kg/day, and the LOEL was 163 mg/kg/day (reduced brain ChE activity, with reduced plasma ChE at 703 mg/kg/day); for males the NOEL was below 33 mg/kg/day (lowest dose tested); the LOEL was 33 mg/kg/day (reduced brain ChE activity at all dietary exposure levels; reduced RBC ChE at 132 and 543 ppm). There were no indications of any dose-related microscopic effects in skeletal muscle tissues or neural tissues; the NOEL for microscopic lesions (and histoneurological effects) is 543 mg/kg/day for males and 703 mg/kg/day for females. This was the highest dose tested (MRID 43445701). This study satisfies the guideline requirement (82-7) for a subchronic neurotoxicity screening study in rats.

c. Chronic toxicity and Carcinogenicity

In a carcinogenicity study, propoxur (99.6%) was given in Altromin diet at 0, 500, 2000 or 8000 ppm to groups of 50 male and 50 female B6C3F1 mice, with an additional 10 animals/sex/ dietary dose level sacrificed at 1 year. Propoxur intake values are reported as: males: 0, 114.3, 472.4 or 2080.6 mg/kg/day; females: 0, 150.4, 591.4 or 2671.1 mg/kg/day. However, these values are based on what appear to be relatively high food consumption values (males: 7.0-7.2 gm/animal/day; females: 8.1-8.5 gm/animal/day), and there may have been considerable wastage. If food consumption values had been 3 gm/animal/day, then propoxur intake would have been: males -- 0, 47.6, 202.5, or 879.1 mg/kg/day; females -- 0, 53.1, 219.0, or 977.2 mg/kg/day.

There was a dose-related trend of increasing incidence of hepatocellular adenomas in male mice (10/49, 10/49, 15/49, and 21/50),

but no other indication of any neoplastic effect. Non-neoplastic effects included an increased incidence of bladder epithelial hyperplasia (classified as minimal and diffuse in all instances) in both sexes at 2000 and 8000 ppm; there was also a significantly increased incidence of ovarian hemorrhage (and thrombus formation) in 8000 ppm females. Mean liver weights (and liver-to-body weight ratios) were increased (usually significantly) in both sexes at 2000 and 8000 ppm. Mean body weight gains were decreased by about 20% in 8000 ppm males, and 33-50% in 8000 ppm females. The NOEL in this study was 500 ppm (males: 114.3 mg/kg/day; females: 150.4 mg/kg/day), and the LOEL (increased mean liver weights in both sexes, increased incidence of liver nodules in males, increased levels of alanine aminotransferase activity, increased incidence of ovarian nodules in females, increased incidence of urinary bladder hyperplasia in both sexes) was 2000 ppm (males: 472.4 mg/kg/day; females: 591.4 mg/kg/day) (MRID 42597701). This study satisfies the guideline requirement (83-2) for a mouse carcinogenicity study.

In a combined chronic toxicity/carcinogenicity study, groups of 50 SPF strain BOR:WISW rats/sex/dietary exposure level were fed 0, 200, 1000 or 5000 ppm propoxur (0, 8.23, 42.03 or 222.3 mg/kg/day for males; 0, 11.02, 56.16 or 292.72 mg/kg/day for females) in Altromin 1321 diet. Satellite groups of an additional 10 animals/sex/group were sacrificed after one year. At 5000 ppm there were significantly ($p \leq 0.01$) lower mean body weights in both sexes throughout the study (week 13: males -16.1% from their controls; females -15.2%), and reduced food consumption relative to controls (males: 16 gm/day vs. 17 gm/day; females: 11 gm/day vs. 14 gm/day). At 1000 ppm males tended to have a significantly ($p \leq 0.05$) lower mean body weight relative to their controls through the first 66 weeks of the study, and sporadically thereafter. Females usually had significantly ($p \leq 0.05$, often ≤ 0.01) lower mean body weight throughout the study.

In both sexes at 5000 ppm there were increases in incidence and degree of what was described as slight peripheral neuropathy (mainly characterized by myelin alterations, such as vacuolization, myelinovoid formation, and occasional phagocytes). Additionally, there was an increased incidence of slight muscular atrophy of the rear extremities.

At 1000 and 5000 ppm there were significant increases in hyperplasia of the urinary bladder in both sexes (males: 1/50, 1/50, 10/50 and 44/100 for the 0, 200, 1000 and 5000 ppm groups; females: 0/50, 0/50, 5/50, 4/48).

At 5000 ppm there were significant increases in incidences of urinary bladder papillomas and carcinomas in both sexes (papillomas: males: 0/50, 0/50, 1/50, 25/50 for the 0, 200, 1000 and 5000 ppm groups respectively; females: 0/50, 0/50, 0/50, 28/50; carcinomas were present in 8/50 males and 5/50 females at 5000 ppm, but were not observed in controls or any of the lower-dose groups). Females at 5000 ppm showed an increased incidence (not quite statistically significant) of carcinoma of the uterus (3/50, 4/50, 3/50 and 8/50 for the 0, 200, 1000 and 5000 ppm groups respectively).

The LOEL is 42.03 mg/kg/day (1000 ppm) for male rats and 56.16 mg/kg/day (1000 ppm) for female rats, based on reduced weight gains and the occurrence of hyperplasia of the urinary bladder in both sexes. The NOEL is 8.23 mg/kg/day (200 ppm) for male rats, and 11.02 mg/kg/day (200 ppm) for female rats (MRID 00142725). This combined chronic toxicity/carcinogenicity study satisfies the guideline requirements (83-1 and 83-2) for a combined rat chronic toxicity and carcinogenicity study.

In a chronic inhalation toxicity study groups of 50 Wistar rats/sex/exposure level received whole body exposure for 6.3 hours/day, 5 days/week over a 2-year period followed by an exposure-free period of 5 months. Nominal exposure levels were 0 (vehicle: a 1:1 mixture of propylene glycol and ethanol), 2, 10 or 50 mg propoxur/meter^3. Corresponding analytical concentrations were 0, 2.2, 10.4 or 50.5 mg/meter^3. There were frequent occurrences of significant cholinesterase inhibition (plasma, RBC and brain) at 10 and 50 mg/m^3. Statistically significant RBC cholinesterase depressions at 2 mg/m^3 at weeks 25-26 and 51 were not part of dose-related trends and/or were probably within the limits of normal variation. There were only slightly (4%) lower mean body weights in 10 and 50 mg/m^3 females at 52 weeks. There were no dose-related effects involving mortality, clinical signs, hematology, clinical chemistry (other than cholinesterase activities), a number of respiratory functions, urinalyses or organ weights. The LOEL is 10.4 mg/m^3 based on significant plasma, RBC and brain cholinesterase inhibition at this exposure level for both sexes on a number of occasions. The NOEL is 2.2 mg/m^3.

There were some slight dose-related increases in tumor incidences [the incidences of urinary bladder papillomas in males were 0/58, 0/60, 1/59 and 2/60 for the controls, 2, 10 and 50 mg/m^3 groups respectively, while for hepatocellular adenomas in males the incidences were 2/58, 0/60, 2/59 and 6/59]. The only occurrence of a papilloma of the urinary bladder in females occurred in the highest exposure group [incidences of 0/60, 0/57, 0/60 and 1/59 for controls, 2, 10 and 50 mg/m^3 groups respectively].

For the females, there was a weak (not statistically significant) trend involving uterine adenocarcinomas [incidences of 0/47, 2/45, 2/50 and 3/47 for the 0, 2, 10 and 50 mg/m^3 groups respectively]. An apparent dose-related increased incidence in pituitary adenomas in males was probably due to an unusually low (3%) incidence of this tumor type in controls (MRIDs 42648001 and 43398501).

While this chronic inhalation study does not satisfy the 83-1 Guidelines data requirement, the findings (particularly the occurrence of urinary bladder papillomas) are consistent with what was observed in the 2-year rat chronic feeding study.

In a one-year dog feeding study groups of 6 male and 6 female thoroughbred beagles received 0, 200, 600 or 1800 ppm propoxur (99.4%) in their diet for a period of 12 months. The high dose dogs received 1800 ppm during weeks 1-40, 3600 ppm for weeks 41-44, and 5400 ppm for weeks 45-52. The mean quantities of propoxur consumed per animal were 0, 62.4, 186.3, or 780.7 mg/day; or values about 0, 6.77, 22.0, or 98.2 mg/kg/day.

At the highest dose level, one male died at week 50. After week 20, highest-dose dogs of both sexes had lower mean body weights than their corresponding controls; at week 41 and thereafter their weights were significantly lower. At week 41 three dogs in the high-dose group showed an increased incidence of vomiting (after the level of propoxur was raised from 1800 to 3600 ppm). One high-dose female had poor weight gain in the first 40 weeks, and appeared emaciated at the end of the study. This dog was one of those vomiting more frequently after week 41, and had gone from 6.6 kg at week 40 to 6.0 kg at week 52. After the level was raised to 5400 ppm, almost all of the high-dose dogs had an increased incidence of vomiting; some also showed more frequent salivation. Most also had spasms throughout their entire bodies after feeding, while two "exhibited an uncertain gait with slightly bent joints." One dog "temporarily showed aggressive behavior" and another "exhibited circular movements."

Mean thrombocyte counts were consistently (and significantly) elevated in high-dose dogs, and there was an additional increase in this parameter after week 40 (when the propoxur concentration was increased). Mean cholesterol levels were significantly elevated in mid- and high-dose dogs from week 6; mean cholesterol levels were consistently elevated, sometimes significantly so, (relative to control values) in 200 ppm dogs from week 6 to termination. At termination, mean N-demethylase activity

was significantly elevated in mid and high-dose dogs; cytochrome P450 was elevated (but not significantly) in high-dose dogs only.

Plasma cholinesterase activities tended to be lower in high-dose dogs relative to control values, and RBC ChE activities tended to be lower (relative to controls) in dogs receiving 1800 ppm one hour after feeding. Mean liver weights and mean thyroid weights were elevated at termination in the high-dose dogs, and the organ-to-body weight ratios were significantly elevated. However, the high mean thyroid weights were due to findings from only two of the high-dose dogs, one of which had a thyroid cyst; without these dogs the mean thyroid weight from high-dose dogs was comparable to that of controls (high-dose dogs: 0.892 gm; controls: 0.928 gm). Mean kidney and mean adrenal weights were somewhat elevated in the high-dose dogs. Mean thymus weights in high-dose dogs were significantly lower (4.07 gm vs. a control value of 0.869) and the thymus-to-body weight ratio was significantly lower in high-dose dogs (0.479 gm/kg vs. 0.872 gm/kg).

Since the low-dose dogs showed an elevated mean cholesterol level which was part of a well-defined dose trend, a NOEL was not observed in the original one-year study (MRID 00149040). Subsequently, in a bridging study (MRID 42041601), groups of 4 male and 4 female beagle dogs were fed diets containing 0 or 70 ppm propoxur for 6 months (males: 0 or 2.46 mg/kg/day; females: 0 or 2.71 mg/kg/day). In this 6-month study, there was no indication of any effect (including an elevation of cholesterol levels) on animals receiving the diet containing 70 ppm propoxur. This establishes a NOEL in the dog of 2.46 mg/kg/day. The combination of the two studies (MRIDs 00149040 and 42041601) satisfies the guideline 83-1 requirement (83-1) for a chronic feeding study in non-rodents.

d. Developmental Toxicity

In a developmental toxicity study in rats, groups of 25 mated female Wistar/HAN rats received oral administrations of 0, 3, 9, or 27 mg/kg propoxur (99.4%) in distilled water mixed with 0.5% cremophor daily during days 6 through 15 of gestation; dams were sacrificed on day 21.

No maternal toxicity was observed at the low dose (3 mg/kg/day). At the mid dose (9 mg/kg/day) maternal toxicity was evident in increased cleaning activity, chewing motions, grinding of teeth, reduction in food consumption, and a marginal (-7.1%) decrease in mean body weight gain for days 6-16. At the high dose (27 mg/kg/day), signs of maternal toxicity included mortality (3/25 dams, with one death after the first administration on day 6, and two deaths after the second administration on day 7),

symptoms similar to those observed in the mid-dose group and, additionally, tremors and ventral recumbency.

In addition, there was a significant ($p \leq 0.05$) reduction in mean food consumption (-14.6%) for days 6-16, and a decrease (-26.2%) in mean body weight gain from day 6 through day 16. There were no indications that propoxur was embryotoxic, fetotoxic, or teratogenic at doses up to and including 27 mg/kg. Under the conditions of this study, the NOEL was 3 mg/kg/day for maternal toxicity and 27 mg/kg/day (highest dose tested) for developmental toxicity. The LOEL for maternal toxicity was 9 mg/kg/day and > 27 mg/kg/day for developmental toxicity (MRID 41061101). This study satisfies the guideline requirements (83-3) for a developmental toxicity study in rats.

In a developmental toxicity study in rabbits, groups of 16 mated female chinchilla rabbits received oral administrations of 0, 3, 10, or 30 mg/kg propoxur (99.4%) in distilled water mixed with 0.5% cremophor daily during days 6 through 18 of gestation; dams were sacrificed on day 28. No maternal, embryo, fetal or developmental toxicity was observed at the 3 or 10 mg/kg/day dose levels.

At the high dose (30 mg/kg/day) maternal toxicity was characterized by mortality (3/16 dams died during the dosing period) and clinical signs (dyspnea and restlessness), and slight decreases in mean body weight and food consumption. Embryo/fetotoxicity was suggested by a slight (not statistically significant) post-implantation loss (17.7% at 30 mg/kg/day, as compared to 10.1% in vehicle control animals), and a corresponding reduction in the mean number of pups per dam. No treatment-related effects were observed on fetal body weights or sex ratios. Propoxur did not induce any external, visceral or skeletal malformations at any of the doses tested.

Under the conditions of this study, the no-observed-effect-level (NOEL) was 10 mg/kg/day for maternal and developmental toxicity. The LOEL was 30 mg/kg/day for both maternal and developmental toxicity (MRID 41061102). This study satisfies the guideline requirements (83-3) for a developmental toxicity study in rabbits.

e. Reproductive Toxicity

In a 2-generation reproduction toxicity study groups of 25 male and 25 female Wistar rats were fed propoxur (99.4%) at concentrations of 0, 100, 500 or 2500 ppm (P1 females: 0, 9.7, 48.1 or 238.9 mg/kg/day; F1 females: 0, 8.8, 43.7, or 228.3 mg/kg/day) in their diet for a 70-day pre-

mating period, then through mating, gestation and lactation. Four groups of 25 males and 25 females (the F1 generation) were selected and maintained on their respective parental diets while producing F2 litters.

On day 21 post partum, all F2 pups and F1 parents were sacrificed. The reproductive NOEL was 500 ppm (approximately 45 mg/kg/day), and the LOEL was 2500 ppm (approximately 233 mg/kg/day) based on a reduced mean number of implantation sites/dam and a reduced mean number of pups/dam at 2500 ppm in the F1 females. The fetotoxicity NOEL is also 500 ppm (45 mg/kg/day) and the LOEL 2500 ppm (233 mg/kg/day) based on reduced mean F1 and F2 pup body weights at birth at 2500 ppm (F1: 2500 ppm: 5.3 gm; controls: 5.8 gm; F2: 2500 ppm: 5.3 gm; controls: 5.7 gm). Other effects noted were body weight reductions in 500 ppm P and F1 males and F1 females. Dose-related urothelial hyperplasia was observed at 2500 ppm (P: 2/25 males and 6/25 females; F1: 8/25 males and 7/25 females). A NOEL for parental toxicity was not observed as RBC ChE was significantly ($p \leq 0.01$) reduced (-21%) in 100 ppm males of the P generation; it was reduced (not significantly) in 100 ppm males of the F1 generation (-12%); brain ChE was significantly ($p \leq 0.01$) reduced in F1 females (-12%). Plasma ChE was significantly reduced in 500 and 2500 ppm F1 females; RBC ChE was significantly reduced in both sexes of the P and F1 at 500 and 2500 ppm, and brain ChE was significantly reduced in P males at 500 and 2500 ppm, in P females at 2500 ppm, in F1 males at 2500 ppm, and in 100, 500 and 2500 ppm F1 females (MRID 41817501).

In a subsequent 2-generation study (MRID 42615403), propoxur (99.8%) was administered in Kliba 343 diet to groups of 25 male and 25 female Wistar rats at concentrations of 0, 30 or 80 ppm (males: 0, 2, or 7 mg/kg/day; females: 0, 3, or 8 mg/kg/day), with selection for an F1 generation (25 males and 25 females per group) which were maintained on their respective parental diets while producing F2 litters. On day 21 post partum, all F2 pups and their F1 parent were sacrificed. No compound-related reproductive toxicity was observed; for F1 males there was a significant ($p \leq 0.01$) decrease (-22%) in mean RBC ChE activity. The NOEL for ChE inhibition was approximately 2.5 mg/kg/day (30 ppm) and the LOEL was 7 mg/kg/day. The two studies together (MRIDs 41817501 and 42615403) adequately satisfy the 83-4 data requirement for a 2-generation study in rats with propoxur.

f. Mutagenicity

Results of the following eight mutagenicity studies indicate that propoxur has little, if any, genotoxic activity.

In a Salmonella typhimurium (Ames) assay, no mutagenic activity was observed with or without metabolic activation (S9 from rat liver) in replicate studies with doses of up to 12,500 µg/plate in Salmonella typhimurium strains TA98, TA100, TA1535, or TA1537. At the highest dose level used there was cytotoxicity in all strains of S. typhimurium used (MRID 00147479).

In a second Salmonella typhimurium (Ames) assay no mutagenic activity were observed with or without metabolic activation (S9 from rat liver) at doses of up to 25,000 µg/plate, with cytotoxicity at highest dose levels in all strains of S. typhimurium used (TA98, TA100, TA1535, TA1537 and TA1538), as well as E. coli strain Wp2 hcr (MRID 00149043). Either of these studies (MRID 00147479 or MRID 00149043) satisfies the Guideline requirement (84-2) for a Salmonella typhimurium reverse mutation assay.

In an in vitro CHO (hgprt) assay there was no evidence of mutagenic activity at doses of 25, 50, 75, 100 or 125 µg/mL in the absence of S9, or at 600, 800, 900 or 1000 µg/mL with S9 (MRID 40836403). This study satisfies the Guideline requirement (84-2) for a mammalian cells in culture forward gene mutation assay.

In a chromosomal aberration study with Chinese Hamster Ovary (CHO) cells propoxur (97.8%) was tested at 157, 313, 625 or 1250 µg/mL without S9 mix and at 625, 1250, 2500 or 5000 µg/mL in the presence of S9 mix. At 2500 and 5000 µg/mL the test material precipitated out. There was no indication of a clastogenic effect at any of the levels evaluated (at 1250 µg/mL without S9 mix there was an insufficient number of metaphase spreads for analysis due to cytotoxicity), either in the absence or presence of S9 mix. However, the 10-hour post-treatment harvest time for cells exposed to 2500 and 5000 µg/mL + S9 was not supported by results from the cell cycle assay (MRID 40953501).

In a second CHO chromosomal aberration assay propoxur (98.4%) was tested at 625, 1250, 2500 or 5000 µg/mL + S9 with 20-hour post-treatment harvest. At 2500 and 5000 µg/mL there were significantly ($p \leq 0.01$) increased incidences of cells with chromosomal aberrations, but at these doses there was also precipitation of the test material. The Agency's test requirements specify that testing a substance in the absence of marked cytotoxicity is necessary only up to solubility limits, as the presence of particulates may result in aberrations from mechanisms other than interactions of the test substance (and/or its metabolites) with chromosomes (MRID 41724601). The combination of these two studies meets the Guideline data requirement (84-2) for an in vitro test for clastogenicity.

In an in vivo chromosomal aberration assay in Chinese hamster bone marrow no evidence of a mutagenic response was observed in animals which had been orally dosed with technical propoxur (several batches: 99.6-99.9%) at 75, 150 or 300 mg/kg and sacrificed at 48 hours. Significant symptoms of toxicity (including death in 2/12 animals) at 300 mg/kg indicates this was an adequately high dose. There was no evidence of a mutagenic response in animals sacrificed at 6 and 24 hours after dosage, but these hamsters received only a dose level of 150 mg/kg (MRID 41008701).

In a subsequent in vivo chromosomal aberration assay in Chinese hamsters with technical propoxur (99.4%) there was no indication of an increased incidence of chromosomal aberrations in bone marrow cells following oral gavage dosing of the test material at 75, 150 or 300 mg/kg with sacrifice at 6 and 24 hours (MRID 42005101). The combination of these two studies satisfies the 84-2 Guideline requirement for an in vivo cytogenetics assay.

In an acceptable mouse micronucleus assay no mutagenic effect was observed in male and female NMRI mice following doses up to and including 20 mg/kg (administered as two 10 mg/kg doses, 24 hours apart, with sacrifice 6 hours after the last dose). Although sacrifice was only 30 hours after the first oral dose, metabolism data (see below) show that propoxur is rapidly and extensively metabolized within a few hours of dosage (MRID 00149041). This study satisfies the 84-2 Guideline requirement for an in vivo cytogenetics assay.

g. Metabolism

In general, the metabolism studies described below show that propoxur is rapidly absorbed following ingestion, and that it is readily metabolized.

In a metabolism study (MRID 00142731), the following metabolites were identified in the urine of rats which had been fed 8000 ppm propoxur for 13 weeks: M1 = 1,2-dihydoxybenzene (= catechol); M2 = 2-isopropoxyphenol; M3 = 2-hydroxyphenyl methylcarbamate; M4 = 2-isopropoxyphenylcarbamic acid; M5 = isopropoxyphenyl-hydroxy(-) methylcarbamate; M6 = 2-isopropoxy-5-hydroxyphenyl-methylcarbamate; M7 = 2-isopropoxy-5-hydroxyphenyl carbamic acid; M8 = 2-isopropoxy-5-hydroxyphenylhydroxymethyl carbamate; M9 = 1,5-dihydroxy-2-isopropoxybenzene. In additional studies (MRID 40629703; MRID 40629702, MRID 40629704), M6 (= 2-isopropoxy-5-hydroxyphenyl-methylcarbamate) was identified as a principle metabolite in hamsters,

mice, and humans. The nitrosated compound M9A (= 1-hydroxy-2-isopropoxy-4-nitrobenzene) has been identified as a metabolite in rats and mice (MRID 40629702), the rhesus monkey (MRID 40629706), and humans (MRID 40629704). Evidence from the human study (MRID 40629704) suggests that M9A is synthesized in the stomach.

In a second metabolism study, groups of 5 female rats received 50, 250 or 500 ppm unlabeled propoxur in their diets for 5 months, then received (by oral gavage) a single dose of 1 mg/kg radiolabelled material. Urine samples taken in the period from 0 to 24 hours after dosage had 87.9 to 99.8% of the total radiolabel; by thin layer chromatography it was found that 97-98% of the activity remained at the origin, and was contained in conjugated metabolites and/or extremely polar metabolites of unknown structure. By enzymatic cleavage 80-86% of the activity was identified as specific metabolites including M1, M2, M3, M4, M5, M6, M7, M8, as well as M6CII (= 2-isopropoxy-5-hydroxyphenyl carbamic acid), MS3 (= 2-isopropoxy-5-hydroxyphenyl-hydroxymethyl carbamate, and M7A (= 2-isopropoxy-3-hydroxyphenyl-methyl carbamate) (MRID 00165000).

In a third metabolism study, seven male rats were used; one received only non-labeled propoxur; the others received 1 mg/kg C^{14}-labeled (ring) with sacrifice at 1, 4, 8, 24, 48 and 72 hours. The rats were sagittally sectioned and exposed (29-124 days) in direct contact with X-ray film. At 1 hour, radioactivity was detectable in all organs (particularly intestines) except the bone. After 24 hours, there were high concentrations of radioactivity in the gastrointestinal tract and bladder, as well as, the mucous membranes of the pharyngeal region. At 48 and 72 hours, some radioactivity was still detectable in the liver, kidneys and mucous membranes of the pharyngeal system. Propoxur (and/or its metabolites) was shown to be distributed via the lymph system (MRID 41345801).

h. Dermal Absorption

Two studies have been reviewed which provide information on the dermal adsorption of propoxur in humans and rats. In the human study, six individuals received a single intravenous dose of ^{14}C-propoxur, 1 Ci/ml. Total urine was collected for five days post-dose and the percent of radiolabeled-dose excreted in the urine was determined. Subsequently the same six individuals received a single dermal dose of ^{14}C-propoxur at 4 ug/cm^2 for an exposure period of 24 hours. Total urine was collected for five days post-dose and the percent of radiolabeled-dose excreted in the urine was determined. The radiolabel excreted was corrected for the

81.8% of label excreted following the i.v. dose. Corrected total excretion was 19.6 percent of the dermally administered dose (Feldman and Maibach).

In the rat study, four doses (0.648, 6.91, 69.5 and 692 ug/cm^2) were administered for durations of 0.5, 1, 2, 4, 8 and 24 hours. Test material was administered in ethanol, a solvent which can increase the absorption of a dissolved chemical. Since percent absorption decreases in a nonlinear manner with dose, the absorption from the dose of 6.91 ug/cm^2 (the nearest dose to that administered in the human study) was selected for comparison with the human study. The results indicate (for durations 0.5, 1, 2, 4, 8, and 32 hours) a total of 7.88, 10.2 17.9, 23.2, and 32.5 percent absorption, respectively (MRID 40953502).

The percent absorbed in the rat study exceeds the percent absorbed in the human study for exposure durations of 8 and 24 hours. This is expected, even without the addition of ethanol, as rat skin is more permeable than human skin. Alternatively, the use of acetone in the human study would show an expected increase of propoxur penetration.

Previously, the Agency had used a value of 50% dermal absorption from the rat dermal absorption study. However, upon review of the human data, the 19.6 percent absorption determined in the human study can be expected to more closely approximate the rate of absorption to be expected in the field than the rates determined in the rat study.

In a dermal absorption study with rats, a mixture of 50% ethanol and 50% water was used as a solvent, with doses of 0.648, 6.91, 69.5, or 692 µg/cm^2 (corresponding nominal doses: 0.009875, 0.105, 1.0625 and 10.5 mg, respectively) radiolabeled propoxur. The highest values for absorption (50 to 64.9%) were observed with the two lowest dose levels, with the highest percentages of radioactivity (0.1-0.18%) in the blood occurring at these dose levels at 0.5 to 1.0 hour after dosage. Because propoxur was applied in a mixture of ethanol and water, the values obtained for dermal absorption were probably somewhat higher than if water alone had been the solvent (MRID 40953502).

i. Incident Information

Epidemiological Information

From OPP's Incident Data System (1992 to April 1996) there are descriptions of 91 human exposures to propoxur. Seventy of the 91 exposures were from two incidents, both of which involved exposures post-

application. Symptoms from these post-application exposures included headaches, nausea, depression and respiratory irritation.

From the California Pesticide Illness Surveillance Program, 1982-1993, 125 persons exposed to propoxur showed systemic symptoms. Sixty-three of the exposed had respiratory symptoms including coughing, tightness in the chest, shortness of breath, and congestion. EPA is requiring label statements to reduce exposure during and after application.

Domestic animal incidents reported to OPP's Incident Data System were linked in most cases to exposure from pet flea collars. Out of 49 animal exposures, fifteen dogs and nine cats were found with their flea collar "bridled" in their mouths. One manufacturer has prepared an instructional video (available through a toll-free number) which assists customers in the proper placement of flea collars.

j. Toxicological Endpoints of Concern Identified for Use in Risk Assessment

The Agency's Health Effects Division's Toxicological Endpoint Selection Committee (document dated April 4, 1996) concluded the following for propoxur:

(1) Dietary Exposure

An acute dietary exposure (1 day) endpoint of 0.15 mg/kg was selected from a published study involving human volunteers (Bull. Wld. Hlth. Org. 1971, 44, 241-249). Symptoms (blurred vision, nausea, sweating, increased blood pressure, vomiting) occurred in a 42-year-old 90-kg male who ingested 1.5 mg/kg; effects were most pronounced 30-45 minutes after ingestion. There was RBC inhibition of 73% 15 minutes after ingestion. Two hours after ingestion, RBC ChE activity was essentially normal. A single dose of 0.36 mg/kg caused a 43% drop in RBC ChE activity, with transient stomach discomfort, blurred vision, moderate facial redness and sweating. RBC ChE was normal within 3 hours. Five doses of 0.15 or 0.2 mg/kg at half-hour intervals resulted in transient RBC ChE depressions. The 0.15 mg/kg dose resulted in the occurrence of 40% RBC ChE inhibition.

(2) Occupational and Residential Exposures

For short term (1-7 day), intermediate term (1 week to several months), and chronic term (several months to lifetime)

dermal occupational and residential exposures, a NOEL of > 1000 mg/kg/day is appropriate, based on the subchronic dermal toxicity of propoxur to rabbit study. The lack of toxic effects observed in this study is indicative of the low level of actual dermal absorption and the rapid rate at which propoxur is metabolized. It is noted that while propoxur is absorbed through the skin, it is also rapidly metabolized (or detoxified in terms of it's cholinesterase-inhibiting potential).

A risk assessment for dermal exposure of any duration is not required because no adverse effects were seen at the highest dose tested. The study indicates very low absorption potential and/or hazard by the dermal exposure route.

For short term (1-7 day), intermediate term (1 week to several months), and chronic term (several months to lifetime) **inhalation** occupational and residential exposures, an appropriate endpoint for risk assessment for inhalation exposure would be the NOEL of 2.2 mg/m^3 from the chronic inhalation studies (MRIDs 42648001, and 43398501). This is based on significant plasma, RBC, and brain cholinesterase inhibition. However, a risk assessment for inhalation exposure is not required because the vapor pressure of propoxur is extremely low, and the registered uses of propoxur are such that significant human exposure via the inhalation route is not expected.

k. Reference Dose

The Agency's Reference Dose (RfD)/Peer Review Committee (document dated September 30, 1994) recommended that an RfD be established based on a human study with a LOEL of 0.15 mg/kg, the lowest dose tested (Bull. Wld. Hlth. Org. 1971, 44, pp 241-249). Multiple doses of 0.15 and/or 0.2 mg/kg were associated with transient red blood cell cholinesterase inhibition. At 0.36 mg/kg, administered as a single dose, red blood cell cholinesterase was inhibited (43%) and clinical signs were also evident. An uncertainty factor (UF) of 10 was applied to account for intra-species variability and an additional UF of 3 was applied to compensate for the lack of a NOEL. On this basis, the RfD was calculated to be 0.005 mg/kg/day.

It should be noted that this chemical has been reviewed by the FAO/WHO joint committee on pesticide residue (JMPR) in 1989 and an acceptable daily intake (ADI) of 0.02 mg/kg/day was established based on the acute no-effect level in humans. In the JMPR evaluation of the human

study, the NOEL was considered to be 0.2 mg/kg/day since the depression of erythrocyte cholinesterase did not exceed 20% and the recovery was very rapid.

It appears, then, that the ADI value generated by the JMPR was based on the same human study used by the Agency in generating the RfD value. However, since the criteria used by the Agency in interpreting the significance of cholinesterase inhibition are different from those used by the international agency, the LOEL as determined by the Agency was, probably, considered to be a NOEL by the JMPR for the same study. Consequently, different uncertainty factors (or safety factors as they are called by the JMPR) were applied by the two agencies to the same dose level.

l. Carcinogenicity Classification and Risk Quantification

The Agency's OPP Health Effects Division Carcinogenicity Peer Review Committee (CPRC) determined that propoxur should be classified as Group B_2, probable human carcinogen (document dated June 17, 1996).

The CPRC evaluated additional data from "special studies" submitted by the registrant, in response to requirements and recommendations made in the previous Peer Reviews. The CPRC concluded that these additional data were inconclusive and did not support reclassification of propoxur. The registrant also submitted a new study in the mouse, in which administration of propoxur was associated with significant increases in hepatocellular adenomas and combined adenoma/carcinoma in males. Based on these data and in consideration of the full weight-of-the-evidence, the CPRC concluded that the classification of propoxur should remain as Group B_2, probable human carcinogen.

Since the male rats did not have statistically significant differential mortality with incremental doses of propoxur, the estimate of unit risk, Q_1^*, was obtained by the application of the Multi-Stage model. The estimate of unit risk, Q_1^*, was based upon tumors in the bladder (papillomas and/or carcinomas) observed in male rats. For the conversion to human equivalents, weights of .40 kg for the rat, 70 kg for humans and the 3/4's scaling factor were used.

The revised unit risk, Q_1^* $(mg/kg/day)^{-1}$ of propoxur, based upon male rat bladder (papillomas and/or carcinomas) tumors is 3.69×10^{-3} in human equivalents (converted from animals to humans by use of the 3/4's scaling factor-1994). The dose levels used in the SPF rat study (8/84) were

0, 200, 1000 and 5000 ppm of propoxur. The corresponding tumor rates in the male rats were 0/57, 0/60, 1/59 and 34/57 respectively.

Dose-Response Analysis

Since the male rats did not have statistically significant differential mortality with incremental doses of Baygon, the estimate of unit risk, Q_1*, was obtained by the application of the Multi-Stage model. The estimate of unit risk, Q_1*, was based upon tumors in the bladder (papillomas and/or carcinomas) observed in male rats. For the conversion to human equivalents, weights of .40 kg for the rat, 70 kg for humans and the 3/4's scaling factor were used. It is to be noted that Q_1* $(mg/kg/day)^{-1}$ is an estimate of the upper bound on risk and that (as stated in the EPA Risk Assessment Guidelines) "the true value of the risk is unknown, and may be as low as zero."

In addition, the findings from a mouse carcinogenicity study (MRID 42597701), demonstrating that propoxur was associated with statistically significant increases in hepatocellular adenomas in males, are considered as additional supporting evidence for the B_2 classification.

2. Exposure Assessment

a. Dietary Exposure

The only food use for propoxur is the crack and crevice treatment in food handling and processing establishments. No tolerances have been established for residues of propoxur in/on any commodity. The registrant has filed a food additive petition (9H5199, 10/16/78) which included residue data that indicated the potential for residues in food adjacent to areas subjected to crack and crevice and spot treatment. The registrant requested a tolerance of 0.2 ppm in/on all foods. Food metabolism/ degradation studies have shown that the residue of concern is the parent compound.

Sufficient data are available to support a 0.2 ppm tolerance from use of propoxur in food processing plants and food handling establishments.

b. Occupational and Residential Exposure Assessment

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators,

etc.) during use or to persons entering treated sites after application is complete.

The endpoints identified for short-term, intermediate-term, and chronic dermal and inhalation exposures do not require a risk assessment as discussed previously. Propoxur is considered to be a B_2 carcinogen with a Q* of 3.7×10^{-3}.

The occupational and residential risk assessment for this RED document reflects the final Special Review Decision not to Initiate a Special Review (FR No. 40, Vol 61, February 28, 1996) and the toxicological conclusion that a non-cancer risk assessment for dermal and inhalation exposure for any duration is not warranted. The Agency decided not to initiate a Special Review of propoxur because the highest risk uses have been eliminated and the estimated excess life time cancer risks for the remaining uses did not exceed the Agency's level of concern.

Occupational-use products and homeowner-use products

At this time products containing propoxur are intended for occupational and homeowner uses. Propoxur is not a Restricted Use Pesticide.

(1) Applicator Exposure

The primary routes of human exposure for handlers and residential applicators from treating buildings with propoxur are dermal and inhalation. Residues may be found on surfaces to which propoxur has been applied. Inhalation exposure occurs from breathing propoxur vapors or dust during and following application of propoxur products. Pest Control Operators (PCOs) and Residential Applicators (RAs) are exposed primarily during the mixing, loading, and application of propoxur products to the interior or around the exterior of buildings. Kennel workers are exposed while treating animals.

EPA assessed human handler exposure to propoxur using data obtained from several sources, including studies submitted by Miles Inc. (now Bayer) in response to the 1987 Data Call-In, data from the technical literature, and surrogate data. The data base for propoxur handler studies is complete (MRIDs 42087201, 41054701, 41054702, 41054703, 41054704, 41054705, and 41858201). The estimates of exposure for Pest Control Operators (PCOs) and

Residential Applicators (RAs) are discussed below and displayed in Table 2.

Crack and crevice study of PCO exposure

In this study, PCOs used a compressed air sprayer to apply a wettable powder formulation of propoxur. The PCOs wore chemical-resistant gloves, cotton/polyester coveralls over a long sleeved shirt and long pants, and leather boots. Dermal exposure was monitored using gauze patches inside and outside clothing. In this study, coveralls were not considered to be baseline PPE, because they were used for monitoring purposes only. Levels of residues on PCOs' hands were measured using an ethanol handwash. Inhalation exposure was measured by using personal sampling devices located in the applicator's breathing zone. Inhalation exposure was found to be negligible compared to dermal.

To estimate PCO exposure to wettable powders, EPA supplemented the crack and crevice data with additional assumptions as follows: the average PCO weighs 70 kg, works 8 hours per day over a 20-year working-life of a 70-year life-span, and handles 924 oz. a.i. per year. Dermal absorption was assumed to be 20 percent based on the human study. Dermal exposure was estimated at 2.1×10^{-3} mg/kg/day.

EPA determined that Ready-to-Use (RTU) liquid products are applied at rates similar to the wettable powder formulations, and residues are not expected to be higher or more persistent than those from the wettable powder formulation. Therefore, the exposure estimate for the wettable powders can be used for the RTUs.

Granular bait study

Granular baits are scattered on paper, pasteboards, or on the floor. Baits are used near baseboards, in closets, under sinks and refrigerators, around structures, patios, sidewalks and other places where insects may be. In this study, PCOs wore gloves, long-sleeved shirts, cotton trousers, and baseball caps over normal clothing which consisted of denim or cotton trousers, long sleeved shirts and shoes. Dermal exposure was measured using gauze patches worn both inside and outside the clothing. Residues on the hands were measured using an ethanol handwash. Airborne residues were determined by drawing air from the breathing zone. Propoxur residues were not detected in most of the samples

analyzed for dermal or respiratory exposure. EPA determined under these conditions that the exposure would be negligible for PCOs.

Aerosol spray study of Residential Applicator (RA)

In this study, the contents of an aerosol can were sprayed into cracks, crevices, baseboards, under sinks, and in other places where insects might be found. Applicators wore long sleeved shirts, long pants, shoes, and baseball caps. Dermal exposure data were gathered from gauze patches attached both outside and inside the clothing and on the cap. Hand exposure data were gathered from an ethanol handwash. Respiratory exposure data were gathered from microfilters contained in a cassette attached to the lapel of the applicator.

For RA exposure to aerosols EPA used additional assumptions to calculate exposure as follows: the RA weighs 70 kg, breathes 1.7 m^3 of air per hour, uses up the contents of an entire can of aerosol with each use, uses four cans per year, and during application wears a short sleeve shirt, shorts, and shoes. Residues below the level of detection were assumed to be present at one-half the level of detection. The RA was assumed to apply propoxur every year from age 18 to age 70. RAs were exposed for 1 hour per application through dermal and inhalation exposure. Dermal absorption was assumed to be 20 percent because a homeowner applicator is assumed to remain in the residence following application. Exposure was calculated at 8.4×10^{-5} mg/kg/day.

EPA also considered RA exposures for outdoor application of propoxur aerosols, which are designed to eradicate hornet and wasp nests around buildings and homes. These products are generally equipped with a delivery system that will allow the operator to apply the aerosol at a safe distance from the nest. An applicator of these formulations of propoxur is likely to be exposed for a shorter time than would occur with indoor use products. It is also likely that the formulations would dissipate more quickly than similar formulations used indoors. Thus, the exposure and corresponding risk from outdoor aerosol uses can be expected to be lower than is estimated for those used in indoor treatments.

For RTU liquid application by RAs EPA has used the aerosol spray study to calculate the maximum exposure RAs incur when applying RTU liquids with a compressed air sprayer to cracks

and crevices. EPA assumed that the RA would wear a short sleeved shirt, shorts, shoes, and no gloves and would apply an RTU liquid four times per year. Only dermal exposure data were used to calculate exposure, because inhalation exposure was considered to be negligible. Exposure was estimated at 8.4×10^{-5} mg/kg/day. If the RA applicator wears clothing similar to a PCO, that is, long sleeved shirt, long pants, and gloves, dermal exposure would be less.

For granular products applied by RAs. Some granular products are registered for use in and around the home (including limited outdoor application to driveways, sidewalks, patios, and foundations). They are not applied by general broadcast treatment indoors or in large quantities. EPA believes that potential dermal exposure would not exceed that received from an aerosol spray can while wearing a long sleeve shirt and long pants. Respiratory exposure would be negligible. Exposure from the limited outdoor applications is not expected to be greater than indoor exposure. The limited outdoor use still permitted is expected to present negligible exposure to RAs.

Aerosol pet spray study

In this study, exposures of five workers using an aerosol spray containing propoxur were measured. Each worker wore a shirt with long or short sleeves and pants, but no other protective clothing. Urine was collected from each subject over a 24 hour period and analyzed for the propoxur metabolite isopropoxyphenol. This is the same as 2-isopropoxyphenol or M2 discussed in the metabolism section. Metabolism studies show that propoxur is rapidly absorbed following ingestion and that it is readily metabolized.

For kennel workers an exposure estimate is not presented here because the Agency does not believe pet aerosol products are routinely used by kennel workers. In addition, propoxur is no longer used in pet shampoos and dips.

In order to calculate lifetime exposure for pet owner applicators, EPA supplemented the mean exposure data from the aerosol exposure study with the following additional assumptions. Pet owners were assumed to weigh 70 kg, wear long sleeved shirts and long pants during application, and treat one dog four times per

year over a 70-year lifetime. Exposure was estimated at 6.4×10^{-3} mg/kg/day per application day.

Other Applicator Exposure

Applicator exposure estimates for PCOs and RAs from impregnated strips, shelf paper, enclosed or containerized baits, and tick and flea collars have not been estimated but are believed to be negligible.

(2) Post-application/Residential Exposure

Other Post-application Exposure Estimates

Residents' (including childrens') post-application exposures from shelf paper, enclosed or containerized baits, and other pet products, including aerosols, have not been estimated but are believed to be negligible. In addition, EPA believes post-application exposure to granular products will not exceed that from aerosol and would probably be much less.

Crack and crevice study of post-application exposure.

A study of post-application residential exposure following a crack and crevice and limited structural surface treatment by commercial applicators was reviewed and found acceptable. Exposures were calculated for three categories of residents based on their ages: an infant, a 12 year old child, and an adult:

- The infant was assumed to weigh 7.5 kg, have a body surface area of 4.8 ft^2, and have a respiratory volume of 0.5 m^3/hr.

- The child was assumed to weigh 40.5 kg, have a body surface area of 14.8 ft^2, and have a respiratory volume of 0.9 m^3/hr.

- The adult was assumed to weigh 70 kg, have a body surface area of 21 ft^2, and have a respiratory volume of 1.0 m^3/hr.

In addition, they were assumed to be exposed 24, 15, and 15 hours/day, respectively. Assumptions about clothing were not specified; rather dermal exposure was expected to occur over 20

percent of the body surface. Individuals were assumed to contact a 50 square foot contact area in a 4-hour interval. Exposure was assumed to occur 365 days/year.

To calculate exposure following application of wettable powders to cracks and crevices, EPA assumed that 64 oz. of a 1.1 percent solution by weight (total of 0.73 oz.) would be applied once a year for cleanout treatment and 16 oz. of a 0.5 percent solution by weight (total of 0.083 oz.) would be applied 11 times a year for maintenance treatments. Residents were assumed to be exposed 365 days per year over a 70-year lifetime. Dissipation was assumed to be 60 percent, and dermal absorption was assumed to be 20 percent of the residue on skin surfaces, because dermal absorption increases with length of time exposed.

To calculate concentrations of propoxur in the air of treated houses, EPA pooled air concentration data for all rooms to yield an average air concentration of 5.1 $\mu g/m^3$. Absorption by the inhalation route was assumed to be 100 percent. The hours/day of inhalation exposure were the same as for dermal exposure. Total dermal and inhalation exposure was calculated at 1.4×10^{-4} mg/kg/day.

For RTU liquids EPA used the wettable powder exposure assessment. EPA also estimated post-application exposure following 12 applications per year of a 0.5 percent RTU product by a PCO. To estimate post-application exposure to an RA, this PCO estimate was reduced by a factor of three. Exposure was estimated at 3.7×10^{-5} mg/kg/day.

To estimate a post-application exposure from the use of aerosols, EPA used the post-application exposure data from the crack and crevice spray study as a surrogate. EPA adjusted the crack and crevice data to reflect the quantity of a.i. applied during application of a 16 oz. can of 1 percent propoxur aerosol four times per year for 70 years. Total dermal and inhalation exposure was estimated at 2.3×10^{-5} mg/kg/day.

Pest Strip Study

For pest strips, EPA assumed that dermal exposure is negligible and 100 percent of propoxur inhaled by the individual is absorbed. Furthermore, the individual was assumed to be exposed 24 hours/day, 365 days/year for 70 years of an average lifetime,

and the strips replaced when efficiency diminishes. EPA believes these exposure estimates are conservative because the only remaining registrations for pest strips are in areas where human exposure is minimal, such as communications boxes. Inhalation exposure was estimated at 1.1×10^{-4} mg/kg/day.

EPA estimated exposure to residents exposed to pet collars using surrogate data based on propoxur pest strips and dog aerosol spray treatment data. EPA assumed that respiratory absorption is 100 percent, and the exposure is constant over a 70-year lifetime. Inhalation exposure was estimated at 6.3×10^{-6} mg/kg/day.

Other Post-application Exposure Estimates

Residents' (including childrens') post-application exposures from shelf paper, enclosed or containerized baits, and other pet products, including aerosols, have not been estimated but are believed to be negligible. In addition, EPA believes post-application exposure to granular products will not exceed that from aerosol and would probably be much less.

Handler and Post-Application Data Requirements

At this time the handler and post-application exposure data bases for propoxur are complete and no additional studies are required.

Table 2. Propoxur Uses and Exposure Estimates for PCOs, RAs, Pet Owners, and Residents of Treated Homes.

Use	Applicator	Applicator Exposure (mg/kg/day)	Resident Post-Application Exposure (mg/kg/day)
Crack and Crevice	PCO	2.1×10^{-3}a	1.1×10^{-4}a,b
	RA	8.4×10^{-5}a	3.7×10^{-5}a,b
Aerosols	RA	8.4×10^{-5}a	2.3×10^{-5}a,b
Granular Baits	PCO	negligible	negligible
	RA	negligible	negligible
Pet Aerosols	Pet Owner	6.4×10^{-3}	negligible
Pest Strips	RA	negligible	1.1×10^{-4}
Shelf Paper	RA	negligible	negligible
Enclosed or Containerized Baits	PCO	negligible	negligible
	RA	negligible	negligible
Pet Tick and Flea Collars	RA	negligible	6.3×10^{-6}

[a] Dermal absorption is assumed to be 20 percent.
[b] Dermal contact area is assumed to be 50 square feet.

3. Risk Assessment

a. Dietary

Acute Dietary Risk

While an acute exposure from the crack and crevice use of propoxur in food handling establishments is possible, it is not likely to result in any exposures of consequence. Therefore, the Agency has not conducted an acute dietary risk assessment for propoxur. Also, the current analysis used to estimate acute dietary exposure and risk, the DRES system, is not capable of accurately estimating risks from the use of a pesticide in food handling establishments. The underlying assumption that would need to be made for such an analysis, that all commodities that are consumed on any given day will contain tolerance level residues of pesticides used in a food handling establishment, is unreasonable and unrealistic. Residues resulting from pesticide use in food handling establishments are not likely to result in incidental contamination of all foods at tolerance levels on a uniform and consistent basis and not all foods consumed by an individual in a day are likely to have come from a food handling establishment that has been treated.

The Agency asked the Scientific Advisory Panel (SAP) to comment on this policy because: the tools/process/information needed to perform such a risk assessment do not exist at this time; and, while there exists the potential that an acute exposure could occur as a result of food handling uses, the Agency believes that this situation is unlikely. The SAP at their September 27, 1995 meeting, agreed that the exclusion of a residue value for food handling establishments when performing acute dietary risk assessments is reasonable. The panel agreed that inclusion of such a value would likely be a gross over-estimate of acute dietary exposure.

Chronic Dietary Risk

The DRES chronic analysis used the proposed tolerance level of 0.2 ppm to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Of these subgroups non-nursing infants (< 1 year old) is the most highly exposed subgroup. Refinements in percent crop treated information were considered in calculating the

Anticipated Residue Contribution (ARC) for those same population subgroups. Non-nursing infants is again the most highly exposed subgroup. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for propoxur to calculate estimates of dietary risk.

Using Tolerances:

The TMRC for the overall U.S. population and the two most highly exposed subgroups from the proposed tolerance being supported in reregistration are listed below.

Overall U.S. population:	139.4% RfD;
Non-nursing infants (< 1 year old):	352.6% RfD;
Children, 1-6 years:	322.1% RfD

Using Anticipated Residues:

The ARC for the overall U.S. population and the two most highly exposed subgroups from the proposed tolerance being supported in reregistration are listed below.

Overall U.S. population:	1.84% RfD;
Non-nursing infants (< 1 year old):	7.23% RfD;
Children, 1-6 years:	4.43% RfD

Cancer Dietary Risk

Using the same assumptions, the total cancer risk estimate for propoxur used in food handling establishments for the overall U.S. population is 3.4×10^{-7}.

b. Occupational and Residential Risk Characterization

Using the exposure estimates discussed above and the Q_1^* for propoxur, EPA estimated the excess lifetime cancer risks to applicators and residents of treated homes. Risk estimates are displayed in Table 3 below.

The Agency issued a final decision not to initiate a Special Review for Propoxur in February, 1996. The risk calculations for the crack and crevice and aerosol uses in that document used a 50% dermal absorption factor. Current data available to the Agency based on a human study suggest that a 20% dermal absorption factor is more appropriate. The calculations in Table 3 reflect the 20% factor for the crack and crevice and

aerosol uses. Further, the risk calculations in the Special Review final decision did not incorporate an interspecies scaling factor when estimating the Q_1*. This factor adjusts the Q_1* by a ratio of body surface to body weight. Its exact value depends on the animal test species used. The Q_1* used in the Special Review document was based on the geometric mean of tumor rates in both the male and female rats. The current Q_1* is based on the highest tumor rate, which was seen in the male rats. These adjustments to the risk calculations have not changed the Agency's basic conclusions regarding the occupational and residential risks from propoxur.

Estimated cancer risks to residents of buildings treated with propoxur ranged from 2.3×10^{-8} to 2.6×10^{-7}. Estimated cancer risk for PCOs while applying propoxur to cracks and crevices is 7.7×10^{-6}. Labels will require PCOs to wear long sleeved shirts, long pants, chemical resistant gloves, and shoes plus socks. The Agency believes there are no other reasonable protective clothing requirements which can be required to reduce the risk further.

Technical propoxur is considered to be Toxicity Category III or IV for dermal, inhalation, eye and skin irritation. Propoxur is not considered to be a skin sensitizer. The endpoints identified for short-term, intermediate-term and chronic dermal and inhalation exposures do not require a risk assessment because no adverse effects were seen at the highest dose tested in the subchronic dermal study and because the vapor pressure of propoxur is low.

Estimated cancer risks are presented below in Table 3.

Table 3. Propoxur Uses and Estimated Excess Lifetime Cancer Risks for PCOs, RAs, Pet Owners, and Residents of Treated Homes.

Use	Applicator	Estimated Applicator Risk	Estimated Resident Post-Application Risk	Estimated Total Residential Risk[a]
Crack and Crevice	PCO	7.7×10^{-6}	4.1×10^{-7}	4.1×10^{-7}
	RA	3.1×10^{-7}	1.4×10^{-7}	4.5×10^{-7}
Aerosols	RA	3.1×10^{-7}	8.4×10^{-8}	3.9×10^{-7}
Granular Baits	PCO	negligible	negligible	negligible
	RA	negligible	negligible	negligible
Pet Aerosols	Pet Owner	2.6×10^{-7}	negligible	2.6×10^{-7}
Pest Strips	RA	negligible	4.1×10^{-7}	4.1×10^{-7}
Shelf Paper	RA	negligible	negligible	negligible
Enclosed or Containerized Baits	PCO	negligible	negligible	negligible
	RA	negligible	negligible	negligible
Pet Tick and Flea Collars	RA	negligible	2.3×10^{-8}	2.3×10^{-8}

[a] When application is by PCO, total residential risk includes only risk from post-application exposure as the PCO is assumed to have left the treated house. When application is by RA, total residential risk includes both RA risk and post-application risk, as the RA is assumed to stay in the treated house.

4. Food Quality Protection Act (FQPA) Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) require EPA to apply an additional 10-fold uncertainty (safety) factor unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity.

Because propoxur has food uses, specific consideration of potential risks to infants and children, as well as cumulative and aggregate exposures, is warranted.

a. Potential Risks to Infants and Children

In determining whether an additional uncertainty factor is or is not appropriate for assessing risks to infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For purposes of assessing the pre- and post-natal toxicity of propoxur, EPA has evaluated two developmental and two reproduction studies. Based on current toxicological data requirements, these studies when considered along with other required toxicity studies, constitute a complete data base for evaluating pre- and post-natal effects for food use chemicals. However, as EPA fully implements the requirements of FQPA,

additional data related to the special sensitivity of infants and children may be required.

Developmental and Reproductive Effects

The effects observed in the propoxur developmental and reproduction studies can be summarized as follows:

In a developmental toxicity study, propoxur was administered by gavage on gestation days 6 through 15 to pregnant Wistar/HAN rats at 0, 3, 9, or 27 mg/kg/day. No maternal toxicity was observed at the low dose (3 mg/kg/day). At the mid dose (9 mg/kg/day) maternal toxicity was evident in increased cleaning activity, chewing motions, grinding of teeth, reduction in food consumption, and a marginal decrease in mean body weight gain for days 6-16. At the high dose (27 mg/kg/day), signs of maternal toxicity included mortality (3/25 dams, with one death after the first administration on day 6, and two deaths after the second administration on day 7), symptoms similar to those observed in the mid-dose group and, additionally, tremors and ventral recumbency. In addition, there was a significant reduction in mean food consumption for days 6-16, and a decrease in mean body weight gain from day 6 through day 16. There were no indications that propoxur was embryotoxic, fetotoxic, or teratogenic at doses up to and including 27 mg/kg. **Under the conditions of this study, the NOEL was 3 mg/kg/day for maternal toxicity, and 27 mg/kg/day (highest dose tested) for developmental toxicity. The LOEL for maternal toxicity was 9 mg/kg/day and > 27 mg/kg/day for developmental toxicity.**

In a developmental toxicity study, chinchilla rabbits were given propoxur at 0, 3, 10, or 30 mg/kg/day by gavage on gestation days 6 through 18. No maternal, embryo, fetal or developmental toxicity was observed at the 3 or 10 mg/kg/day dose levels. At the high dose (30 mg/kg/day) maternal toxicity was characterized by mortality (3/16 dams died during the dosing period) and clinical signs (dyspnea and restlessness), and slight decreases in mean body weight and food consumption. Embryo/fetotoxicity was suggested by a slight (not statistically significant) post-implantation loss, and a corresponding reduction in the mean number of pups per dam. No treatment-related effects were observed on fetal body weights or sex ratios. Propoxur did not induce any external, visceral or skeletal malformations at any of the doses tested. **Under the conditions of this study, the NOEL was 10 mg/kg/day for maternal and developmental toxicity. The LOEL was 30 mg/kg/day for both maternal and developmental toxicity.**

In a 2-generation reproductive toxicity study, Wistar rats were fed propoxur (99.4%) at concentrations of 0, 9.7, 48.1, and 238.9 mg/kg/day for the P1 females and 0, 8.8, 43.7, and 228.3 mg/kg/day for F1 females in their diet for a 70-day pre-mating period, then through mating, gestation, and lactation. **The reproductive NOEL was 45 mg/kg/day, and the LOEL was 233 mg/kg/day based on a reduced mean number of implantation sites/dam and a reduced mean number of pups/dam in the F1 females. The developmental NOEL is also 45 mg/kg/day and the LOEL 233 mg/kg/day based on reduced mean F1 and F2 pup body weights at birth.** Other effects noted were body weight reductions at 45 mg/kg/day parental in F1 males and F1 females. Dose-related urothelial hyperplasia was observed at 233 mg/kg/day. A NOEL for parental toxicity was not observed as RBC ChE was significantly reduced in 9.3 mg/kg/day males of the parental generation; it was reduced in 9.3 mg/kg/day males of the F1 generation; brain ChE was significantly reduced in F1 females. Plasma ChE was significantly reduced in 45 and 233 mg/kg/day F1 females; RBC ChE was significantly reduced in both sexes of the parental and F1 at 45 and 233 mg/kg/day, and brain ChE was significantly reduced in parental males at 45 and 233 mg/kg/day, in parental females at 233 mg/kg/day, in F1 males at 233 mg/kg/day, and in all doses of the F1 females.

In a subsequent 2-generation study, propoxur (99.8%) was administered in the diet to groups of 25 male and 25 female Wistar rats at concentrations of 0, 30 or 80 ppm (males: 0, 2, or 7 mg/kg/day; females: 0, 3, or 8 mg/kg/day), with selection for an F1 generation (25 males and 25 females per group) which were maintained on their respective parental diets while producing F2 litters. No compound-related reproductive toxicity was observed. For F1 males there was a significant decrease in mean RBC ChE activity. The NOEL for ChE inhibition was approximately 2.5 mg/kg/day and the LOEL was 7 mg/kg/day.

The developmental data for propoxur indicate that there is no evidence of an increased sensitivity to propoxur from pre- or post-natal exposures. In the rat developmental toxicity study, no developmental effects were noted at the highest dose tested at which significant maternal effects were noted (e.g., mortality, tremors, ventral recumbency, reductions in food consumption and mean body weight gains). In the rabbit study, possible developmental toxicity was noted at the highest dose tested (slight increase in postimplantation loss with a corresponding reduction in mean fetuses per dam) in the presence of significant maternal toxicity including mortality, dyspnea, restlessness and slight decreases in mean food consumption and mean body weight. Further, no enhanced post-natal sensitivity was observed in a two generation reproduction study in which

reproductive effects (reductions in mean pup numbers in F1 females) were noted at the highest dose tested whereas, parental toxicity (RBC and/or brain cholinesterase) was observed at all doses tested (i.e., a NOEL was not established).

Uncertainty Factor

Based on the reliable data outlined above, the Agency concludes that an additional uncertainty factor is not warranted for the propoxur chronic risk assessment, nor is the use of an additional uncertainty factor indicated for estimating risk from acute or short-term exposures detailed below.

(1) Aggregate (Multipathway) Exposure

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. These other exposures may include drinking water and non-occupational exposures, e.g., to pesticides used in and around the home.

Propoxur has both food and non-occupational uses; therefore, the possible considerations for aggregate exposure are those from food, drinking water, and residential (non-occupational) sources.

Propoxur products provide contact and residual control of common indoor insects such as ants and cockroaches. Residential uses include the control of fleas and ticks on pets, as a wasp and hornet spray, and as a crack and crevice application to and around building surfaces and foundations, patios, driveways and sidewalks. The only food use for propoxur is as a crack and crevice treatment to food areas of food handling establishments.

Acute Dietary Risk - Food Source: While an acute dietary exposure from the crack and crevice use of propoxur in food handling establishments is possible, it is not likely to result in any exposures of consequence. Therefore, the Agency has not conducted an acute dietary risk assessment for propoxur.

Chronic Dietary Exposure - Food Source: The only food use for propoxur is as a crack and crevice treatment for food handling establishments. No tolerances have been established for residues of propoxur in/on any commodity. The registrant has filed a food

additive petition (9H5199, 10/16/78) under Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) which included residue data that indicated the potential for residues in food adjacent to areas subjected to spot, crack and crevice treatment. The registrant requested a tolerance of 0.2 ppm in/on all foods. Due to the enactment of the Food Quality Protection Act (August 1996) all tolerances are now required to be established under section 408 of the FFDCA.

Chronic Dietary Exposure - Drinking Water Source: According to the Agency's Pesticides In Ground Water Database, 21,405 samples from wells in five states have been analyzed for residues of propoxur. There were only five detections of propoxur from these 21,405 samples. Based on the low percentage of detections (0.02%) the Agency has no concerns for drinking water exposure to propoxur from groundwater.

Propoxur has been detected in 85 of 624 surface water samples analyzed (STORET, 1988). Samples were collected at 21 surface water locations. The maximum concentration found in surface water was 0.96 µg/L. However, these data were collected at a time when propoxur was registered for use on ornamentals, lawns/turf and mosquito control. Since the time these data were collected, all propoxur outdoor broadcast uses have been canceled. Therefore, considering the low surface water concentrations found when broadcast applications were registered, and the lower likelihood of surface water residues resulting from remaining uses, surface water contamination with propoxur is not expected to be a drinking water risk concern.

Non-occupational Exposure: Propoxur products are available for use by homeowners. Homeowner uses include crack and crevice treatments, and pet sprays. Products are sold as aerosols, dusts and powders, pest strips, shelf paper, ready-to-use solutions, granular baits, containerized bait, and tick and flea collars.

EPA has determined that there is a potential for dermal and inhalation exposure to homeowners during and after use of propoxur. Homeowners are exposed primarily during application of propoxur in and around the home and while treating pets. Residents of treated buildings are exposed to airborne and surface residues following application. Exposures could also occur from an oral route from residues on food, food preparation surfaces, or other objects such as toys.

Chemical-specific data for some residential handler exposure and residential post-application exposure scenarios are available for propoxur non-occupational exposure scenarios. Where there were no data in the Agency's files, the Agency supplemented existing exposure data with assumptions to determine the exposure potential of these scenarios. These assumptions included weight of the applicator, type of clothing worn by the applicator, treatment duration, frequency of treatment, body surface area and respiratory volume. For a detailed description of exposure scenarios and assumptions used, see Federal Register Vol. 60, No. 9, pages 3210-3220.

Resident post-application exposure values ranged from 1.1×10^{-4} to 6.3×10^{-6} mg/kg/day. Residential applicator exposure values ranged from 6.4×10^{-3} to 8.4×10^{-5} mg/kg/day. In many cases exposure was determined to be negligible.

Chronic and Short-term Non-occupational risk: Risk assessments for chronic (non-cancer) and short-term, dermal and inhalation exposures to propoxur were not required because no adverse effects were seen at the highest dose tested of 1000 mg/kg/day in a dermal study, the vapor pressure of propoxur is extremely low, and the registered uses of propoxur are such that significant human exposure via the dermal or inhalation route is not expected.

Chronic Dietary Risk, food source: A chronic dietary risk assessment was conducted for the crack and crevice treatment of propoxur in food handling establishments. The proposed tolerance level of 0.2 ppm was used in the DRES analysis. Refinements in percent crop (2%) treated information were considered in calculating the Anticipated Residue Contribution (ARC). The proposed tolerance results in a ARC (% CT only) which represents 1.84% of the RfD for the U.S. general population, 7.23% for non-nursing infants (< 1 year old), and 4.43% for children 1-6 years old.

Cancer Dietary Risk, food source: Propoxur is classified as a B_2 carcinogen for which the carcinogenic potential has been quantified at 3.7×10^{-3}. The cancer risk estimated for the general U.S. population considering 2% crop treatment for propoxur is 3.4×10^{-7}.

Conclusions Regarding Aggregate Risk to Propoxur

The total dietary cancer risk using the proposed tolerances for the overall U.S. population is 3.4×10^{-7}. Significant levels of

propoxur are not expected in surface or ground water so dietary risk from drinking water will be negligible.

For the non-occupational uses of propoxur which include crack and crevice treatments, aerosols, tick and flea collars, and spot treatment the Agency assumes that minimal exposure may occur. Using combined residential applicator and resident (including children) post-application exposure estimates the Agency calculated that the lifetime cancer risks from exposures to propoxur ranged from 2.3×10^{-8} for tick and flea collars to 4.5×10^{-7} for crack and crevice treatment.

When the dietary and residential uses are combined the cancer risk to propoxur products ranges from 3.6×10^{-7} to 7.9×10^{-7}.

The Agency concludes that aggregate risks to the general U.S. population, and to the population subgroups of infants and children, resulting from propoxur uses are not of concern.

(2) Cumulative Effects

Propoxur is structurally similar to other carbamates such as carbaryl, methomyl, carbofuran, methiocarb, aminocarb, bendiocarb, and IPBC. Further, other pesticides may have common toxicity endpoints with propoxur.

The Agency has not made a determination whether propoxur and any other pesticide have a common mechanism of toxicity for either cancer or non-cancer effects and require cumulative risk assessment. For the purposes of this Reregistration Eligibility Decision document, the Agency has considered only risks from propoxur. If required, cumulative risks will be assessed when methodologies for determining common mechanism of toxicity and for performing cumulative risk assessment are finalized.

C. Environmental Assessment

1. Ecological Toxicity Data

To support the currently registered uses of propoxur (indoor and residential outdoor), six basic studies are required. Acceptable data are available for each of these guidelines, and no further testing is required. Some additional ecotoxicity data which either meet existing guidelines or provide useful information (e.g.

supplemental studies) are included in this assessment. Results of studies determined to be unacceptable by the Agency are not included in this assessment.

Toxicity Summary:

Based on the results of studies using the TGAI, propoxur is categorized as very highly toxic to birds on an acute basis (some LD_{50}s are < 10 mg/kg); highly toxic to birds on a subacute dietary basis (an LC_{50} is in the range of 51-500 ppm); moderately toxic to freshwater fish (some LC_{50}s are in the range of > 1-10 ppm); and very highly toxic to freshwater invertebrates (daphnid EC_{50} is < 1 ppm).

a. Toxicity to Terrestrial Animals

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of propoxur to birds. The preferred test species is either the mallard duck (a waterfowl) or the bobwhite quail (an upland gamebird). Results of tests conducted with the TGAI and a formulated 2% bait product are tabulated below. Formulated product testing is not required to support residential outdoor use.

(1) Birds, Acute and Subacute

Table 4. Avian Acute Oral Toxicity

Species	% ai	LD_{50} (mg ai/kg)	Toxicity Category
Mallard duck	98	9.44	very highly toxic
Bobwhite quail	2 (bait)	23 (mg ai/kg)	very highly toxic
		1005 (formulated product)	
Canada goose	87	5.95	very highly toxic
Sharp-tailed grouse	97	120	moderately toxic
California quail	97	25.9	highly toxic
Japanese quail	97	28.3	highly toxic
Pheasant	98	20	highly toxic
Chukar	98	25.8	highly toxic
Sandhill crane	98	60.4	highly toxic
Rock dove	97	60.4	highly toxic
House sparrow	97	12.8	highly toxic
Mourning dove	97	4.2	very highly toxic
House finch	97	3.55	very highly toxic
Dark-eyed junco	97	4.76	very highly toxic

Technical propoxur ranges from moderately toxic to very highly toxic on an acute oral basis. Except for the bobwhite quail data, all data are supplemental although data are derived from scientifically sound studies. Collectively the data fulfill the guideline requirement. The guideline (71-1) is fulfilled (MRIDs 00160000 and 41625101).

Two subacute dietary studies using the TGAI are required to establish the toxicity of propoxur to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are in Table 5.

Table 5. Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC_{50} (ppm)	Toxicity Category
Northern bobwhite quail[1]	unknown	2828	slightly toxic
Mallard duck[1]	98.8	> 5000	practically non-toxic
Northern bobwhite quail[2]	unknown	206	highly toxic
Japanese quail[2]	unknown	> 5000	practically non-toxic
Ring-necked pheasant[2]	unknown	approx. 1750	slightly toxic
Mallard[2]	unknown	< 1000	moderately toxic

[1] These studies by Lamb, 1981 (MRIDs 42757101, 42301201 and 0149015) are classified supplemental.

[2] These studies by Hill, *et al*, 1975 (MRID 0022923) although classified as supplemental are derived from scientifically sound studies and, collectively, fulfill the guideline requirement. Although the actual % ai was not reported, it is assumed it was greater than 95%.

As shown above, propoxur dietary studies have demonstrated a tremendous variation in toxicity results. It would appear that birds, within the same species, are able to metabolize propoxur in some instances. To date, there has been no plausible explanation for this phenomenon. The Agency has more confidence in the Hill bobwhite and mallard toxicity values. As noted in an Agency memo, dated, September 21, 1993, "In the oral acute toxicity using Baygon 2% bait the LD_{50} was determined to be 1005 mg/Kg. This was estimated to be equivalent to an LD_{50} level of 23 mg ai/Kg for the active ingredient. Using the equation Estimated LC_{50} = LD_{50} X Avg. Bird Wt. in gms/food consumed per day (using food consumption and bird weight presented in the Miles dietary study) and allowing for a 10X error factor the Agency calculated the expected LC_{50} would range between 150 ppm and 1500 ppm which would more closely relate to the LC_{50} values calculated by Hill."

The USDI data (Hill *et. al.* 1975) are considered to be derived from scientifically sound studies and useful for risk assessment purposes. Since one of the reported LC_{50} values falls in the range of 51 - 500 ppm, technical propoxur is classified as highly toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 0022923).

(2) Birds, Chronic

Results of avian reproduction studies using the TGAI are tabulated below. Avian reproduction testing is not normally required to support a residential outdoor use.

Table 6. Avian Reproduction

Species	% ai	NOEC/LOEC (ppm)	LOEC Endpoints
Northern bobwhite quail[1] (*Colinus virginianus*)	98	> 320 ppm, highest dose level tested	-
Mallard duck[2] (*Anas platyrhynchos*)	98	80 ppm/320 ppm	reduced egg production and embryo viability

[1] This study is reclassified supplemental because a NOEC for reproductive effects was not established. The NOEC for brain cholinesterase inhibition was 80 ppm.

[2] This study is classified supplemental because the raw data were not provided to allow statistical verification of the results.

The No Observable Effects Concentration (NOEC) for bobwhite quail exposed to propoxur in the diet for an undetermined number of weeks was > 320 ppm, the highest dose level tested. The NOEC for brain cholinesterase was 80 ppm based on a 28% reduction in mean brain cholinesterase activity of females at the 320 ppm treatment level (MRID 149017).

The NOEC for mallard exposed to propoxur in the diet for 23 weeks was 80 ppm, based upon the following findings: (1) no significant effects on reproduction and brain cholinesterase inhibition were noted at the 20 ppm treatment level; and (2) reproductive effects were manifested in reduced egg production and embryo survival at the highest treatment level, 320 ppm (MRID 149016).

Although the outdoor use of propoxur outdoor use is not limited to "crack and crevice" treatment, given the limited use, the Agency will not require new avian reproduction testing, but will use the results of these supplemental studies to assess chronic risk.

(3) Mammals

Wild mammal testing is not required to support the registered residential outdoor use patterns of propoxur. Rat/mouse toxicity values are reported below in Table 7.

Table 7. Mammalian Toxicity

Species	% ai	Test type	Toxicity value	Endpoints
various rodents	unknown	acute oral	ranges 68-94 mg/kg	-
laboratory rat (*Rattus norvegicus*)	70 (wettable powder)	acute oral	125 mg/kg (males)	-
laboratory rat (*Rattus norvegicus*)	99.8	2-generation reproduction	reproductive effect NOEC > 80 ppm	no reproductive toxicity was observed at levels up to 80 ppm in diet

Since there are some reports of LD_{50} values lower than 100 mg/kg, propoxur is classified as moderately toxic to mammals (MRIDs 00152443, 00256151 and 42615403).

(4) Insects

A honey bee acute contact study is not required to support the registered residential outdoor use pattern of propoxur, however, an acute honey bee contact study which was reviewed indicates that technical propoxur is highly toxic to bees (< 11 μg/bee) on an acute contact basis (MRID 60633).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Two freshwater fish acute toxicity studies using the TGAI are required to establish the toxicity of propoxur to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of tests conducted with the TGAI and certain formulated products are tabulated below. Formulated product testing is not required to support the registered residential outdoor use.

Table 8. Static Freshwater Fish Acute Toxicity Tests

Species	% ai	96-hour LC_{50} (ppm)	Toxicity Category
Rainbow trout (*Oncorhynchus mykiss*)	98.8	3.7	moderately toxic
	88	8.2[1]	moderately toxic
	2	92 (formulated product - bait)	-
Bluegill sunfish (*Lepomis macrochirus*)	98.8	6.2	moderately toxic
	88	4.8[1]	moderately toxic
	technical (% unknown)	6.1	moderately toxic
	70	9.0 (formulated product - wettable powder)	-
	2	> 180 (formulated product - bait)	-
Brook trout (*Salvelinus fontinalis*)	70	3.55 (formulated product - wettable powder)	-
fathead minnow (*Pimephales promelus*)	88	25[1]	moderately toxic

[1] Although the J. McCann (USEPA) and USDI (MRID 40098001) data are classified supplemental, they are derived from scientifically sound studies and are useful for risk assessment purposes.

Since some the LC_{50} values fall in the range of 3-10 ppm, technical propoxur is categorized as moderately toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID 00149171).

(2) Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity study using the TGAI is required to establish the toxicity of propoxur to freshwater aquatic invertebrates. The preferred test species is the daphnid. Results of tests conducted with the TGAI are tabulated below.

Table 9. Freshwater Aquatic Invertebrate Acute Toxicity

Species	% ai	EC/LC_{50} (ppm)	Toxicity Category
Daphnid (*Daphnia magna*)	98.8	0.011	very highly toxic
Amphipod (*Gammarus lacustris*)[1]	88	0.034	very highly toxic
stonefly (*Pteronarcys*)[1]	88	0.18	very highly toxic

[1] Although scientifically sound, study is classified supplemental because species used and study duration (96-hr) not recommended (MRID 40098001).

Since the EC_{50} is < 1 ppm, technical propoxur is categorized as very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 00149172).

(3) Estuarine and Marine Animals

Results of an estuarine aquatic invertebrate study on pink shrimp (*Penaeus duoraum*) using the TGAI indicate that the 48-hour LC_{50} is 0.041 (MRID 40228401). Since the EC_{50} is < 1 ppm, technical propoxur is categorized as very highly toxic to estuarine invertebrates on an acute basis. Although scientifically sound, this study is classified supplemental because the duration of the test was too short (48-hr instead of 96-hr). This study is not required to support the registered residential outdoor use pattern of propoxur.

2. Environmental Fate

a. Environmental Fate Assessment

For the currently registered uses of propoxur, the Agency typically requires an abbreviated set of environmental fate data on hydrolysis, metabolism, and mobility. Only supplemental data are available for propoxur. While shortcomings in the studies preclude a comprehensive assessment of the environmental fate of propoxur, a general assessment can be made.

Based on supplemental data, propoxur is likely to be moderately persistent (the metabolic half-life is on the order of several months), mobile, and may potentially leach to groundwater. It is apparently hydrolytically stable at acid to neutral pHs (3 to 7) but degrades rapidly at alkaline pH values. The parent chemical appears susceptible to photolysis in water but not on soil. However, the intensity of light in the studies did not reflect that of natural sunlight. Aerobic and anaerobic soil metabolism half-lives are on the order of several months. Degradate characterization was incomplete in these studies. Laboratory mobility studies indicate that propoxur is very mobile (K_d values less than 1). Propoxur exhibits fate and transport characteristics similar to chemicals that are known to leach to groundwater.

Well-designed, scientifically-valid studies could result in changes in the overall assessment, particularly in relation to persistence. For instance, photolysis may play a role in degradation of propoxur applied outdoors. However, considering the nature of the listed outdoor uses, additional studies are not required at this time. The limited data available only support the uses discussed in this document. Any additional uses will require data to support them.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis (161-1)

An open literature study of several carbamates found that propoxur was stable to hydrolysis at pH 3.0-7.0 but degraded at alkaline pH values. The half-life for hydrolysis was 16 days at pH 8, 1.6 days at Ph 9, and 0.17 days at pH 10 (MRID 0085762).

A new hydrolysis study may be required if other outdoor uses are considered in the future.

Photodegradation in water (161-2)

Propoxur degraded in neutral, aqueous solutions (5 ppm propoxur) with a half-life of 10 days without a photosensitizer and 0.7 days with an acetone sensitizer. The degradation half-life was 41 days in the dark control. Compensating for hydrolysis effects, the unsensitized half-life was projected at 13 days. The major degradates were isopropoxy phenol, unidentified polar compounds, and CO_2. The artificial light source had an intensity less than that of natural sunlight in Kansas City, MO (800 u-watts/cm^2 vs. 3300-4400 u-watts/cm^2 at midday in summer, MRID 0085763).

Photodegradation in soil (161-3)

Propoxur photodegraded on a pH 8.2 sandy loam soil with a half-life of 77 days (extrapolated beyond the 28 day study). After 28 days, propoxur comprised 75% of the applied radioactivity, unextracted residues 12%, and volatiles 10%. The artificial light source was the same as that used in the aqueous photolysis study (MRID 0085763).

Aerobic soil metabolism (162-1)

The degradation of Propoxur under aerobic conditions in silt loam and sandy loam soils followed first order kinetics for the first 112 and 180 days, respectively. The half-life values were 80 days for the silt loam and 210

days for the sandy loam. Propoxur was the major extractable residue found in the studies. CO_2 (30% after 112 days; 35% after 336 days) and unextracted residues (up to 40%) also comprised major portions of the applied radioactivity. The primary mode of degradation appears to be hydrolysis of the carbamate linkage (MRID 0085768).

Anaerobic soil metabolism (162-2)

Propoxur degraded in a silt loam soil under anaerobic conditions with a half life of 80 days, the same as found in the aerobic metabolism study above. The anaerobic half-life resulting from the flooding of a sandy loam that had been incubated aerobically for 30 days was 108 days. The half-life in sterile soils was the same as that measured in non-sterile soils (MRID 0085768).

(2) Mobility

Leaching & adsorption/desorption (163-1)

In soil thin-layer mobility studies on six soils, propoxur was found to be mobile, with R_f values of 0.70 to 0.89 (MRID 0029887).

In batch equilibrium studies, propoxur was very mobile, with Freundlich K_d values of 0.05 (sandy loam), 0.30 (silt loam), and 0.27 (silty clay). K_{oc} values, calculated from the K_d and organic carbon (from organic matter) data supplied in the report, were 3.4 (sandy loam), 11.2 (silt loam), and 102.6 (silty clay) (MRID 0085770).

After 28 days of aerobic incubation in a silt loam soil, propoxur was found to be mobile in 12-inch soil columns. The leachate contained 69 to 74% of the applied radioactivity after 100 ml of water was applied over a 45 day period (MRID 0085769).

(3) Field Dissipation

Terrestrial field dissipation (164-1)

Rough data from 10 studies on the persistence of propoxur in several different soil types suggest that the

chemical moves rapidly through all the soil profiles below the 12" sampling depth (MRID 0085772).

Environmental fate data on aqueous and soil photolysis, aerobic and anaerobic soil metabolism, leaching and adsorption/desorption, and terrestrial field dissipation are not required to support the current uses for propoxur. New studies may be required if other outdoor uses are considered in the future.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

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

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds) (2) LD_{50} (birds and mammals) (3) EC_{50} (aquatic plants and aquatic

invertebrates) and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement end point is production of offspring or survival.

(1) Exposure and Risk to Nontarget Terrestrial Animals

Risk presumptions for terrestrial and aquatic animals, along with the corresponding RQs and LOCs can be found in Table 10.

Table 10. Risk Presumptions for Terrestrial Animals

Species	Risk Presumptions	RQ	LOC
Birds	Acute High Risk	EEC[1]/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3]	0.5
	Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3] (or LD_{50} < 50 mg/kg)	0.2
	Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3]	0.1
	Chronic Risk	EEC/NOEC	1
Wild Mammals	Acute High Risk	EEC/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3]	0.5
	Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3] (or LD_{50} < 50 mg/kg)	0.2
	Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3]	0.1
	Chronic Risk	EEC/NOEC	1

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

[2] $\frac{mg/ft^2}{LD_{50} * wt. of bird}$

[3] $\frac{mg\ of\ toxicant\ consumed/day}{LD_{50} * wt. of bird}$

(2) Exposure and Risk to Nontarget Aquatic Animals

Table 11, below, describes the risk presumptions for nontarget aquatic animals.

Table 11. Risk Presumptions for Aquatic Animals

Risk Presumptions	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm or ppb in water)

b. Environmental Risk Characterization

Propoxur is federally registered for indoor and residential outdoor uses. Previously registered uses, including ornamental, lawns/turf, and mosquito control, have been canceled.

c. Exposure and Risk to Nontarget Terrestrial Animals

The likelihood of wildlife exposure from certain formulations/ product types is considered slight. These include the aerosols, bait stations, pastes, liquids and traps. The Agency is assuming that the registered liquid products are used only for spot or crack and crevice treatment around buildings. Risk assessments were performed for two products with potential for wildlife exposure: (1) a 2% bait applied around patios, driveways, sidewalks and foundations, and (2) an insecticide tape formulation used on boat mooring lines (due to the product's close proximity to water).

10% Insecticidal Tape Product

Minimal to no terrestrial exposure is expected from this product. Therefore, a terrestrial risk assessment was not performed. Aquatic animal LOCs for acute effects were not exceeded for the registered boat guard product. Based on these risk assessment findings, the Agency presumes minimal risk to aquatic organisms from this registered use.

Residential Outdoor Use of 2% Bait Formulation

(1) Birds

Birds may be exposed to propoxur bait by ingesting it when foraging for food or grit. The number of lethal doses (to 50% of the population or LD_{50}s) that are available within one square foot immediately after application ($LD_{50}s/ft^2$)is used as the risk quotient

for these types of products. Risk quotients are normally calculated for three separate weight class of birds: 1000 g (e.g., waterfowl), 180 g (e.g., upland gamebird) and 20 g (e.g., songbird). Since the birds expected to be found in residential settings are small birds (e.g., sparrows, finches, wrens, juncos, bluejays, flickers and blackbirds), only the risk quotient for small weight-class bird was calculated. The application rate, 4 oz per 1000 sq. ft. is equivalent to 3.4848 oz ai/a or 0.2178 lb ai/a. The acute risk quotient for small birds of 20 gram weight is tabulated below.

Table 12. Avian Risk Quotient for 2% Bait Products[1]

Rate in lbs ai/A	Pesticide left on surface	Body Weight (g)	LD 50 (mg/kg)	Acute RQ[2] (LD_{50}/ft^2)
0.2178	1%	20	3.55	31.90

[1] Based on a house finch LD_{50} of 3.55 mg ai/kg.

[2] $RQ = \frac{\text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/lbs}/43{,}560 \text{ ft}^2/\text{A})}{LD_{50} \text{ mg/kg} * \text{Weight of Animal (g)} * 1000 \text{ g/kg}}$

The results indicate that for applications of bait products, avian acute high risk, restricted use, and endangered species levels of concern are exceeded at the registered application rate of 4 oz ai per 1000 sq ft. However, because of the limited outdoor use, avian exposure is expected to be minimal.

The Agency does not currently have procedures for assessing chronic risk for bait products. However, if a similar foliar application rate of 0.2 lb ai/A were used, this would result in a Kenaga EEC of 48 ppm on short grass, which does not exceed the chronic LOC (EEC/NOEC; 48 ppm/80 ppm). In addition it is not expected that birds will receive chronic exposures to propoxur, such as occurs when feeding on large treated areas (cropland) over long periods of time.

There are no reports of avian poisoning incidents in the Agency's files.

(2) Mammals

Mammalian species also may be exposed to granular/bait pesticides by ingesting granules. The number of lethal doses (LD_{50}s) that are available within one square foot immediately after application can be used as a risk quotient ($LD_{50}s/ft^2$) for the various types of exposure to bait pesticides. Risk quotients are calculated for three separate weight classes of mammals: 15 g, 35 g and 1000 g.

The acute risk quotients for applications of 2% bait products are tabulated below. Risk quotients were calculated for all three separate weight classes of mammals.

Table 13. Mammalian Acute Risk Quotients for 2% Bait Products[1]

Rate in lbs ai/A	Pesticide left on surface	Body Weight (g)	LD 50 (mg/kg)	Acute RQ[2] (LD_{50}/ft^2)
0.2	1%	15	86	1.61
0.2	1%	35	86	0.69
0.2	1%	1000	86	0.02

[1] Based on a rat LD_{50} of 86 mg ai/kg.

[2] RQ = $\frac{\text{App. Rate (lbs ai/A) * (453,590 mg/lbs/43,560 ft}^2\text{/A)}}{LD_{50}\text{ mg/kg * Weight of Animal (g) * 1000 g/kg}}$

The results indicate that for small mammals (15 gram weight), acute high risk, restricted use, and endangered species levels of concern are exceeded at the registered application rate of 4 oz per 1000 sq. ft., by 3, 8, and 16 times respectively. The results indicate that for medium-size mammals (35 gram weight), acute high risk, restricted use, and endangered species levels of concern are exceeded by 1, 3, and 7 times respectively. In summary, acute risks could exist for mammalian species, especially small rodents and/or insectivores ingesting dead/dying insects that have ingested the bait.

(3) Aquatic Organisms

Minimal aquatic exposure from runoff or drift is expected from the bait product. Therefore, an aquatic risk assessment was not performed.

10% Insecticidal Tape Product

Propoxur is registered for use on boat mooring lines, water lines and utility supply lines to control the spread of insect pests. The product is a plastic cylindrical device containing propoxur in combination with chlorpyrifos and formulated as an insecticide strip. The device is snapped to the mooring lines.

A risk assessment for the registered product, Boat Guard, EPA Reg. No. 62451-1, was performed by the Agency in the early 1990's. Propoxur is applied at a very low rate (0.5%) to the inside of the partially enclosed trap guard units. The estimated environmental concentration in water after considering the leaching

rate (assumed to be 0.1%) and the number of boats using the device in a marina (assumed to be 50) was calculated as 0.059 ppb for propoxur. The acute risk quotient (EEC/toxicity value) derived from using the lowest toxicity value for an aquatic animal (daphnid = 11 ppb) does not exceed any acute level of concern. Based on these findings, minimal to no risk is expected to aquatic organisms from this use.

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 propoxur as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing propoxur. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propoxur, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of propoxur and to determine that propoxur can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing propoxur as the active ingredient, when labeled and used as specified in this document, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient propoxur, the Agency has sufficient information on the health effects of propoxur and on its

potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that propoxur products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency concludes that products containing propoxur for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of propoxur (listed in Section II) are eligible for reregistration.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that a tolerance needs to be established for the crack and crevice uses of propoxur in food processing plants and food handling establishments, and that the proposed tolerance would meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. Sufficient data are available to establish a tolerance.

Significant levels of propoxur are not expected in surface or ground water; therefore, risk from drinking water would be negligible, and has not been included in the chronic dietary risk assessments.

In assessing chronic dietary risk, EPA estimates that the anticipated residue contribution of propoxur (assuming 2% of all food commodities are treated) would be 1.84% of the RfD for the U.S. general population, 7.23% for non-nursing infants (< 1 year old), and 4.43% for children 1-6 years old. Endpoints, other than cancer, for non-occupational chronic exposure were not identified. Thus, "aggregate" non-cancer risk is limited to dietary exposure as described above.

The propoxur cancer dietary risk estimate for the U.S. general population (again assuming that 2% of all food commodities are treated) is 3.4×10^{-7}. In addition, there are non-occupational cancer risks resulting from propoxur exposure. For all use scenarios, the highest aggregated

dietary and non-occupational risk estimate is 7.9 x 10^{-7}. Therefore, the Agency concludes that aggregate risks to the general U.S. population are not of concern.

b. Determination of Safety for Infants and Children

EPA has determined that the proposed tolerance for propoxur would meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of propoxur residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from propoxur residues, EPA considered the completeness of the database for developmental and reproductive effects as well as other relevant toxicity studies, the nature of the effects observed, and other information.

Based on the current data requirements, propoxur has a substantially complete database for developmental and reproductive toxicity. The available data for propoxur indicate that there is no evidence of an increased sensitivity to propoxur from pre- or post-natal exposures. Fetal effects were observed in only one of the developmental studies, and these occurred at the same dose levels as maternal effects. In the reproduction studies, no enhanced post-natal sensitivity was observed in a two generation reproduction study in which reproductive effects were noted at the highest dose tested. Parental toxicity was observed at all doses tested. Therefore, based on reliable data, the Agency has concluded that an additional uncertainty factor is not warranted for pre- and post-natal effects.

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

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer

appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

2. Worker Risk/Cancer

Propoxur has an estimated cancer risk for workers of 7.7×10^{-6}. The Agency's policy for applicator risk is that risk should be as close to negligible (i.e., 1×10^{-6}) as possible. Revisions to propoxur labels stipulated by this RED require PCOs to wear long-sleeved shirts, long pants, chemical resistant gloves and shoes plus socks. The Agency believes there are no other reasonable measures or protective clothing requirements that could be imposed to further reduce the risk. Thus, this level of risk is in compliance with the Agency's worker risk policy. Furthermore, the Agency believes that 7.7×10^{-6} may be an overestimate of the actual risk to applicators from the crack and crevice use. Many of the replicates in the exposure study used to derive the risk estimate showed no detectible residues under the clothing for the chest, back and other areas. For these replicates, the Agency made a protective assumption that some pesticide could still be present and included half the level of detection rather than zero in its calculations, thereby possibly overestimating the risk.

3. Endocrine Disrupter Effects

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

4. Tolerances

A tolerance needs to be established for propoxur use in food processing plants and food handling establishments.

5. Occupational and Residential Labeling Rationale/Risk Mitigation

At this time, some products containing propoxur are intended primarily for occupational use and some are intended primarily for homeowner use.

Requirements for Handlers

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

- Based on the risks posed to handlers by the active ingredient, EPA may establish active ingredient-specific (ai-specific) handler requirements for end-use products containing that active ingredient. If the risks to handlers posed by the active ingredient are minimal, EPA may establish no ai-specific handler requirements.

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

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

Occupational-Use Products

EPA is establishing ai-specific PPE for some use patterns of propoxur. The use patterns and PPE are specified in Section V.

Homeowner-Use Products

EPA is not establishing ai-specific requirements for homeowner handlers for propoxur.

Post-Application/Entry Restrictions

Based on a review of the incidents related to the use of propoxur, the Agency believes that limiting entry immediately following applications of propoxur liquid or aerosol either by a PCO or homeowners is a prudent health and safety practice. Therefore, EPA is establishing entry restrictions for propoxur end-use products, other than those for use on pets. For specific language see Section V.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing propoxur. EPA believes that the risks previously identified for pets will be mitigated based on the changes implemented by the registrant for the proper adjustment of flea collars on pets. For specific labeling statements, refer to Section V of this document.

6. Ecological Effects

a. Avian and Mammalian Risks

Although calculated acute avian risks exceed the LOCs, the Agency believes risks to birds from the limited outdoor bait applications are not excessive. There are no reported bird poisoning incidents from propoxur, even though incidents are more apt to be observed on use patterns, such as, home lawns rather than in agricultural settings away from human activity. It is likely that potential exposure to birds has been drastically reduced since the 1992 deletion of broadcast uses on lawns/turf.

Outdoor applications are limited to applications to exteriors of buildings, on and immediately around patios, sidewalks and building foundations, and insecticidal tape on boat mooring lines, water lines and utility supply lines. Exposure of propoxur to avian and mammalian wildlife species with the current outdoor uses results in slight exposures, if any. Expanding outdoor uses, however, would increase the Agency's concerns.

b. Aquatic Invertebrates

Minimal aquatic exposure from runoff or drift is expected from propoxur outdoor bait products. Although the toxicity is high, the aquatic risk does not exceed the Agency's LOCs. Based on the limited outdoor bait applications of propoxur, minimal to no risk is expected to aquatic organisms.

c. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the

adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of propoxur for the above eligible uses has been reviewed and determined to be substantially complete.

2. Labeling Requirements for Manufacturing-Use Products

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

> "Only for formulation into an insecticide for the following use(s) (list those uses that are being supported by the MP registration)."

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

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling Requirements for End-Use Products

PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain propoxur must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

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

Products Intended Primarily for Occupational Use

For crack and crevice treatments

PPE must include:

--long-sleeved shirt and long pants,
--chemical-resistant gloves, and
--shoes plus socks.

For PCOs applying granular and bait forms

PPE must include:

--long-sleeved shirt and long pants, and
--shoes plus socks.

If an end-use product is toxicity category I or II for eye irritation, protective eye wear will be required.

Entry Restrictions

Sole-active-ingredientend-use products that contain propoxur must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

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

Products Intended for Occupational Use and Homeowner Use

Entry restrictions:

- For liquid applications to surfaces other than on pets: "Do not allow people or pets to enter the treated area until sprays have dried."

- For all other applications, there is no entry restriction.

Placement in labeling: Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing propoxur that are intended for occupational use or intended for homeowner use.

Application Restrictions

For products which have applications to surfaces other than on pets:

"Do not apply this product in a way that will contact any person or pet, either directly or indirectly. Keep people and pets out of the area during application."

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."

{Select the following only if gloves and/or protective eyewear are required for applicators:}

- "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

For products with residential outdoor uses

This product is toxic to wildlife and aquatic invertebrates. Birds and small mammals feeding on treated bait may be killed. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

- "Birds and small mammals feeding on treated bait may be killed"

- "Do not apply as a landscape treatment (to lawns, shrubs or trees, garden plants)"

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 propoxur 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

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES; COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT INDOOR								
BAIT/SOLID	0.250	Bait traps. Place traps in homes, cabins, apartment buildings, stores, restaurants, trailers, campers and warehouses. Use a key to press in semi-perforated sides. Place traps where ants are numerous (under sinks, stoves, refrigerators and cabinets).						
	2.0	Apply bait lightly to floors near baseboards, in closets, under sinks and refrigerators, around and inside garbage cans, cracks and crevies and other places where insects are found. Place traps in homes, cabins, apartment buildings, stores, restaurants, trailers, campers and warehouses. Use a key to press in semi-perforated sides. Place traps where roaches are numerous (under sinks, stoves, refrigerators and cabinets). Pre-filled disposable syringe or tube applicator. Use paste as a spot or crack and crevice treatment. Apply under surface of counters, tables, shelving, drawers, under sinks, around pipe collars, under refrigerators, stoves, electrical boxes and computer housing. Bait station. Place bait station near home entry points, doors, garage doors and porches. Also place in bathrooms, pantries, and kitchens, especially near water pipes and refrigerators.	4 oz per 1000 sq.ft. 4-6 trays per 100 sq.ft. Use all 12 bait stations at one time.	Repeat as necessary. Replace every 4 weeks or as needed. Re-apply in 1-2 weeks if no bait is visible. Replace traps every 2-3 months for continued control.				
PRESSURIZED LIQUIDS	0.493	Aerosol can. Spot treatment only. Insert extension tube into actuator. Apply to cracks and crevices around baseboards, shelves, cupboards, around door sills and window frames.		Repeat as necessary.				
	0.5	Aerosol can. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, furniture, refrigerators, sinks, moist areas, bath tubs, drains, laundry tubs, stoves, around air ducts, and in and around waste containers. Spray ant trails and places where they enter. Applications of this product in food preparation areas are limited to crack and crevice treatments only.	1-2 feet per second or until surfaces are wet.	Repeat as needed.				
	0.529	Aerosol can. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, furniture, refrigerators, sinks, moist areas, bath tubs, drains, laundry tubs, stoves, around air ducts, and in and around waste containers. Spray ant trails and places where they enter. Applications of this product in food preparation areas are limited to crack and crevice treatments only.	1 foot per second or until surfaces are wet.	Repeat as needed.				
	0.665	Aerosol can. Spray cracks, crevices, along baseboards, doors and windowsills. Spray behind and beneath sinks, stoves, refrigerators and around garbage cans and plumbing. Apply to ant trails.	Spray until wet.	Repeat as necessary.				

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
	0.67	Aerosol can. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, furniture, refrigerators, sinks, moist areas, bath tubs, drains, laundry tubs, stoves, around air ducts, and in and around waste containers. Spray ant trails and places where they enter. Applications of this product in food preparation areas are limited to crack and crevice treatments only.	1 foot per second or until surfaces are wet.	Repeat as needed.				
	1.0, 1.054, 2.0	Aerosol can. Apply using supplied actuator and injection tubes or other Whitmire equipment. Spot treatments. Spray around baseboards, into cracks and crevices, behind and beneath sinks, stoves cabinets, refrigerators, damp areas and in and around waste containers. Around door and window frames, plumbing and other places where insects may enter. Spray into voids and channels created by termites, carpenter ants and carpenter bees.	Spray until surfaces are wet. One linear foot per second. 1 second per spot with spots 12 inches apart. Inject 5-10 seconds of spray into insect tunnels and cavities.	Repeat as necessary.				
CONCENTRATED LIQUID	5.0, 8.0, 10.0	Sprayer. Coarse spray. Spot treatment. Spray around baseboards, into cracks and crevices, behind and beneath sinks, stoves cabinets, refrigerators, damp areas and in and around waste containers. Around door and window frames, plumbing and other places where insects may enter.	Mix one part product with nine parts of water or kerosene.	Retreat as needed.				
	10.2	Compressed air sprayer. Apply as a coarse wet spray until surfaces are wet. Spray around baseboards, into cracks and crevices, behind and beneath sinks, stoves cabinets, refrigerators, damp areas and in and around waste containers. Around door and window frames, plumbing and other places where insects may enter.	Dilute one part of product with ten parts of water.	Repeat as needed.				
	13.75 13.9, 14.6, 14.8,	Hand or power operated sprayers. Apply as a residual spray. Apply as a coarse spray. Spray around baseboards, into cracks and crevices, behind and beneath sinks, beneath shelves and drawers, stoves cabinets, refrigerators, damp areas and in and around waste containers and utility installations. Around door and window frames, plumbing and other places where insects may enter.	11 fluid oz. per 1 gal water. 8 fluid oz of product in 1 gal water.	Repeat as necessary.				
WETTABLE POWDER	70.0	Sprayer. Apply as a coarse spray. Spray around baseboards, into cracks and crevices, behind and beneath sinks, beneath shelves and drawers, stoves cabinets, refrigerators, damp areas and in and around waste containers and utility installations. Around door and window frames, plumbing and other places where insects may enter.	2 oz of 70WP in 1 gallon water.					
LIQUID-RTU	0.5, 0.643	Power operated or hand pressurized sprayers. For areas other than those in commercial Food Handling Establishments spray into cracks, crevices, around baseboards, behind and beneath cabinets, to the floor, refrigerators, sinks, stoves, and in and around waste containers. Spray ant trails and places where they enter.		Repeat as needed.				

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
	1.0, 1.11	Power operated or hand pressurized sprayers. Apply with a paint brush. Apply with a low pressure sprayer as a coarse spray. Use as a spot treatment. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, to the floor, refrigerators, sinks, stoves, and in and around waste containers. Spray ant trails and places where they enter.	As a coarse spray until surfaces are wet. Spray until surfaces are coated with a dew-like mist.	Repeat as needed.				
OIL SOLUBLE LIQUID	4.0	Sprayer. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, to the floor, refrigerators, sinks, stoves, and in and around waste containers. Spray ant trails and places where they enter.	Mix one part of product with three parts of oil.	Reapply for cockroach control every 1-2 weeks until control is acheived.				
IMPREGNATED PAPER	1.0	Use shelf and lining paperto line drawers and cabinets, use in storage areas and around garbage areas. put under sinks and in broom closets and other secluded areas where insects may congregate. Use in basements and other damp areas.						
FOOD HANDLING ESTABLISHMENTS; FOOD PROCESSING PLANT PREMISES; MEAT PROCESSING PLANT PREMISES; FOOD STORAGE AREAS; RESTAURANTS; TRANSPORTATION EQUIPMENT; ETC.: NON-FOOD AREAS (includes garbage rooms, entries and vestibules, lavatories, floor drains, offices, locker rooms, boiler rooms, machine rooms, boiler rooms, garages, mop closets, storage after canning/bottling, warehouses where food is not exposed, buses, boats, ships, trains, trucks, planes). FOOD AREAS: treatments are limited to crack and crevice applications only.								
LIQUID-RTU	0.5, 0.643	Power operated or hand pressurized sprayers. Equipment capable of delivering a pin stream of insecticide. NON-FOOD AREAS: Apply to baseboard areas, cracks and crevices, around water pipes, behind and beneath sinks, lockers, window and door screens, tables, pallets, etc. FOOD AREAS: Apply a small pin stream directly into cracks, crevices, wall voids, hollow equipment legs, etc.		Repeat as necessary				
	1.0, 1.11	Power operated or hand pressurized sprayers. Compressed air sprayers. Low pressure sprayer as a coarse spray. NON-FOOD AREAS: Apply to baseboard areas, cracks and crevices, around water pipes, behind and beneath sinks, lockers, window and door screens, tables, pallets, etc. FOOD AREAS: Apply a small pin stream directly into cracks, crevices, wall voids, hollow equipment legs, etc.		Repeat as necessary				
WETTABLE POWDER	70.0	Sprayer. NON-FOOD AREAS: Apply to baseboard areas, cracks and crevices, around water pipes, behind and beneath sinks, lockers, window and door screens, tables, pallets, etc. FOOD AREAS: Apply a small amount directly into cracks, crevices, wall voids, hollow equipment legs, etc.	2 oz 70WP in 1 gallon water.	Repeat as needed.				
PRESSURIZED LIQUIDS	0.67	Aerosol can. Spot treatments.	Spray untiil surfaces are wet.					

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
	1.0, 1.054, 2.0	Supplied actuator and injection tubes or other Whitmire equipment. Spray into cracks and crevices and void spaces. Spot treatments. FOOD AREAS: includes areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas. Crack and Crevice treatments only in food areas.	One linear foot per second or 10 seconds per 3 cubic feet. 1 second per spot, spots 12 inches apart.	Repeat as necessary.				
OIL SOLUBLE LIQUID	4.0	Sprayer. Spray into cracks, crevices, around baseboards, behind and beneath cabinets, to the floor, refrigerators, sinks, stoves, and in and around waste containers. Spray ant trails and places where they enter.	Mix one part of product with three parts of oil.	Reapply for cockroach control every 1-2 weeks until control is acheived.				
CONCENTRATED LIQUID	8.0, 10.0	Sprayer. Coarse wet spray. Crack and crevice only. Apply a small amount of material directly into cracks and crevices such as expansion joints between different elements of construction or between equipment bases and floor, wall voids, motor housing, junction boxes, conduits, hollow equipment leg.	Mix one part of product with nine parts of water or kerosene.	Repeat as necessary.				
	10.2	Compressed air sprayer. Apply as a coarse wet spray until surfaces are wet. Spray around baseboards, into cracks and crevices, behind and beneath sinks, stoves cabinets, refrigerators, damp areas and in and around waste containers. Around door and window frames, plumbing and other places where insects may enter.	Dilute one part of product with ten parts of water.	Repeat as needed.				
	13.75 13.9, 14.6, 19.6	Hand or power operated sprayers. Apply in NON-FOOD areas. FOOD AREAS: Apply as a crack and crevice treatment. Apply a small amount of material directly into cracks and crevices such as expansion joints between different elements of construction or between equipment bases and floor, wall voids, motor housing, junction boxes, conduits, hollow equipment leg.	11 fluid oz of product in 1 gal water. 8 fluid oz of product in 1 gal water.	Repeat as needed.				
BAIT/SOLID	2.0	Apply bait on paper, pasteboard or other material that will permit removal. Locate bait these stations on windowsills, on floors near walls, in storage areas and other areas where insects have been observed.		Repeat as necessary.				
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR); HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES								
GRANULAR	0.2	Application equipment not on label. For use on commercial and residential building exteriors, around patios, driveways, sidewalks, and foundations.	4 oz of bait per 500 sq.ft.	Repeat when necessary.				
WETTABLE POWDER	70.0	Sprayer. Spray thoroughly areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	2 oz of 70WP in 1 gallon water.					

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
PRESSURIZED LIQUID	0.25	Aerosol can. For best results spray in early morning or early evening. Point spray opening toward nest. Spray until nest is thoroughly saturated.						
	0.493	Aerosol can. Spot treatment only. Treat ant trails, around door sills and window frames, apply to ant hills, apply to outside of foundations, doors, windows, screens, porches, light fixtures, apply to wasp nests, surfaces of garages and outbuildings.		Repeat as necessary.				
	0.5	Aerosol can. Spray outside surfaces of screens, doors, window frames, foundations, patios, etc. Spray ant runways. Apply to wasp and hornet nests. Spray ant hills and runways. Install delivery tube and spray into ant mound. Spray spider webs under porches and eaves. Manholes, utility poles, farms, and around food processing plants.	1 foot per second or until surfaces are wet. Spray for ten seconds or until surface is moist.	Repeat as necessary.				
	0.475, 0.5	Aerosol can. Control of yellow jackets, wasps, hornets, and bees. Outdoor use only, specific sites not identified.	Spray until area is saturated.					
	0.529	Aerosol can. Spray door sills, window frames, outside foundations and porches. Spray directly on ant hills and on swarming ants outdoors. Apply to screens, walls, door and window frames, light fixtures and other outdoor surfaces. Apply to paper wasp and mud dauber wasp nests.	1 foot per second or until surfaces are wet.	Repeat as needed.				
	0.665	Aerosol can. Spray door sills, window frames, outside foundations and porches. Spray directly on ant hills and on swarming ants outdoors. Apply to screens, walls, door and window frames, light fixtures and other outdoor surfaces.	Until surfaces are wet.	Repeat as needed.				
	0.67	Aerosol can. Spray door sills, window frames, outside foundations and porches. Spray directly on ant hills and on swarming ants outdoors. Apply to screens, walls, door and window frames, light fixtures and other outdoor surfaces. Apply to paper wasp and mud dauber wasp nests.	Until surfaces are wet.	Repeat as needed.				
	1.0, 1.07, 1.054	Aerosol can. Spray around foundations and porches, outside surfaces of screens, doors, window frames, patios. Spray on ant hills and ant trails. Inject into insect tunnels and cavities. Treat trails, points of entry from voids around doors and windows.	Until surfaces are wet.	Repeat as necessary				
LIQUID-RTU	0.5, 0.643	Power operated or hand pressurized sprayers. Spray thoroughly areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	Coarse spray until surfaces are wet.	Repeat as necessary				

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
	1.0, 1.11	Power operated or hand pressurized sprayers. Low pressure sprayer as a coarse spray. Spray thoroughly areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	Coarse spray until surfaces are wet. 1 gallon per 500 square feet or to runoff.	Repeat as necessary				
CONCENTRATED LIQUID	5.0, 8.0, 10.0	Sprayer. Brush. Coarse spray. Spot treatment. Spray or brush areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	Mix one part of product with nine parts of water or kerosene.	Repeat treatment when necessary..				
	10.2	Compressed air sprayer. Apply as a coarse wet spray until surfaces are wet. Spray or brush areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Ant runways and hills.	Mix one part of product with ten parts water.	Repeat as needed.				
	13.75 13.9, 14.6, 14.8, 19.6	Hand or power operated sprayers. Paint brush. Spray or brush areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	11 fluid oz of product in 1 gal. water. For sand flies and punkies mix 11 fluid oz of product in 1 quart of water. 8-11 fluid oz of product in 1 gal water. For sand flies and punkies mix 8 fl. oz. of product with 1 quart of water (4.5% con-centrate).	Repeat as needed.				
OIL SOLUBLE LIQUID	4.0	Sprayer. Coarse spray. Spray thoroughly areas such as surfaces of screens, doors, window frames, foundations, patios, around light fixtures, in garages, etc. Perimeter treatments of structures. Ant runways. Saturate wasp and hornet nests.	Mix one part of product with three parts of oil.	Repeat when necessary.				
BAIT/SOLID	0.250	Bait traps. Place traps near ant colonies and along ant trails. Use a key to press in the semi-perforations on side of trap.						
	2.0	Apply bait evenly in a band 2-3 feet wide around foundations, patios, driveways, sidewalks, cracks and crevices, beneath concrete drain splashpans.	4 oz per 1000 sq.ft.					
DOGS/CANINES (ADULTS/PUPPIES)								

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
PRESSURIZED LIQUID	0.25	Spray bottle (non-gas aerosol). Thoroughly spray pet until wet. Fluff long hair so spray reaches skin.				7		
IMPRG. COLLAR/TAG	4.3	Collar (net wt. = .90 oz) Place collar around neck of dog.	One collar per dog.	Replace collar every 5 months, or when effectiveness diminishes.				
	9.0	Collar (net wt. = 0.85 oz) Place collar around neck of dog.	One collar per dog.	Replace collar every 5 months or sooner if necessary to maintain control.				
	9.4	Collar (net wt. not on label) Place collar around neck of dog.	One collar per dog.	Replace when effectiveness diminishes.				
	10.0	Collar (net wt. = small dog collar = 0.42 oz medium dog collar = 0.96 oz large dog collar = 1.33 oz) Place collar around dogs neck.	One collar per dog.	Replace collar after 6 months or when effectiveness diminishes.				
CATS (ADULTS AND KITTENS)								
PRESSURIZED LIQUID	1.O	Aerosol can (foam). Apply a line of product along the back starting at the tail and ending at the neck.	2 seconds for each five pounds of cat.			Repeat every 7 days for tick control and every 14 days for fleas.		
IMPRG COLLAR/TAG	2.4	Collar (net wt. = 0.5 oz) Place collar on cats neck.	1 collar per cat.	Replace every 5 months or when effectiveness diminishes.				
	9.4	Collar (net wt. not on label) Place around cats neck.	One collar per cat.	Replace when effectiveness diminishes.				
	10.0	Collar (net wt. = 0.42 oz) Place around animals neck.	One collar per cat.	Replace collar after 6 months or when effectiveness diminishes.				
PET LIVING/SLEEPING QUARTERS								
PRESSURIZED LIQUID	0.25	Spray bottle (non-gas aerosol). For dogs only.				7		
	0.493	Aerosol can. Spray cracks, crevices and areas where pet lies down.						

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
	0.5	Aerosol can. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	1 foot per second or until surfaces are wet.	Repeat as necessary.				
	0.529	Aerosol can. Spray cracks, crevices and areas where pets normally lie down. For dog kennels apply to outside runways, window sills and ledges.						
	0.665	Aerosol can. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	Until surfaces are wet.	Repeat as necessary.				
	0.67	Aerosol can. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	Until surfaces are wet.	Repeat as necessary.				
	1.0, 1.054	Aerosol can. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	Until surfaces are wet.	Repeat as necessary.				
CONCENTRATED LIQUID	5.0, 8.0, 10.0	Sprayer. Coarse spray. Spot treatment. Spray around baseboards, window and door frames, wall cracks, and local areas of floors. Apply a spot treatment to pets beds and resting areas.	Mix one part of product with nine parts of water or kerosene.	Repeat as needed.				
	10.2	Compressed air sprayer. Coarse wet spray until surfaces are wet. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	Mix one part of product with ten parts of water.	Repeat as needed.				
OIL SOLUBLE LIQUID	4.0	Sprayer. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.		Repeat when necessary.				
LIQUID-RTU	0.5	Power operated or hand pressurized sprayers. Spray around baseboards, window and door frames, wall coverings.	Coarse spray until surface is wet.	Repeat as necessary.				
	1.0	Power operated or hand pressurized sprayers. Spray around baseboards, window and door frames, wall cracks, and local areas of floors.	Coarse spray until surfaces are wet.	Repeat as necessary.				
ANIMAL KENNELS/SLEEPING QUARTERS (COMMERCIAL); RESEARCH FACILITIES (ANIMAL QUARTERS)								
PRESSURIZED LIQUIDS	0.493	Aerosol can. Spot treatment only. Apply to outside runways, window sills, and ledges, outdoor surfaces of screens, window frames, and other surfaces where insects congregate.						
	0.5	Aerosol can. Apply to outside runway, windowsills, and ledges.	1 foot per second or until surface is wet.	Repeat as necessary.				

FORMULATION	% AI	EQUIPMENT AND USE DIRECTIONS	RATE	TIMING	MAX RATE	MIN INT	PHI	REI
LIQUID-RTU	0.5	Power operated or hand pressurized sprayers. Spray around baseboards, window and door frames, wall coverings.	Coarse spray until surface is wet.	Repeat as necessary.				
	1.0	Compressed air sprayers.		Repeat as needed.				
BAIT/SOLID	2.0	No specific instructions given for application.	Possibly 4 oz per 1000 sq.ft.	Repeat as necessary.				
BOAT MOORING LINES								
INSECTICIDAL TAPE	10.0	Insect control system Apply trap, cartridge (containing insect repellent) and Insectape to the mooring lines of boat.	One trap per mooring line.	Replace as needed.				
	10.0	Insecticidal strip and trap. For control of boll weevil, adult gypsy moth and Mediterranean fruit flies in insect traps. areas for traps to be placed not specified on label.	Strip size will vary depending on insects to be controlled0.25x1.0 inch up to 6 1x4 inch strip per trap.	Replace as effectiveness diminishes.				
	10.0	Specially formulated package for protection of telecommunications, power and electronic equipment. Reppels imported fire ants and roaches. Also use in boar guard systems. Kills and controls insects from entering equipment.	Can apply entire 4x6 inch strip. Do not apply more than 12 1x4 inch strips per 3 cu.ft. of equipment.	Replace as effectiveness diminishes.				
SPECIAL LOCAL NEEDS (SLN's)								
INSECTICIDAL TAPE	10.0 Parent label # is 8730-4-ZA.	California only. Urban and agricultural areas under quarantine pest surveillance. Apply to detection traps from the time they are deployed until the end of the trapping season.	Affix one strip of product per trap.	Replace when necessary to maintain effectiveness.				
FOR MANUFACTURING USE ONLY								
LIQUID	5.0, 5.88, 5.89	May be used to formulate products for use in residential indoor, food, nonfood, and industrial use areas.						
	10.0, 70.0, 99.6	INDOOR USES: Only for formulation into insecticides for residential and commercial indoor, food, nonfood and institutional areas. OUTDOOR USES: Residential and commercial applications to surfaces of buildings and around patios, driveways, sidewalks and foundations.						
	3.35	This product may NOT be used to formulate products for the following uses: 1) food producing livestock - direct application to meat and dairy animals, treatment of occupied premises or when animal food or feed is present, 2) growing crops - edible crops and pre- and post-harvest sprays, 3) fumigated commodities and 4) aquatic uses.						

GUIDE TO APPENDIX B

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

Data Supporting Guideline Requirements for the Reregistration of Propoxur

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	42286601, 42715301
61-2A	Start. Mat. & Mnfg. Process	all	40711201, 42286601, 42286602, 42715301
61-2B	Formation of Impurities	all	42286601
62-1	Preliminary Analysis	all	40951301, 42286602, 42715300
62-2	Certification of limits	all	42286602, 42715302
62-3	Analytical Method	all	40951301, 42715302, 42911001
63-2	Color	all	40711202
63-3	Physical State	all	40711202
63-4	Odor	all	40711202
63-5	Melting Point	all	10711202, 42601201
63-7	Density	all	40711202, 42601201
63-8	Solubility	all	40711202, 42601201
63-9	Vapor Pressure	all	40711202
63-11	Octanol/Water Partition	all	40711202
63-13	Stability	all	40711202, 42286603, 43158001
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	all	160000, 41625101
71-1B	Acute Avian Oral - Quail/Duck TEP	all	41625101
71-2A	Avian Dietary - Quail	all	149015, 22923, 42301201, 42757101
71-2B	Avian Dietary - Duck	all	149015, 22923, 42301201, 42757101
71-3	Wild Mammal Toxicity	all	152443, 256151, 42615403
71-4A	Avian Reproduction - Quail	k	149017

Data Supporting Guideline Requirements for the Reregistration of Propoxur

REQUIREMENT		USE PATTERN	CITATION(S)
71-4B	Avian Reproduction - Duck	k	149016
72-1A	Fish Toxicity Bluegill	all	149171
72-1C	Fish Toxicity Rainbow Trout	all	149171
72-3C	Estuarine/Marine Toxicity - Shrimp	all	40228401
72-2A	Invertebrate Toxicity	all	149172
72-4A	Early Life Stage Fish	WAIVED	
141-1	Honey Bee Acute Contact	k	60633
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	all	149030, 152443
81-2	Acute Dermal Toxicity - Rabbit/Rat	all	40836401
81-3	Acute Inhalation Toxicity - Rat	all	40836402
81-4	Primary Eye Irritation - Rabbit	all	41737801
81-5	Primary Dermal Irritation - Rabbit	all	41870801
81-6	Dermal Sensitization - Guinea Pig	all	41652401
81-8-SS	Acute Neurotoxicity Study - Rat	all	43445701
82-1B	90-Day Feeding - Non-rodent	all	41066001
82-3	90-Day Dermal - Rodent	all	41066001
82-7-SS	90-Day Neurotoxicity Screening - Rat	all	42041601, 43445701
83-1A	Chronic Feeding Toxicity - Rodent	all	142725

Data Supporting Guideline Requirements for the Reregistration of Propoxur

REQUIREMENT		USE PATTERN	CITATION(S)
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	**all**	**149040, 42041601**
83-2A	**Oncogenicity - Rat**	**all**	**142725**
83-2B	**Oncogenicity - Mouse**	**all**	**42597701**
83-3A	**Developmental Toxicity - Rat**	**all**	**41061101**
83-3B	**Developmental Toxicity - Rabbit**	**all**	**41061102**
83-4	**2-Generation Reproduction - Rat**	**all**	**41817501, 42615403**
84-2A	**Gene Mutation (Ames Test)**	**all**	**147479, 149043, 40836403**
84-2B	**Structural Chromosomal Aberration**	**all**	**149041, 40953501, 41008701, 41724601, 42005101**
84-4	**Other Genotoxic Effects**	**all**	**41169901**
85-1	**General Metabolism**	**all**	**142731, 165000, 40629702, 40629703, 40629704, 40629706, 41345801**
85-2	**Dermal Penetration**	**all**	**40953502**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
133-3	**Dermal Passive Dosimetry Exposure**	**all**	**41054701, 41054702, 41054703, 41054704, 41054705, 41858201, 42087201**
133-4	**Inhalation Passive Dosimetry Exposure**	**all**	**41054701, 41054702, 41054703, 41054704, 41054705, 41858201, 42087201, 42648001, 43398501**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	**all**	**85762**
161-2	**Photodegradation - Water**	**k***	**85763**
161-3	**Photodegradation - Soil**	**k***	**85763**
162-1	**Aerobic Soil Metabolism**	**k***	**85768**

Data Supporting Guideline Requirements for the Reregistration of Propoxur

REQUIREMENT		USE PATTERN	CITATION(S)
162-2	Anaerobic Soil Metabolism	k*	85768
163-1	Leaching/Adsorption/De-sorption	k*	29887, 85769, 85770
164-1	Terrestrial Field Dissipation	k*	857721
165-1	Confined Rotationl Crop	WAIVED	
165-2	Field Rotational Crop	WAIVED	
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	l	42286610
171-4B	Nature of Residue - Livestock	WAIVED	
171-4C	Residue Analytical Method - Plants	l	42756701
171-4D	Residue Analytical Method - Animal	l	42756701
171-4E	Storage Stability	l	42286612
171-4I	Magnitude of Residues - Food Handling	l	42286604, 42286605, 42286606, 42286607, 42286608, 42286609, 42286610, 42286611, 42286612

* These studies are not generally required for residential uses. However because data were available for porpoxur they were reviewed and considered in the risk assessment.

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00029887	Thornton, J.S.; Hurley, J.B.; Obrist, J.J. (1976) Soil Thin-Layer Mobility of Twenty Four Pesticides (sic) Chemicals: Report No. 51016. (Unpublished study received Jan. 28, 1980 under 5F1547; submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL: 099216-I)
00060633	Atkins, E.L., Jr.; Anderson, L.D. (1967) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. University of California Agricultural Extension Services. (M-16; submitter report no. 22259; also "In" unpublished submission received March 27, 1974 under 4F1485; submitted by Chemagro Crop., Kansas City , Mo.; CDL:092011-M)
00085762	Aly, O.M.; El-Dib, M.A. (1971) Studies on the persistence of some carbamate insecticides in the aquatic environment-I: Hydrolysis of Sevin, Baygon, Pyrolan and Dimetilan in waters. (Without title) ?:1191-1205. (Submitter 34648; also "In" unpublished submission received Oct 21, 1981 under 3125-306; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246088-C)
00085763	Gronberg, R.; Pither, K.M. (1981) Photodecomposition of Baygon in Aqueous Media: Report No. 53613. (Unpublished study received Oct 21, 1981 under 3125-306; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246088-D)
00085768	Gronberg, R.R.; Hanna, G.R.; Atwell, S.H. (1981) The Metabolism of Baygon in Sandy Loam and Silt Loam Soils: 69617. (Unpublished study received Oct 21, 1981 under 3125-306; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246088-J)
00085769	Atwell, S.H. (1976) Leaching Characteristics of Baygon on Aged Soil: Report No. 50718. (Unpublished study received Oct 21, 1981 under 3125-306; submitted by Mobay Chemcial Corp., Kansas City, Mo.; CDL:246088-L)

BIBLIOGRAPHY

MRID	CITATION
00085770	Lenz, M.F.; Gronberg, R.R. (1980) Soil Adsorption and Desorption of Baygon: 69016. (Unpublished study received Oct 21, 1981 under 3125-306; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246088-N)
00085772	Mobay Chemical Corporation (1981) Residue of Baygon--Various Soils. (Compilation; unpublished study, including report nos. 69240, 69241, 69242,..., received Oct 21, 1981 under 3125-306; CDL:246088-Q)
00142725	Suberg, H.; Loeser, E. (1984) Chronic Toxicological Study with Rats (Feeding Study over 106 Weeks): Report No. 12870. Unpublished Mobay Study No. 88501 prepared by Bayer Institute of Toxicology. 846 p.
00142731	Klein, W. (1984) Effect of an Active Ingredient and Three Metabolites on the DNA Metabolism: Report No. A050. Unpublished Mobay Study No. 88852 prepared by Bayer Institute of Toxicology. 36 p.
00147479	Herbold, B. (1982) Carbamate UN Technical: Salmonella/Microsome Test to Evaluate for Point Mutation: Bayer Report No. 11301. Unpublished Mobay report no. 82726 prepared by Bayer AG. 20 p.
00149015	Lamb, D. (1981) Acute Dietary LC_{50} of Technical Propoxur (Baygon) to Bobwhite Quail: Study No. 80-175-06: Mobay Report No. 80046. Unpublished study prepared by Mobay Chemical Corp. 9 p.
00149016	Carlisle, J.; Carsel, M. (1982) Propoxur Reproduction Study with Mallard Duck: Study No. 81-675-06: Mobay Report No. 82265. Unpublished study prepared by Mobay Chemical Corp. 55 p.
00149017	Lamb, D.; Carsel, M. (1982) Propuxur Reproduction Study with Bobwhite Quail: Study No. 81-675-04: Mobay Report No. 82269. Unpublished study prepared by Mobay Chemical Corp. 58 p.
00149030	Heimann, K. (1982) Carbamate UN, Technical: Study for Acute Toxicity on Rats: Report No. 11329. Unpublished Mobay Report No. 82740 prepared by Bayer AG. 8 p.
00149040	Hoffmann, K.; Groning, P. (1984) BOQ 58 123 15 (BOE 58 123 15, C.N. Propoxur): Chronic Toxicity to Dogs on Oral Administration: (12month

BIBLIOGRAPHY

MRID	CITATION
	Feeding Study): Report No. 12605. Unpublished Mobay Report No. 86665 prepared by Bayer AG. 240 p.
00149041	Herbold, B. (1980) Micronucleus Test on Mouse To Evaluate BOE 5812315 for Mutagenic Potential: BOE 5812315: Report No. 9274. Unpublished Mobay Report No. 69317 prepared by Bayer AG. 17 p.
00149043	Ohta, T.; Moriya, M. (1983) Propoxur: Microbial Mutagenicity Study. Unpublished study prepared by Institute of Environmental Toxicology. 7 p.
00149171	Lamb, D. (1981) Acute Toxicity of Technical Propoxur (Baygon) to Bluegill and Rainbow Trout: Study Nos. 81-066-02 and 80-066-11. Unpublished study prepared by Mobay Chemical Corp. 9 p.
00149172	Lamb, D. (1981) Acute Toxicity of Technical Propoxur (Baygon) to Daphnia magna: Study No. 81-067-01. Unpublished study prepared by Mobay Chemical Corp. 9 p.
00152443	Flucke, W. (1980) Boe 5812315 (Propoxur) Acute Toxicity Studies: Report No: 9295. Unpublished study prepared by Bayer AG. 7 p.
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
00165000	Karl, W. (1985) Biotransformation of Propoxur Quantitative Determination of Metabolite Spectrum in Rats Dosed Once with Carbon 14 Propoxur after Being Fed Compound at Three Subchronic Dietary Levels. Unpublished Mobay Report No. 90441 prepared by Bayer AG. 33 p.
40629702	Eben, C. (1987) Investigations on the Biotransformation of Propoxur in Mice: Report Nos. 15697: 95615. Unpublished study prepared by Bayer Ag. 47 p.
40629703	Eben, C. (1986) The Biotransformation of Propoxur in Golden Hamsters: Report No. 93152. Unpublished study prepared by Bayer Ag. 44 p.
40629704	Eben, C. (1985) Studies on Biotransformation of Propoxur in Humans: Report No. 91951. Unpublished study prepared by Bayer Ag. 39 p.

BIBLIOGRAPHY

MRID	CITATION
40629705	Eben, C. (1985) Supplementary Studies on Biotransformation of Propoxur in the Rat: Report No. 91979. Unpublished study prepared by Bayer Ag. 33 p.
40629706	Eben, C. (1986) Propoxur (the Active Ingredient of Baygon) Biotransformation Studies on Monkeys: Report No. 94293. Unpublished study prepared by Bayer Ag. 41 p.
40711201	Talbott, T. (1988) Product Chemistry of Baygon Technical: BR 1599. Unpublished study prepared by Mobay Corp. 27 p.
40711202	Talbott, T. (1988) Product Chemistry of Baygon Technical: BR 1600. Unpublished study prepared by Mobay Corp. 104 p.
40836401	Sheets, L. (1988) Acute Dermal Toxicity of Technical Grade Baygon in Rabbits: Study No. 88-023-AQ. Unpublished study prepared by Mobay Corp. 19 p.
40836402	Pauluhn, J. (1988) Study of the Acute Inhalation Toxicity in Accordance with OECD Guideline No. 403: BOQ 5812315 (Propoxur): Report No. 98291. Unpublished study prepared by Bayer AG. 83 p.
40836403	Lehn, H. (1988) Propoxur: Mutagenicity Study for the Detection of Induced Forward Mutations in the CHO-HGPRT Assay in vitro: Report No. 98290; 17090. Unpublished study prepared by Bayer AG. 33 p.
40951301	Talbott, T. (1988) Product Chemistry of Baygon Technical: Brochure No. 1639. Unpublished compilation prepared by Mobay Corp. 202 p.
40953501	Putman, D.; Morris, M. (1988) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Final Report: Laboratory Study No.: T8297.337. Unpublished study prepared by Microbiological Associates, Inc. 28 p.
40953502	Eigenberg, D. (1988) Dermal Absorption of Propoxur Technical in Rats Using Carbon 14-Propoxur: Study No. 88-721-AT. Unpublished study prepared by Mobay Corp. 84 p.
41008701	Herbold, B. (1988) Propoxur: Cytogenetic Studies of the Bone Marrow of the Chinese Hamster in vivo to Test for Harmful Effect on Chromosomes: Rept.

BIBLIOGRAPHY

MRID	CITATION
	No. 17111. Unpublished Mobay report 98468 prepared by Bayer AG, Institute of Toxicology. 53 p.
41054701	Knarr, R. (1988) Exposure of Applicators to Propoxur During Trigger Pum Spray Application of a Liquid Product: 99100. Unpublished study prepared by Mobay Corp. 195 p.
41054702	Dean, V. (1988) Exposure of Mixer/Loader-Applicators to Propoxur During Mixing/Loading and Application of Baygon 70 WP Insecticide as a Crack/Crevice Limited Surface Treatment in Residences: Report No. 99101. Unpublished study prepared by Mobay Corp. 222 p.
41054703	Knarr, R. (1988) Exposure to Propoxur of Residents of Homes Treated with Baygon 70% WP: 99102. Unpublished study prepared by Mobay Corp. 599 p.
41054704	Dean, V. (1988) Exposure of Applicators to Propoxur During Application of Baygon 2% Bait Insecticide Around Foundations, Patios, Driveways or Sidewalks: 99131. Unpublished study prepared by Mobay Corp. 227 p.
41054705	Knarr, R. (1988) Exposure of Applicators to Propoxur During Residential Application of an Aerosol Spray Containing 1% Propoxur: 99132. Unpublished study prepared by Mobay Corp. 192 p.
41061101	Becker, H.; Mladenovic, P.; Terrier, C. (1989) Embriotoxicity Study (Including Teratogenicity) with BOQ 5812315 (C. N. Propoxur) in the Rat: Report No. 98566. Unpublished study prepared by RCC. 337 p.
41061102	Becker, H.; Mladenovic P.; Terrier, C. (1989) Embrotoxicity Study (Including Teratogenecity) with BOQ 5812315 (C. N. Propoxur) in the Rabbit: Report No. 98567. Unpublished study prepared by RCC. 269 p.
41066001	Diesing, L.; Flucke, W. (1989) Subchronic Dermal Toxicity Study in Rabbits: BOQ 5812315 (Propoxur): Study No. T 8030050/ T 5030543. Unpublished Mobay report 98568 prepared by Bayer AG. 269 p.
41169901	Curren, R. (1989) Unscheduled DNA Synthesis in Rat Primary Hepatocytes: Baygon Technical: Laboratory Study No. T8297.380: Report No. 99173. Unpublished study prepared by Microbiological Associates, Inc. 26 p.

BIBLIOGRAPHY

MRID	CITATION
41345801	Kao, L. (1989) Disposition and Metabolism of Propoxur in Rats - A Review: Lab Project Number: 99792. Unpublished study prepared by Mobay Corp. 187 p.
41625101	Campbell, S. (1990) An Acute Oral Toxicity Study with the Northern Bobwhite: Baygon 2% Bait (Encapsulated): Lab Project Number: 149-159: 100240. Unpublished study prepared by Wildlife International Ltd. 21 p.
41652401	Sheets, L. (1990) Dermal Sensitization Study with Technical Grade P Propoxur (Baygon) in Guinea Pigs: Lab Project Number: 90-324-GJ: RPT. 100275. Unpublished study prepared by Mobay Corp. 21 p.
41724601	Putman, D.; Morris, M. (1990) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Baygon Technical: Supplemental to: Lab Project Number: T8297.337. Unpublished study prepared by Microbiological Associates, Inc. 13 p.
41737801	Sheets, L. (1990) Primary Eye Irritation Study with Technical Grade Propoxur (Baygon) in Rabbits: Lab Project Number: 90-335-GZ. Unpublished study prepared by Mobay Corp. 16 p.
41817501	Suter, P.; Biedermann, K.; Luetkemeier, H.; et al. (1990) BOQ 5812315 (c.n. Propoxur): Two-Generation Reproduction Study in the Rats: Report 100650: Lab Project Number: 207314. Unpublished prepared by Research and Consulting Co., Ag.; Umweltchemie Ag. 679 p.
41858201	Knarr, R. (1991) Exposure of Applicators to Propoxur During Residential Application of an Aerosol Spray Containing 1 % Propoxur: Lab Project Number: 98896. Unpublished study prepared by Mobay Corp. 256 p.
41870801	Sheets, L.; Fuss, M. (1991) Primary Dermal Irritation Study with Technical Grade Propoxur (Baygon) in Rabbits: Lab Project Number 90-325-HA. Unpublished study prepared by Mobay Corp. 16 p.
42005101	Herbold, B. (1991) Propoxur: Cytogenetic Studies of the Bone Marrow of the Chinese Hamster in vivo to Test for Harmful Effect on Chromosomes: Supplement to MRID 41008701: Lab Project Number: 98468: 17111. Unpublished study prepared by Bayer Ag., Inst. of Toxicology. 51 p.

BIBLIOGRAPHY

MRID	CITATION

42041601 Ruf, J.; Mager, H. (1991) Chronic Toxicity to Dogs (26-Week Feeding Study) with Propoxur: Lab Project Number: 101280: 19964: T/9030763. Unpublished study prepared by Bayer Ag. (Wuppertal). 245 p.

42087201 Waggoner, T. (1991) Propuxur--Dermal and Inhalation Exposure: Lab Project Number: RPT 74253: TRPROP91DF004: ADC 1240-2. Unpublished study prepared by Mobay Health Corp in coop. with Analytical Development Corp. 156 p.

42286601 Fountaine, L. (1992) Supplemental Product Chemistry of Baygon Technical (Supp. to MRIDS 40711201 and 40951304): Lab Project Number: MCL0163A; MCL0163B. Unpublished study prepared by Miles, Inc. 7 p.

42286602 Fountaine, L. (1992) Supplemental Product Chemistry of Baygon Technical (Supp. to MRID 40951301): Lab Project Number: 86193. Unpublished study prepared by Miles, Inc. 7 p.

42286603 Fountaine, L. (1992) Supplemental Product Chemistry of Baygon Technical (Supp. to MRID 40711202): Lab Project Number: BR 1796. Unpublished study prepared by Miles, Inc. 8 p.

42286604 Gronberg, R. (1992) Residues of Baygon in Milk after Treatment of a Dairy Processing Plant with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66123-R-1. Unpublished study prepared by Miles Inc. 6 p.

42286605 Gronberg, R. (1992) Residues of Baygon in Raisin Bran Dry Cereal after Treatment of Cereal Manufacturing Plant with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66246-R-1. Unpublished study prepared by Miles Inc. 6 p.

42286606 Gronberg, R. (1992) Residues of Baygon in Pasta (Spaghetti, Macaroni and Noodles) after Treatment of a Macaroni Manufacturing Plant with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66247-R-1. Unpublished study prepared by Miles Inc. 6 p.

BIBLIOGRAPHY

MRID	CITATION
42286607	Gronberg, R. (1992) Residues of Baygon in Corn Flour and Meal after Treatment of a Grain Mill with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66198-R-1. Unpublished study prepared by Miles Inc. 6 p.
42286608	Gronberg, R. (1992) Residues of Baygon in Foods and Beverages after Treatment of a Delicatessen with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66200-R-1. Unpublished study prepared by Miles Inc. 6 p.
42286609	Gronberg, R. (1992) Residues of Baygon in Food and Beverages after Treatment of a Cafeteria with Baygon 70 WP by Crack and Crevice Spot Applications (Addendum I): Lab Project Number: 66199-R-1. Unpublished study prepared by Miles Inc. 6 p.
42286610	Gronberg, R. (1992) Nature of Propoxur Residues in Foods Following Various Processing Procedures (Addendum I): Lab Project Number: 99723-1. Unpublished study prepared by Miles Inc. 9 p.
42286611	Gronberg, R. (1992) A Gas Chromatographic Method for the Determination of Residues of Baygon in Foods, Foodstuffs and Beverages (Addendum I): Lab Project Number: 54213-R-1. Unpublished study prepared by Miles Inc. 6 p.
42286612	Gronberg, R. (1992) The Stability of Baygon in Liver, Kidney and Milk (Addendum I): Lab Project Number: 31339-R-1. Unpublished study prepared by Miles Inc. 6 p.
42301201	Stafford, T. (1992) Study Upgrade: Acute Dietary LC_{50} of Technical Propuxur (Baygon) to Bobwhite Quail (Supp. to): Lab Project Number: 80-175-06: 80046-1. Unpublished study prepared by Miles Inc. 10 p.
42601201	Fontaine, L. (1992) Product Chemistry of BAYGON: Supplemental to MRID 42286603: Lab Project Number: 102591: 103874: 103880. Unpublished study prepared by Miles Inc. 25 p.
42615403	Dotti, A.; Kinder, J.; Biedermann, K.; et al. (1992) Two-generation Reproduction Study in Rats: BOQ 5812315: Lab Project Number: 286997: T

BIBLIOGRAPHY

MRID **CITATION**

5039706. Unpublished study prepared by Research & Consulting Co. Ltd. and Biological Research Labs Ltd. 734 p.

42648001 Pauluhn, J. (1992) BOQ 5812315: Study for Chronic Inhalation Toxicity in the Rats: Lab Project Number: 21848. Unpublished study prepared by Bayer AG. 4358 p.

42715300 Miles, Inc. (1993) Supplemental submission of product chemistry data in support of the reregistration of Propoxur (Baygon). Transmittal of 2 studies.

42715301 Fontaine, L. (1993) Product Chemistry of Baygon Technical: Supplement to MRID 42286601: Lab Project Number: ANR-00093: RM 301405: BR 1822. Unpublished study prepared by Miles Inc. 14 p.

42715302 Fontaine, L. (1993) Product Chemistry of Baygon Technical: Supplement to MRID 42286602: Lab Project Number: 86193: TM G-19.33: ANR-00193. Unpublished study prepared by Miles Inc. 30 p.

42756701 Stanley, C.; Thornton, J. (1990) (Reformat of MRID 121227) Gas Chromatographic Method for Residues of BAYGON and Its Major Metabolite in Animal Tissues and Milk: Lab Project Number: 30451-R: 30451. Unpublished study prepared by Mobay Corp. 18 p.

42757101 Hancock, G. (1993) Acute Dietary LC_{50} of Technical Propoxur (Baygon) to Bobwhite Quail: Study Upgrade: Lab Project Number: 80-175-06: 80046-2. Unpublished study prepared by Miles Inc. 10 p.

42757102 Hancock, G. (1993) Acute Dietary LC_{50} of Technical Propoxur (Baygon) to Mallard Duck: Study Upgrade: Lab Project Number: 80-175-10: 69609-2. Unpublished study prepared by Miles Inc. 9 p.

42911001 Fontaine, L. (1993) Supplement to MRID 42715302: Product Chemistry of BAYGON Technical: Lab Project Number: 106255: TM C-19.33: TM G-19.33. Unpublished study prepared by Miles, Inc. 28 p.

43158001 Fontaine, L. (1994) Supplement to MRID 42286603: Product Chemistry of Baygon Technical: Lab Project Number: 106474: BR 1867. Unpublished

study prepared by Miles Inc. 9 p.

43398501 Pauluhn, J. (1994) Chronic Inhalation Toxicity Study on Rats: BOQ 5812315 (c.n.: Propoxur): Addendum: Lab Project Number: 103955-1: 21848: T0019172. Unpublished study prepared by Bayer Ag Department of Toxicology. 20 p.

43445701 Dreist, M.; Popp, A. (1994) BOQ 5812315 (c.n. Propoxur): Acute Oral Neurotoxicity Screening Study in Rats: Lab Project Numbers: 23338: T 3050251: 106387. Unpublished study prepared by Bayer AG. 402 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the

request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

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

PROPOXUR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 propoxur. 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 propoxur 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 propoxur are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on propoxur 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 propoxur products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Bonnie Adler at (703) 308-8523.

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

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

RE: propoxur

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.

`EPA'S BATCHING OF PROPOXUR PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost

Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred and sixty two products were found which contain propoxur as the active ingredient. These products have been placed into twenty-six batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the batched products. Table 2 lists the products which have been placed in the "no batch" category. Due to the varied effects of different propellant systems on eye irritation, propellant spray products (whether in a batch or in the "no batch" group) cannot cite another product's eye irritation data unless the propellant systems of the two products are identical.

TABLE 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	4822-95	0.5	Liquid
	4833-111	0.665	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	655-642	0.5	Liquid
	655-641	1.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	1440-7	1.0	Liquid
	1459-27	1.0	Liquid
	11694-89	1.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	52-215	1.0	Liquid
	655-546	1.0	Liquid
	769-761	1.0	Liquid
	769-792	1.0	Liquid
	2155-59	1.0	Liquid
	6218-24	1.0	Liquid
	6720-160	1.0	Liquid
	11474-20	1.0	Liquid
	45385-13	1.0	Liquid
	58254-2	1.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	334-334		Spray
	506-133		Spray
	5887-76		Spray
	6959-89		Spray
	7754-42		Spray
	10900-73		Spray
	11715-12		Spray
	35138-66		Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
6	11474-39	0.5	Spray
	45385-1	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
7	1021-1005	6.2	Liquid
	1021-1090	3.6	Liquid
	1021-1121	3.35	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
8	69421-33	0.5	Spray
	69421-40	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
9	1021-1095	6.2	Liquid
	1021-1133	5.89	Liquid
	4972-30	5.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
10	498-73	0.5	Spray
	5887-74	0.5	Spray
	11623-2	0.5	Spray
	11623-10	0.75	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
11	239-2360	1.0	Spray
	239-2390	0.5	Spray
	498-158	0.5	Spray
	655-351	1.0	Spray
	802-438	0.5	Spray
	1203-5	1.0	Spray
	1270-94	0.5	Spray
	4822-127	0.75	Spray
	4822-315	1.25	Spray
	4822-316	1.25	Spray
	9444-186	1.0	Spray
	33176-23	0.493	Spray
	42057-59	1.0	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
12	498-123	1.0	Spray
	4822-100	1.0	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
13	498-74	0.5	Spray
	9444-92	1.0	Spray
	9444-94	2.0	Spray
	9444-115	2.0	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
14	10806-1	0.5	Spray
	10806-19	0.5	Spray
	10806-80	0.5	Spray
	10806-96	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
15	498-165	0.5	Spray
	4822-224	0.475	Spray
	4822-318	1.0	Spray
	10807-165	0.5	Spray
	13283-10	0.5	Spray
	56276-20	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
16	1021-1007	4.085	Liquid
	1021-1175	4.0	Liquid
	1021-1196	5.88	Liquid
	1021-1466	4.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
17	769-929	0.5	Spray
	769-935	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
18	861-93	1.0	Liquid
	3125-177	1.0	Liquid
	9367-50	1.0	Liquid
	28293-273	1.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
18A	498-155	0.5	Spray
	498-168	0.5	Spray
	3125-176	0.5	Spray
	3125-262	1.0	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
19	422-18	19.6	Liquid
	655-796	19.6	Liquid
	2553-37	19.6	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
20	3125-313	70.0	Solid
	3125-146	70.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
21	8730-49	10.0	Tape
	8730-53	10.0	Tape

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
22	506-125	2.0	Solid
	769-817	2.0	Solid
	3095-25	2.0	Solid
	3095-67	2.0	Solid
	3125-121	2.0	Solid
	3125-293	2.0	Solid
	5887-65	2.0	Solid
	8848-60	2.0	Solid
	10370-174	2.0	Solid
	62577-5	2.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
22A	506-137	0.25	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
23	2517-60	9.0	Collar
	2517-61	9.0	Collar
	2724-254	9.4	Collar
	2724-275	9.4	Collar
	8730-51	10.0	Collar

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
24	3125-445	1.0	Spray
	4822-449	1.0	Spray
	11715-301	1.0	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
25	3125-174	99.6	Solid
	11556-33	99.6	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
26	4822-101	0.475	Spray
	4822-333	0.25	Spray
	44446-26	0.5	Spray

NO BATCH

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
None	239-2426	2.0	Bait
	402-95	1.0	Spray
	491-194	1.0	Spray
	491-214	9.4	Liquid
	498-121	0.665	Spray
	499-289	1.0	Spray
	655-328	10.0	Liquid
	769-807	8.0	Liquid
	769-823	13.75	Liquid
	769-917	0.5	Spray
	1203-39	0.67	Spray
	1270-172	0.94	Liquid
	1270-197	0.5	Spray
	1270-199	10.0	Liquid
	1553-87	10.2	Liquid
	1685-69	1.0	Liquid
	1685-71	1.0	Spray
	1769-164	1.0	Spray
	2517-45	4.2	Collar
	2517-46	2.4	Collar
	2517-58	1.0	Foam
	2517-65	0.25	Spray
	3125-344	0.5	Spray
	3125-345	0.5	Spray

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
None	3125-450	19.6	Liquid
	4000-92	0.5	Spray
	4816-409	5.0	Liquid
	4822-84	1.0	Liquid
	4822-331	0.24	Spray
	8660-114	13.9	Liquid
	8730-35	10.0	Bait
	9444-112	0.5	Spray
	9591-124	1.0	Spray
	10807-4	0.5	Spray
	10807-48	0.5	Spray
	10807-85	1.0	Liquid
	10807-125	1.0	Spray
	11556-62	0.25	Spray
	11694-25	0.5	Spray
	11694-26	1.0	Spray
	11715-106	1.0	Liquid
	11715-109	0.5	Spray
	11715-129	1.0	Liquid
	44446-26	0.5	Spray
	4700-18	1.0	Spray
	62451-1	10.0	Solid
	62451-2	10.0	Solid
	62577-6	1.0	Solid
	66733-3	1.0	Spray

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

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, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved OMB No. 2070-0106, 2070-0057 Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	**Company Number**

Product Name	**EPA Reg. No.**

I Certify that:

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

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

Name of Firm(s)	**Date of Offer**

Certification:

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

Signature of Company's Authorized Representative	**Date**

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for propoxur that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using WWW (World Wide Web) on WWW.EPA.GOV., or contact Bonnie Adler at (703)-308-8523.

1. **PR Notice 86-5.**

2. **PR Notice 91-2 (pertains to the Label Ingredient Statement).**

3. **A full copy of this RED document.**

4. **A copy of the fact sheet for propoxur.**

The following documents are part of the Administrative Record for propoxur and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. **Health and Environmental Effects Science Chapters.**

2. **Detailed Label Usage Information System (LUIS) Report.**

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. **The Label Review Manual.**

2. **EPA Acceptance Criteria**