



Reregistration Eligibility Decision (RED)

**3-Iodo-2-propynyl
butylcarbamate (IPBC)**



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 3-Iodo-2-propynyl butylcarbamate (IPBC) which includes the active ingredient IPBC. 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 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 or generic data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Richard Gebken (703) 308-8591.

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** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**.

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

3-iodo-2-propynyl butyl carbamate (IPBC)

LIST B

CASE 2725

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IPBC REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	The Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	The Federal Food, Drug, and Cosmetic Act
FQPA	The Food Quality Protection Act of 1996
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 ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

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

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide case IPBC, which includes the active ingredient 3-iodo-2-propynyl butylcarbamate. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Additionally, the Agency has examined information concerning the exposure and susceptibility of infants and children to IPBC, and available information concerning aggregate exposure to IPBC as well as the potential for cumulative effects from IPBC and other substances that have a common mode/mechanism of toxicity.

IPBC is a fungicide/antimicrobial used as a preservative in paint, adhesives, emulsions, metal cutting fluids, oil recovery drilling mud/packer fluids, plastics, textiles, inks, paper coatings, and wood products. It is also used in residential settings as a wood preservative stain to combat wood rot/decay, and as a preservative in paints. IPBC is also used in heating, ventilation, and air conditioning (HVAC) ducts/systems to control mold and fungi. The Agency has concluded that all uses, with the exception of industrial wood protection treatments to milled forest products, the HVAC uses, textile uses, and non-industrial wood treatments other than brush, roller and airless or compressed air sprayer, as prescribed in this document, will not cause unreasonable risks to humans or the environment. Therefore, all products, except those labelled for the above-mentioned uses, are eligible for reregistration. Additional exposure data are being required to be submitted so that the Agency can assess exposure and risk from the industrial wood treatment use, HVAC use, textile use, and certain non-industrial wood treatments. The Agency cannot make reregistration eligibility decisions on these uses at this time.

The Agency has concluded that an additional uncertainty factor for estimating risk to infants and children is not warranted, that aggregate exposures from all non-occupational sources are not likely to be of concern, and that the contribution of IPBC exposures to the risks from other carbamate pesticides is likely to be minimal.

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

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered before 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 ingredients 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) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by setting a new safety standard for the establishment of tolerances. Because IPBC has no food uses, and therefore no tolerances have been established, the specific considerations outlined in FQPA are not required for this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, the potential for aggregate exposures and cumulative effects is prudent for IPBC because children and other individuals could be exposed to this compound in non-occupational settings.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of IPBC. The document consists of six sections. Section I is the introduction. Section II describes IPBC, 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 IPBC. Section V discusses the reregistration requirements for IPBC. 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:** IPBC
- **Chemical Name:** 3-Iodo-2-propynyl butylcarbamate
- **Chemical Family:** carbamate
- **CAS Registry Number:** 55406-53-6
- **OPP Chemical Code:** 107801
- **Empirical Formula:** C₈H₁₂INO₂
- **Trade and Other Names:** Troysan Polyphase Anti-Mildew
Troysan Polyphase KK-108A
Permatox IBP
ASC 67000
Carbamic acid, butyl-, 3-iodo-2-propynyl ester
- **Basic Manufacturers:** Troy Corp.
72 Eagle Rock Ave.
East Hanover, NJ 07936

Olin Corp.
350 Knotter Dr.,
Cheshire, CT 06410

B. Use Profile

Use Patterns

3-iodo-2-propynyl butyl carbamate (IPBC) is a fungicide and antimicrobial used in both industrial processes and residential settings. IPBC is used in the following industrial products and processes: paint/adhesive/emulsion manufacturing, metal cutting fluids, oil recovery drilling mud/packer fluids, plastics manufacturing, textile manufacturing, ink manufacturing, paper coating, canvas manufacturing, and milled wood products manufacturing. IPBC is also a wood preservative used to combat fungal wood rot/decay. For residential use, IPBC can be applied with a paint brush, paint roller, and airless sprayer. IPBC is also applied to heating, ventilation

and air conditioning (HVAC) ducts to control mold and fungi. IPBC is formulated as solids and liquids (0.05 to 97% active ingredient).

Use Groups and Sites:

TERRESTRIAL NONFOOD Wood protection treatment of milled forest products used for non-aquatic purposes; oil recovery, oil drilling mud and packer fluids

OUTDOOR RESIDENTIAL Wood protection treatment of buildings/products outdoor (e.g., decks and siding)

INDOOR NONFOOD Industrial adhesives/coatings, metalworking cutting fluids, latex/oil/varnish paints, plastic products, specialty industrial products, textiles/fibers/cordage

INDOOR RESIDENTIAL Wood protection treatment of buildings/products indoor

Pests: black mold, brown mold, brown rot, white rot, mold/mildew, black mold/mildew, fungal rot/decay, industrial wood protection treatment to milled forest products, fungal slime, blue stain, bacteria

Formulation Types:

Single Active Ingredient Products

- Emulsifiable concentrate--4 to 5.97%
- Soluble concentrate liquid--2.4 to 40%
- Liquid ready to use--0.4 to 0.8%
- Soluble concentrate solid--20 to 97%

Multiple Active Ingredient Products

- Liquid ready to use--0.05 to 0.5% + one other AI

Methods and Rates of Application:

Emulsifiable concentrate

Apply treatment by brush, sprayer, or tank at 0.013 gal product/gal.

Soluble concentrate liquid

Apply by brush, tank, or sprayer at 0.12 to 0.48 lb. or 0.01 to 0.02 gal product/gal. During manufacture of the product, apply industrial preservative or make up fluids treatment at 0.2 to 0.48 lb. product/gal.

Liquid ready to use

Apply by brush, roller, tank, sprayer, or pad at 2.5 to 20 gal. product/1000 ft².

Soluble concentrate solid

During manufacture, apply industrial preservative or make up fluid treatment at 0.048 lb. AI/gal.

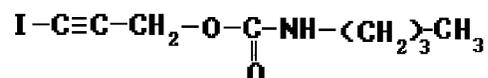
C. Regulatory History and Data Requirements

IPBC was first registered in the United States in 1975 for use as a disinfectant, fungicide and algicide. The Agency issued a Phase IV reregistration Data Call-In September 1993 requesting technical product chemistry, ecological effects, and environmental fate studies. These data were required to supplement the existing database for the Agency's assessment of IPBC under reregistration. This data base is included in Appendix B.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

● **Chemical Structure:**



Physical and Chemical Characteristics:

- Color: Off-white, dull color
- Physical State: Powder
- Odor: Sharp pungent odor
- Melting Point: 65 - 66° C.
- Boiling Point: N/A
- Bulk Density: 1.77 gm/cc
- Solubilities: Data gap
- Vapor Pressure: <1.8 X 10⁻⁶ & 5 X 10⁻⁶ torr at 20 & 30°C.
- Dissociation Constant: N/A
- Octanol/Water Partition Coefficient: N/A
- pH: 7.01
- Stability: Data gap

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on IPBC is adequate to support reregistration eligibility. While submitted studies on chronic toxicity/carcinogenicity, developmental toxicity in a second species, reproduction, and metabolism were not required to support the current use patterns, the Agency included them in its assessment. The Agency's conclusions follow.

a. Acute Toxicity

Table 1 Acute Toxicity

Study	Results	Category
oral LD50--rat 99% Technical	1.1 g/kg (F) 1.5 g/kg (M&F)	III
Dermal LD50--rabbit 98% IPBC	>2,000 mg/kg	III
Inhalation LC50--rat 98.2% IPBC	0.68 mg/L (M&F)	III
Eye Irritation--rabbit 97%IPBC	severely irritating	I
Dermal Irritation--rabbit*	slightly irritating	IV
Dermal Sensitization--Guinea Pig*	non-sensitizer at 0.32%	N/A

* Not required for TGAI but included here for additional information

Acceptable acute toxicity studies with IPBC indicate low toxicity except eye irritation. The Acute Oral LD₅₀ in female rats was 1.1 g/kg with a Toxicity Category of III (guideline 81-1; MRID 00148277). The Acute Dermal LD₅₀ in rabbits was found to be >2,000 mg/kg with a Toxicity Category of III (guideline 81-2; MRID 42135501). The acute inhalation LC₅₀ in male and female rats was 0.68 mg/L with a Toxicity Category of III (guide-line 81-3; MRID 42204301). In a primary eye irritation study in rabbits (guideline 81-4; MRID 41627109), IPBC technical was severely irritating to the eyes of white rabbits, with corneal opacity and corneal vascularization reported in unwashed eyes by day 21 post-treatment. The technical grade of IPBC was slightly irritating to the skin of white rabbits (guideline 81-5; MRID 41627110). In a dermal sensitization study in Guinea pigs (guideline 81-6; MRID 43005701), IPBC technical, at a concentration of 0.32%, produced no evidence of sensitization in male and female Guinea pigs.

b. Subchronic Toxicity

In a subchronic oral toxicity study, male and female Sprague-Dawley rats received IPBC technical by gavage for 13 weeks at doses of 0, 20, 50, and 125 mg/kg/day. An additional satellite group was dosed at 125 mg/kg/day and held for a 28-day observation period following the 13-week dosing regimen. At the 125 mg/kg/day dose level, body weight gain was decreased by 19% in male rats for weeks 1-13 of the study, and by 12% in female rats over the same period. Absolute liver weight was increased by 20% in male rats at the 125 mg/kg/day dose, and by 31% in female rats at this dose level. Liver to body weight ratio was significantly increased

by approximately 31% in both male and female rats at the 125 mg/kg/day dose level, while kidney to body weight ratio in female rats was increased 18% at the 125 mg/kg/day dose level. The systemic NOEL was considered to be 20 mg/kg/day, while the systemic LEL was considered to be 50 mg/kg/day, based on increased liver to body weight ratio. This study is classified as core supplementary data (guideline 82-1; MRID 40947401). Although this guideline is not satisfied, acceptable chronic toxicity data are available and therefore, additional oral subchronic data are not required.

In a subchronic dermal toxicity study, male and female Sprague-Dawley rats (10/sex/dose) received dermal doses of 50, 200, and 500 mg/kg/day IPBC technical grade (97.5%) to the shaved skin for five days a week, six hours per day. At the 500 mg/kg/day dose, decreased body weight (4-6%) and weight gain (11%) were observed in male rats, but not in female rats. In female rats, significant increases in hemoglobin, hematocrit, and eosinophils were observed at the 500 mg/kg/day dose level. Reticulocytes as a percentage of red cells were decreased in the 50 and 200 mg/kg/day dose groups but not at the 500 mg/kg/day dose level. Decreased serum glucose and decreased serum creatinine were observed in male rats at 500 mg/kg/day. Minimal to mild skin irritation (acanthosis and hyperkeratosis) was observed in both male and female rats. Increased serum gamma-glutamyl transpeptidase (24% increase) was observed in female rats. At the 200 mg/kg/day dose, decreased serum glucose was observed in male rats, as was minimal to mild acanthosis and hyperkeratosis in male and female rats. Females in this study showed inhibition of plasma cholinesterase at 500 mg/kg/day test article, which may have been the result of either direct liver toxicity or inhibition of cholinesterase itself. Based upon the results of this study, the systemic NOEL is 200 mg/kg/day, the systemic LEL is 500 mg/kg/day for male and female rats. This study is classified as core minimum data (guideline 82-3, MRID 42168201).

c. Chronic toxicity/Carcinogenicity

In a 2-year chronic toxicity/carcinogenicity study, technical grade IPBC (98.68% ai) was administered to male and female Sprague Dawley rats (50/sex/group) at dose levels of 0, 20, 40, and 80 mg/kg/day. There were no statistically significant increases in tumor incidences in male rats. The incidence of mammary gland fibroadenoma and combined fibroadenoma/carcinoma in female rats was significantly increased at the 20 mg/kg/day dose level vs. control by pair wise comparison ($p < 0.01$), but there was no dose-related trend. Except for the 20 mg/kg/day dose level, the incidence of this tumor type was within historical control range for Sprague-Dawley rats. Since the mammary tumor incidence at 80 mg/kg/day was almost equal to control, the Agency's (OPP) Health Effects Division Carcinogenicity Peer Review Committee concluded that the mammary fibroadenomas were not related to treatment with IPBC.

At the 80 mg/kg/day dose level, body weight gain decrements of 20% and 15% were observed in male and female rats, respectively, during the first 13 weeks of the study. At study termination, body weight gain in male rats at the 80 mg/kg/day dose level was decreased to 71% of control, and in female rats, to 76% of control. Significant changes in serum chemistry were observed in male rats at the 80 mg/kg/day dose, as were significant non-neoplastic changes in

the stomach (submucosal edema, submucosal inflammation, acanthosis, hyperkeratosis, ulceration, and basal cell proliferation) in both sexes. The non-neoplastic changes in the stomach were considered the result of chronic irritation, and were not considered indicative of a neoplastic response. The systemic NOEL was determined to be <20 mg/kg/day (lowest dose tested), and the systemic LEL was determined to be 20 mg/kg/day, based on decreased body weight gain in male rats. The 80 mg/kg/day dose level was considered adequate for testing of carcinogenic potential of IPBC, based upon decreased body weight gain in male and female rats. This study is classified as core minimum data (guideline 83-5; MRID 42008206).

A 78-week carcinogenicity study was conducted in male and female CD-1 mice in which 50 mice/sex/dose were administered technical IPBC in the diet at dose levels of 0, 20, 50, and 150 mg/kg/day. In male mice, a statistically significant trend was observed for hepatocellular adenoma and hepatocellular adenoma/carcinoma combined ($p < 0.01$). A statistically significant pair-wise comparison was also observed for the incidence of hepatocellular adenoma and adenoma/carcinoma combined at 150 mg/kg/day vs. control ($p < 0.05$). At the 150 mg/kg/day dose, the incidence of hepatocellular adenoma (24%) and combined adenoma/carcinoma (33%) exceeded the historical control range for CD-1 mice provided by the registrant (average benign hepatocellular tumor incidence 11%, malignant tumor incidence 7%). There was no increase in hepatocellular tumor incidence in female mice. There was a significant dose-related positive trend in pulmonary carcinoma for female mice, but no significant pair-wise comparison at any dose level tested in this study. Since the formation of pulmonary carcinomas in mice is considered part of a continuum from pulmonary adenomas, the positive trend in carcinomas was not considered biologically significant.

At the highest dose level used (150 mg/kg/day), body weight gain in male mice was decreased to 73% of control for weeks 0-13 of the study, and to 77% of control at study termination. In female mice, body weight gain for weeks 0-13 at the high dose level was decreased to 70% of control, and to 80% of control at study termination. No significant effects on food consumption were observed in this study. In addition, no statistically significant effects on survival were seen in this study. The systemic NOEL was determined to be < 20 mg/kg/day, and the systemic LEL was determined to be 20 mg/kg/day, based on the increased incidence of non-neoplastic pathology of the thyroid in both sexes (atrophic vacuolation, follicular coalescence, and general follicular enlargement). This study is classified as core minimum data (guideline 83-2; MRID 42008202).

d. Developmental Toxicity

The developmental toxicity of IPBC was assessed in pregnant Sprague-Dawley rats on gestation days six through 15 by oral administration of the test chemical at doses of 0, 20, 50, and 125 mg/kg/day. Maternal toxicity as reduced body weight gain during dosing was observed at the 125 mg/kg/day dose level. Developmental toxicity consisted of an increased incidence of skeletal abnormalities at the 125 mg/kg/day dose level. The maternal toxicity NOEL was determined to be 50 mg/kg/day, and the maternal toxicity LEL was determined to be 125 mg/kg/day, based on reduced body weight gain. The developmental toxicity NOEL was

determined to be 50 mg/kg/day, and the developmental toxicity LEL was determined to be 125 mg/kg/day, based on incompletely ossified frontal skull bones and pelvic girdles. This study is classified as core minimum data (guideline 83-3; MRID 40990401).

A developmental toxicity study was conducted in female New Zealand white rabbits, in which pregnant rabbits received oral doses of 0, 2, 20, and 50 mg/kg/day IPBC on gestation days 6 through 19 inclusive. At 50 mg/kg/day, maternal toxicity in the form of increased mortality and abortion was observed. Although changes in cesarean section observations were reported at the 50 mg/kg/day dose level, these changes are likely a secondary effect of maternal toxicity, and not a primary effect of test chemical. The maternal toxicity NOEL was determined to be 20 mg/kg/day, and the maternal toxicity LEL was determined to be 50 mg/kg/day, based on increased mortality, clinical signs, and decreased body weight gain. The developmental toxicity NOEL was determined to be ≥ 50 mg/kg/day, and the developmental toxicity LEL was determined to be >50 mg/kg/day. This study is classified as core minimum data (guideline 83-3; MRID 42481604).

A 2-generation reproductive toxicity study was conducted in male and female Sprague-Dawley rats. IPBC technical was administered over two generations at doses of 0, 120, 300, and 750 ppm (0, 6, 15, and 37.5 mg/kg/day). Reduced body weight and food consumption was observed for P₁ and F₁ males during the premating period at the 37.5 mg/kg/day dose. A decreased mean live birth index was reported for P₁ and F₁ generations without an effect on viability and development of pups. No adverse effects on reproductive indices or mating performance were observed at any dose level. The parental toxicity NOEL was determined to be 15 mg/kg/day, and the parental toxicity LEL was determined to be 37.5 mg/kg/day, based on decreased body weight and food consumption during premating for P₁ and F₁ males, and decreased mean live birth index for the P₁ and F₁ generations. The reproductive toxicity NOEL was determined to be ≥ 37.5 mg/kg/day, and the reproductive toxicity LEL was determined to be >37.5 mg/kg/day. This study is classified as core minimum data (guideline 83-4; MRID 40990402).

e. Mutagenicity

In a mutagenicity study, IPBC technical was tested for the ability to cause mutations in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100. In the five strains used, IPBC was found to be non-mutagenic in the presence or absence of metabolic activation at the concentrations tested, 1-1000 jig/plate (guideline 84-2; MRID 41975206). In a micronucleus assay in mice, IPBC at doses of 200, 600, and 2000 mg/kg did not induce any significant increase of the PCE containing micronuclei from the treated mice when compared to that of the vehicle control mice (guideline 84-2; MRID 40990404). In two independent unscheduled DNA synthesis (UDS) assays in primary rat hepatocytes, eight doses of IPBC ranging from 3.0 to 13.5 ug/ml did not cause an appreciable increase in mean net nuclear grain counts. Doses >13.5 ug/ml were cytotoxic, supporting the conclusion that IPBC induced cytotoxicity but no genotoxicity in this assay (guideline 84-2; MRID 40990403).

f. Metabolism

Disposition of C¹⁴ IPBC was examined in male and female Sprague-Dawley rats at single oral doses of 20 and 125 mg/kg, at 20 mg/kg x 14 days, and as a single intravenous dose of 0.5 mg/kg. The time course of tissue distribution, conducted in 5 rats of each sex administered 7 daily doses of 20 mg/kg/day, was also performed.

Several deficiencies were noted in the original review of this study, including an inadequate number of rats per dose group, inadequate design of the repeat dose study, no justification for dose levels used in the study, and no identification of major metabolites (MRID 40947404).

In another rat metabolism study (MRID # 43570701), IPBC was administered orally in 0.5% carboxymethylcellulose to groups of male and female Crl:CD@BR rats in the following manner: Groups of 5 male and 5 female rats (groups A and B) received either a single oral high dose of radiolabelled IPBC (125mg/kg) or a repeated low oral dose of non-radiolabelled IPBC followed by a single radiolabelled dose (20 mg/kg). Separate groups of rats (9/sex/group, groups C and D) received single oral doses (20 and 125 mg/kg) of radiolabelled IPBC, and 3 rats/sex were sacrificed at 2, 4, and 120 hours post-dose for determination of tissue distribution of radioactivity. Urine, feces and expired air were collected at 24 hour intervals for groups A and B, while urine and feces were collected from groups C and D.

Absorption of test chemical at the low and high dose was between 80-90% for all dose groups, as suggested by excretion data showing the majority of a dose eliminated through urine or exhaled air.

Excretion of IPBC-derived radioactivity was mainly via the urine, with between 50-70% of an administered dose excreted by this route at 168 hours post-dose. Feces was a minor route of excretion in all dose groups (4-7% of the administered dose), while radiolabelled CO₂ constituted between 18-24% of the administered dose. Repeated low oral dosing or a single high oral dose appeared to result in a decrease in the percentage of radioactivity excreted as 14-CO₂ compared to a single low dose (38.22% in MRID # 40947404).

Based on the metabolite identification data, a scheme for metabolism of IPBC was proposed. According to this scheme, IPBC undergoes reductive dehalogenation followed by de-alkylation to form the URM-9 and URM-10 metabolites. In addition, de-carboxylation following reductive dehalogenation yields carbon dioxide. Various other metabolites formed from dehalogenation are glucuronidated and constitute minor metabolites of IPBC.

This study was submitted in order to address deficiencies from review of a previous metabolism study (MRID # 40947404). The data provided in this study in conjunction with MRID # 40947404, satisfy the data requirement for a metabolism study in rats under Subdivision F guideline 85-1.

g. Toxic Endpoints of Concern

The Agency's (OPP) Toxic Endpoint Selection Committee concluded (June 4, 1996) that for dermal absorption a calculated value of 10% should be used. This value was derived from the LOEL of 50 mg/kg/day in the 90 day oral study in rats (MRID 40947401) and the LOEL of 500 mg/kg/day in the 90 day dermal study in rats (MRID 42168201). The LOELs were used because of the minimal effects seen at the LOELs.

The short term occupational or residential exposure (1 to 7 days) and the intermediate term occupational or residential (1 week to several months) exposure endpoint was selected from the subchronic dermal toxicity study in rats (MRID 42168201). Systemic toxicity was observed in both male and female rats from repeated dermal administration of IPBC at 500 mg/kg/day.

In males, decreased body weight gain, clinical chemistry alterations, and dermal irritation were observed at 500 mg/kg/day.

In female rats, significant changes in hematological and clinical chemistry parameters were observed at 500 mg/kg/day in addition to dermal irritation. Females in this study showed inhibition of plasma cholinesterase at 500 mg/kg/day test article, which may have been the result of either direct liver toxicity or inhibition of cholinesterase itself.

Based upon the results of this study, the systemic NOEL is 200 mg/kg/day, and the systemic LEL is 500mg/kg/day for male and female rats.

The endpoint for use in risk assessment is the NOEL of 200 mg/kg/day based on decreased body weight gain, alterations in clinical chemistry parameters, and dermal irritation at 500 mg/kg/day.

The endpoint for chronic exposure, several months to lifetime was selected from the chronic toxicity/carcinogenicity study in rats. The endpoint for use in risk assessment is the NOEL of 20 mg/kg/day, based on the observation in male and female rats of decreased body weight gain at the LEL of 20 mg/kg/day dose level (MRID 42008206).

h. Cancer Classification

The Agency's (OPP) Health Effects Division Carcinogenicity Peer Review Committee (CPRC) classified (June 16, 1993), IPBC as a **Group C** - possible human carcinogen. The Group C classification was based on a statistically significant increase in hepatic adenomas and combined adenomas/carcinomas in male CD-1 mice, by both pair-wise and trend analysis. The incidence of adenomas was above the mean and the upper end of the range of historical controls. There are also structure-activity relationships between IPBC and compounds that are classified as liver and/or bladder carcinogens. However, there was no compound-related increase in tumors in female mice or in Sprague-Dawley rats. Since there was only one statistically-significant, compound-related tumor type (liver) in one sex (male) and one species (mouse), and

there was no apparent genotoxicity concern, the committee recommended the RfD approach for any future dietary risk assessment.

On September 18, 1996, at the request of the registrants and supported by an additional review (MRID 43819001) of the slides of male and female mouse livers from the chronic mouse study (MRID 42008202), the CPRC re-evaluated the carcinogenic potential of 3-iodo-2-propynyl butyl carbamate using the Agency's revised Guidelines for Carcinogen Risk Assessment. The CPRC concluded that the additional evidence provided by the registrant supports re-classification of IPBC as "not likely" to be carcinogenic. In the context of the revised guidelines, this decision was based on: a) the lack of a carcinogenic response for combined adenoma/carcinoma of the liver in male mice as a result of the re-evaluation of the tumor incidence in the 18-month mouse carcinogenicity study; b) the lack of carcinogenic response in female mice and in male or female rats; c) the absence of mutagenic activity; and d) the absence of data suggesting formation of a reactive metabolite of IPBC which might be responsible for initiation of the tumors observed.

i. Neurotoxicity

Since IPBC is classified as a carbamate, additional confirmatory data are being required to satisfy the following neurotoxicity guidelines:

- 81-8 Acute Rat Neurotoxicity with cholinesterase
- 82-7 90-day Rat Neurotoxicity with cholinesterase

C. Exposure Assessment

a. Occupational and Residential Exposure

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

b. Summary of Use Patterns, and Formulations, and Types of Exposures

IPBC is a fungicide used in both industrial and residential settings. It has many industrial manufacturing applications as specified above as well as use in residential settings as a wood preservative. IPBC can be applied with a paint brush, paint roller, or airless/compressed-air sprayer, and as an on-site wood dip treatment. IPBC is formulated as a ready-to-use liquid, liquid concentrate, and solid concentrate for occupational and residential/homeowner use.

From these uses of IPBC products, the Agency believes there are potential exposures to mixers, loaders, applicators, and other people during and after application. The Agency has identified two levels of exposures:

- primary handlers -- persons directly handling IPBC pesticide products; and
- secondary handlers -- persons handling manufactured products, such as paints and adhesives, to which IPBC has been added as a preservative.

(1) Occupational Handler Exposure Scenarios

Primary Handler Exposures: Based on the use patterns, several major occupational *primary handler* exposure scenarios were identified for IPBC. In industrial manufacturing settings these include mixing/loading of liquid formulations of IPBC products for:

- paint/adhesives/emulsion/paper coatings;
 - metal cutting fluids;
 - oil recovery drilling fluids;
 - plastics;
 - textiles;
 - inks;
 - pulp and paper mill systems;
 - canvas;
 - wood products (mixing/loading and application);
- and mixing/loading solids for paint/adhesives/emulsion/paper coating manufacturing.

In non-industrial and residential settings, primary handler scenarios include:

- mixing/loading liquid for brush application;
- mixing/loading liquid for roller application;
- mixing/loading liquid for airless/compressed-air sprayer application;
- mixing/loading liquid for on-site wood dip application;
- applying with a brush;
- applying with a roller;
- applying with an airless/compressed-air sprayer;
- and applying as an on-site wood dip.

Secondary Handler Scenarios: Based on the use patterns and potential exposure scenarios, several major occupational *secondary handler* exposure scenarios were identified for handling and/or applying manufactured products that had been treated with IPBC:

- paints and wood stains;
- adhesives and emulsions;
- plastics, textiles, and canvas;
- paper products;
- metalworking fluids;
- wood products;
- air-conditioner and furnace filters.

(2) Homeowner Handler Exposure Scenarios

Primary Homeowner Handler Scenarios: Based on the use patterns, the Agency has identified several major exposure scenarios for primary homeowner handlers:

- mixing/loading liquid for brush application;
- mixing/loading liquid for roller application;
- mixing/loading liquid for airless/compressed-air sprayer application;
- mixing/loading liquid for on-site wood dip application;
- applying with a brush;
- applying with a roller;
- applying with an airless/compressed-air sprayer;
- and applying as an on-site wood dip.

Secondary Homeowner Handler Scenarios: Based on the use patterns, the Agency has identified two major exposure scenarios for secondary homeowner handlers:

- exposures while handling/applying IPBC-containing paint/stain;
- exposures while handling/using IPBC-treated wood and other products;

(3) Occupational and Homeowner Handler Exposure Estimates and Assumptions

The Agency assumes that the scenarios below represent reasonable worst-case exposures to handlers of IPBC:

- oil-well mud-packer fluids for uses in oil-recovery drilling muds, secondary-oil recovery injection water, and oil-well injection fluids;
- preservative uses in paint manufacturing for uses in oil/latex paint, industrial adhesives, industrial coatings, paper coating, resin/latex/polymer emulsions; plastic manufacturing, textile manufacturing, ink manufacturing, and canvas manufacturing;
- pulp and paper mill systems uses;
- metalworking fluids [Note: machinists' exposure to metalworking fluids containing IPBC is not addressed in detail in this document. However, there may be a risk concern for machinists. Evaluation of the risk of machinists from exposure to IPBC is deferred to OSHA (Occupational Safety and Health Administration)];
- industrial wood product treatments for wood treatment (pressurized and non-pressurized) of forest products;
- painting using latex paint, adhesives, emulsions, and wood stains; and
- painting and dipping wood products for wood protection treatment to buildings/products outdoors, and wood or wood structure protection treatments (indoors and outdoors).

For handler exposure estimates the Agency relied on available data from an exposure study submitted by the Chemical Manufacturers Association (MRID #s 41412201, 41742601, 42587501), and from a composite of exposure studies in the Pesticide Handlers Exposure

Database (PHED). These studies use pesticides other than IPBC, however, the testing scenarios are applicable to this pesticide and most of its use patterns selected for risk assessment. Based on these data and the following formulas and assumptions, the Agency calculated estimates of short, intermediate, and chronic exposures.

The Daily Dose is calculated using the following formula:

1. Short-Term and Intermediate-Term Daily Dose =
Unit Exposure (mg ai/lb ai) x Use Rate (lb ai/day).

This dose is used for the short term and intermediate MOE calculation for risk assessment, where a dermal NOEL is used. No dermal absorption adjustment is required.

2. Chronic Daily Dose = Unit Exposure (mg ai/lb ai) x Use Rate (lb ai/day) x 10%
Dermal Absorption Adjustment.

This dose is used in the chronic MOE calculation, where an oral NOEL is used and a 10 percent dermal absorption adjustment is required.

The actual daily exposure is calculated by dividing the Daily (Total) Dose by the average body weight of a person. Since the toxicological endpoints for short-term, intermediate-term, and chronic exposures are not maternal or developmental, 70 kilograms (adult male) is the body weight used for the risk calculations.

$$\text{Actual Daily Exposure(mg/kg/day)} = \frac{\text{Daily Dose (mg ai/day)}}{\text{Body Wt (70kg)}}$$

The following assumptions are made:

- Occupational and homeowner handlers may be exposed more than 7 days per year (reasonable worst-case estimate). Therefore, the exposure/risk assessment for all occupational and homeowner (primary and secondary) handlers must consider both short-term (less than 7 days per year) and intermediate-term (7 or more days per year) exposure scenarios.
- Primary and secondary occupational handlers in industrial settings may be chronically exposed in the following settings: (1) general preservative (represented by paint manufacturing); (2) industrial wood-products treatment; (3) industrial/commercial wood products manufacturing, and (4) machinists using IPBC-containing metal cutting fluids. Therefore, the exposure/risk assessment for all such occupational (primary and secondary) handlers must consider chronic exposure scenarios.
- Primary and secondary occupational handlers in non-industrial settings may be chronically exposed in the following settings: (1) mixing/loading the concentrate for wood treatment, (2) applying the dilute wood treatment, (3) handling/applying

IPBC-containing paint, adhesives, and other products. Therefore, the exposure/risk assessment for all such occupational (primary and secondary) handlers must consider chronic exposure scenarios.

- Primary and secondary occupational handlers in industrial settings are unlikely to be chronically exposed in the following settings: (1) oil-well mud-packer fluids, oil-recovery drilling muds, secondary-oil recovery injection water, oil-well injection fluids, (2) pulp and paper mills, and (3) adding IPBC to metal cutting fluids. Therefore, the exposure/risk assessment for all such handlers need not consider chronic exposure scenarios.
- No homeowner (primary or secondary) handlers are chronically exposed. Therefore, the exposure/risk assessment for all homeowner handlers need not consider chronic exposure scenarios.

Short-term, intermediate-term, and chronic exposure estimates are presented in Table 2 for occupational handlers (primary and secondary) in industrial settings. Short-term and intermediate-term exposure assessments are presented in Table 3. for occupational and homeowner handlers (primary and secondary) in non-industrial settings. Chronic exposure assessments are presented in Table 3A. for occupational and homeowner handlers (primary and secondary) in non-industrial settings.

Table 2: Short-Term, Intermediate-Term and Chronic IPBC Exposures to Handlers in Industrial Settings

Operation	Handlers	Setting	UE (mg/lb ai) ^a	Daily Rate Lb ai/used ^b	Daily Dose (mg/day) ^c	
					Short- & Intermediate-Term ^c	Chronic ^d
Open Pour Liquid	Primary	General Preservative ^e	0.14	8.34	1.2	0.12
Open Pour Solid	Primary	General Preservative	0.479	8.0	3.8	0.38
Open Pour Liquid	Primary	Metal Working Fluid Treatment	0.133	7.5	1.0	N/A
Pump Liquid	Primary	Oil Recovery & Drilling Mud/ Packer Fluid	0.0075	28	0.21	N/A
Pump Liquid	Primary	Pulp & Paper Mill Systems	0.0075	1,000	7.5	N/A
Industrial Wood Protection Treatment to Milled Forest Products						
Mixer/Loader	Primary	Industrial Wood Products Treatment	No data	No data	No data	No data
Handling Treated Wood Products	Secondary	Industrial/Commercial Wood Products Manufacturing	No data	No data	No data	No data

^a Unit Exposure (UE) was derived from the CMA study (including dermal and inhalation exposure). Gloves were worn for the exposure studies represented. However, the inhalation component is insignificant.

^b lb ai/used was derived from the CMA study and the pesticide labels cited below:

Preservatives: Liquid (paint scenario; EPA Reg. No. 5383-50)

(100 gallons * 8.34 lbs/gal * 0.01 ai) = 8.34 lbs ai/used/day.

Preservatives: Solid (paint scenario; EPA Reg. No. 5383-51)

(100 gallons * 10.0 lbs/100 gal * 0.8 ai) = 8.0 lbs ai/used/day.

Metal Working Fluids (EPA Reg. No. 5383-50)

(300 gallons * 8.34 lbs/gal * 0.003 ai) = 7.5 lbs ai/used/day.

Oil Recovery & Drilling Mud/Packer Fluid (EPA Reg. No. 1022-575)

(4200 gallons * 8.34 lbs/gal * 0.002 * 0.4 % ai) = 28 lb ai/used/day.

Pulp and Paper Mill (EPA Reg. No. 5383-50) (100 tons * 2,000 lbs/ton * 0.005 ai) = 1,000 lb ai/used/day.

^c Daily Dose (mg/day) = UE x lb ai/used for short-term and intermediate, where dermal NOEL is used in MOE calculation and no dermal absorption adjustment is required.

^d Daily Dose (mg/day) = UE x lb ai/used x 0.1 (10% dermal absorption for chronic, where oral NOEL is used in MOE calculation and a dermal absorption adjustment is required).

^e Preservative uses include paint, textile, plastic, ink, paper coating, and canvas manufacturing. Data for preservative uses is from paint preservatives, which represents the worst-case scenario based on available data.

Table 3: Short-Term and Intermediate-Term IPBC Exposure Assessment for Handlers in Industrial and Non-Industrial Settings

Exposure Scenario	Handlers	Baseline Dermal Unit Exposure ^a (mg/lb ai)	Baseline Inhalation Unit Exposure ^b (μg/lb ai)	Maximum Label Application Rate ^c (lb ai/gallon)	Daily Max. Handled ^d (gallons)	Daily Dermal Dose ^e (mg/day)	Daily Inhalation Dose ^f (mg/day)	Daily Total Dose ^g (mg/day)
Mixing/Loading Liquid Concentrate for Brush Application	Primary	2.9	1.2	0.63	0.07 (H) 0.35 (O)	0.13 (H) 1.15 (O)	0.00005 (H) 0.0005 (O)	0.1 (H) 1.2 (O)
Applying Dilute Solution with Brush	Primary	182	570	0.04	1 (H) 5 (O)	7.28 (H) 36.4 (O)	0.023 (H) 0.11 (O)	7.3 (H) 36.5 (O)
Applying Paint with Brush	Secondary	182	570	0.1	1 (H) 5 (O)	18.2 (H) 91.0 (O)	0.057 (H) 0.29 (O)	18.3 (H) 91.3 (O)
Mixing/Loading Liquid Concentrate for Roller Application	Primary	No data	No data	No data	No data	No data	No data	No data
Applying Dilute Solution with Roller	Primary	No data	No data	No data	No data	No data	No data	No data
Applying Paint with Roller	Secondary	No data	No data	No data	No data	No data	No data	No data
Mixing/Loading Concentrate for Sprayer Application	Primary	2.9	1.2	0.63	0.35 (H) 3.3 (O)	0.64 (H) 6.03 (O)	0.0003 (H) 0.002 (O)	0.6 (H) 6.0 (O)
Applying Dilute Solution with Airless/Compressed Air Sprayer	Primary	38.4	830	0.04	5 (H) 50 (O)	7.68 (H) 76.8 (O)	0.17 (H) 1.66 (O)	7.7 (H) 78.5 (O)
Applying Paint with an Airless/Compressed Air Sprayer	Secondary	38.4	830	0.1	5 (H) 50 (O)	19.2 (H) 192.0 (O)	0.42 (H) 4.15 (O)	19.6 (H) 196.2 (O)
Mixing/Loading Concentrate for On-Site Wood Dip Treatment	Primary	No data	No data	No data	No data	No data	No data	No data
Applying the Dilute Solution as an On-Site Wood Dip Treatment	Primary	No data	No data	No data	No data	No data	No data	No data

a *UE = Unit Exposure for open-pour liquid mixing/loading, UE derived from PHED dermal exposure only (without gloves), based on 53 replicates for hands and 25 to 122 replicates for other dermal. For brush painting, UE derived from PHED dermal exposure only (without gloves), based on 15 replicates, using brush as wood painting application. For airless spray painting, UE derived from PHED dermal exposure only (without gloves) based on 15 replicates and is equipped with gasoline siphon/nozzle sprayer.

b Baseline inhalation unit exposure (derived from PHED) is based on 29 L/min as an inhalation rate and represents no respirator.

c For Primary Handlers: The concentrate is Woodtreat PT which contains 7.6% ai); the dilute is 0.5% a.i. (one gal of concentrate to 15 gal. water; For secondary handlers, the paint contains 0.1% a.i.

d Values represent the maximum likely handled per day

[(H) = homeowner, (O) = occupational] treatments for each exposure scenario of concern.

e Daily dermal dose (mg/day) = Unit Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/gal) * Max. Handled (gallons).

f Daily inhalation dose (mg/day) = Unit Exposure (ug/lb ai) * (1mg/1000ug) conversion * Max Appl Rate (lb ai/gal) * Max Handled (gallons).

g Daily total dose (mg/day) = Daily dermal dose + Daily inhalation dose.

Table 3A: Chronic IPBC Exposure Assessment for Handlers in Occupational Non-Industrial Settings

Exposure Scenario	Handlers	Baseline Dermal Unit Exposure ^a (mg/lb ai)	Baseline Inhalation Unit Exposure ^b (μg/lb ai)	Maximum Label Application Rate ^c (lb ai/gallon)	Daily Max. Treated ^d (gallons)	Daily Dermal Dose ^e (mg/day)	Daily Inhalation Dose ^f (mg/day)	Daily Total Dose ^g (mg/day)
Mixing/Loading Liquid Concentrate for Brush Application	Primary	2.9	1.2	0.63	0.35	0.06	0.0003	0.064
Applying Dilute Solution with Brush	Primary	182	570	0.04	5	3.64	0.11	3.8
Applying Paint with Brush	Secondary	182	570	0.1	5	9.10	0.29	9.4
Mixing/Loading Liquid Concentrate for Roller Application	Primary	No data	No data	No data	No data	No data	No data	No data
Applying Dilute Solution with Roller	Primary	No data	No data	No data	No data	No data	No data	No data
Applying Paint with Roller	Secondary	No data	No data	No data	No data	No data	No data	No data
Mixing/Loading Concentrate for Sprayer Application	Primary	2.9	1.2	0.63	3.3	0.60	0.002	0.6
Applying Dilute Solution with Airless/Compressed-Air Sprayer	Primary	38.4	830	0.04	50	7.68	1.66	9.3
Applying Paint with an Airless/Compressed-air Sprayer	Secondary	38.4	830	0.1	50	19.20	4.15	23.4
Mixing/Loading Concentrate for On-Site Wood Dip Treatment	Primary	No data	No data	No data	No data	No data	No data	No data
Applying the Dilute Solution as an On-Site Wood Dip Treatment	Primary	No Data	No Data	No Data	No Data	No Data	No Data	No Data

a UE = Unit Exposure; for open-pour liquid mixing/loading, UE derived from PHED (without gloves), based on 53 replicates for hands and 25 to 122 replicates for other dermal. For brush painting, dermal exposure only (without gloves), is based on 15 replicates, using brush as painting application. For airless/compressed-air spray painting, is equipped with gasoline power siphon/nozzle sprayer.

b Baseline inhalation unit exposure (derived from PHED) is based on 29 L/min as an inhalation rate and represents no respirator.

c For Primary Handlers: The concentrate is Woodtreat PT which contains 7.6% ai; the dilute is 0.5% ai (one gal of concentrate to 15 gal. water. For secondary handlers, the paint contains 0.1% ai

d Values represent the maximum likely handled per day

e Daily dermal dose (mg/day) = Unit Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/gal) * Max. Handled (gallons) * 0.1 (10% dermal absorption).

f Daily inhalation dose (mg/day) = Unit Exposure (ug/lb ai) * (1mg/1000ug) conversion * Max Appl Rate (lb ai/gal) * Max Handled (gallons).

g Daily total dose (mg/day) = Daily dermal dose + Daily inhalation dose.

(a) Post-Application Exposures and Assumptions

The Agency believes there are potential post-application exposures to IPBC following applications in commercial, industrial, and residential settings.

Such exposures could include:

- exposures following applications of IPBC to open vats of hot liquids, such as paper-pulp, adhesives, coatings, emulsions, and paints, or where these treated products are used;
- exposures to persons in and near areas where commercial wood-product treatments are taking place;
- exposures in areas where metalworking fluids are being used;
- exposures in areas where IPBC-containing plastic and textile products are being manufactured;
- exposures to persons occupying areas recently treated with IPBC wood preservative, or paints or stains; and
- exposures where IPBC-containing air-conditioning and furnace filters are used in commercial buildings.

The Agency does not have post-application chemical specific data to quantitatively determine the amount of pesticide to which a person reentering a treated area would be exposed. However, the Agency does not anticipate significant dermal or inhalation post-application exposures for these scenarios

c. Occupational and Residential Risk Characterization

(1) Poisoning Incident Data

Four incidents from January 1994 - April 1995 were identified in the OPP Incident Data System database. Two of the incidents involved employees at a manufacturing plant who were not wearing protective equipment and developed skin rashes and respiratory tract problems. The other two involved consumers who also had skin irritations. It should be noted that the condition of one man was severe enough to require blood analysis and pulmonary studies.

(2) Risk Estimates

EPA used the following equation to derive a margin of exposure (MOE) to estimate risks.

$$\text{MOE} = \frac{\text{NOEL}}{\text{Actual Daily Exposure}}$$

1. Risk Assessment

The Agency assessed the risk resulting from short-term and intermediate-term IPBC exposures associated with occupational and homeowner handlers (primary and secondary). The Agency also assessed the risk resulting from chronic IPBC exposures to certain occupational handlers (primary and secondary) as specified above. The NOEL for short and intermediate-term exposure is 200 mg/kg/day (from the subchronic dermal rat study) and the NOEL for chronic exposures is 20 mg/kg/day (from the chronic rat study). The Actual Daily Exposure (or Dose) are estimates from the exposure assessments above and in Tables 2-3A.

a. Occupational Handler Risks

Primary Occupational Handler Risks: Margins of exposure (MOEs) for primary occupational handlers were calculated for short-term (1-7 days) exposure and intermediate-term (one week to several months) exposure and, when applicable, for chronic exposure (several months to lifetime). The calculations indicate that MOEs of above 100 occurred for all primary occupational scenarios for which there were data. See Table 4 for a detailed breakdown of the MOE calculations for primary occupational handlers in industrial settings and Table 5 for a detailed breakdown of the MOE calculations for primary occupational handlers in non-industrial settings.

Secondary Occupational Handler Risks: Margins of exposure (MOEs) for secondary handlers were calculated for short-term (1-7 days) exposure and intermediate-term (one week to several months) exposure and, when applicable, for chronic exposure (several months to lifetime). The calculations using PHED V1.1 surrogate exposure data indicate that the MOEs for short-term, intermediate-term, and chronic occupational exposures with baseline PPE exceeded 100 for all scenarios for which there were data, except for painters using an airless/compressed-air sprayer. The MOEs for the spray painting scenario are 71 for short- and intermediate-term exposures and 61 for chronic exposures. Although data are not available for application by roller, the Agency assumes the exposure and risk will be no greater than that from application by brush. Refer to Tables 4 and 5 for these MOEs.

Table 4. Short-Term, Intermediate-Term and Chronic IPBC Exposures to Handlers in Industrial Settings

Operation	Handlers	Exposure Scenario	Daily Dose (mg/day)		Actual Daily Exposure (mg/kg/day) ^a		MOEs	
			Short & Intermediate Term Exposures	Chronic Exposures	Short & Intermediate Term Exposures	Chronic Exposures	Short & Intermediate Term Exposures	Chronic Exposures
Open Pour Liquid	Primary	General Preservative*	1.2	0.12	0.02	0.002	10000	10000
Open Pour Solid	Primary	General Preservative*	3.8	0.38	0.005	0.005	4000	4000
Open Pour Liquid	Primary	Metal Working Fluids	1.0	N/A	0.014	N/A	14286	N/A
Pump Liquid	Primary	Oil Recovery & Drilling Mud/Packer Fluid	0.21	N/A	0.003	N/A	66667	N/A
Pump Liquid	Primary	Pulp and Paper Mill	7.5	N/A	0.11	N/A	1818	N/A
Pump Liquid	Primary	Wood Products	No data	No data	No data	No data	No data	No data
Handling Treated Wood Products	Secondary	Industrial/Commercial Wood Products Manufacturing	No data	No data	No data	No data	No data	No data

a Actual daily exposure (mg/kg/day) = Daily Dose (mg/day)/70 kg.

b MOE = NOEL/ Actual daily exposure where short-term and intermediate-term NOEL = 200 mg/kg/day and chronic NOEL = 20 mg/kg/day).

* Preservative uses include paint, textile, plastic, ink, paper coating, and canvas manufacturing. Data for general preservative uses is from paint preservatives, which represents the worst-case scenario based on available data.

N/A = not applicable

Table 5. Short-Term, Intermediate-Term and Chronic IPBC Exposures to Handlers in Non-Industrial Settings

Exposure Scenario	Handlers	Daily Total Dose (mg/day)		Daily Total Exposure (mg/kg/day)		MOEs	
		Short- & Intermediate-Term	Chronic	Short- & Intermediate-Term ^a	Chronic ^b	Short- & Intermediate-Term	Chronic
Mixing/Loading Liquid Concentrate for Brush Application	Primary	0.1 (H) 1.2 (O)	N/A (H) 0.064 (O)	0.002 (H) 0.016 (O)	N/A (H) 0.0009 (O)	100,000 (H) 12,500 (O)	N/A (H) 22,222 (O)
Applying Dilute with Brush	Primary	7.3 (H) 36.5 (O)	N/A (H) 3.8 (O)	0.104 (H) 0.52(O)	N/A (H) 0.054(O)	1,923 (H) 384 (O)	N/A (H) 370 (O)
Paint Brush	Secondary	18.3 (H) 91.3 (O)	N/A (H) 9.4 (O)	0.26 (H) 1.30 (O)	N/A (H) 0.13 (O)	769 (H) 154 (O)	N/A (H) 154 (O)
Mixing/Loading Liquid Concentrate for Roller Application	Primary	No data	No data	No data	No data	No data	No data
Applying Dilute with Roller	Primary	No data	No data	No data	No data	No data	No data
Paint Roller	Secondary	No data	No data	No data	No data	No data	No data
Mixing/Loading Concentrate for Sprayer Application	Primary	0.6 (H) 6.0 (O)	N/A (H) 0.6 (O)	0.009 (H) 0.09 (O)	N/A (H) 0.009 (O)	22,222 (H) 2,222 (O)	N/A (H) 2,222 (O)
Applying Dilute with an Airless/Compressed-Air Sprayer	Primary	7.7 (H) 78.5 (O)	N/A (H) 9.3 (O)	0.11 (H) 1.12 (O)	N/A (H) 0.13 (O)	1,818 (H) 178 (O)	N/A (H) 153 (O)
Airless/Compressed-Air Sprayer	Secondary	19.6 (H) 196.2 (O)	N/A (H) 23.4 (O)	0.28 (H) 2.8 (O)	N/A (H) 0.33 (O)	714 (H) 71 (O)	N/A (H) 61 (O)
Mixing/Loading Concentrate for On-Site Wood Dip Treatment	Primary	No data	No data	No data	No data	No data	No data
Applying Dilute as an On-Site Wood Dip Treatment	Primary	No data	No data	No data	No data	No data	No data

(H) = homeowner; (O) = occupational; N/A = not applicable.

a Short-term and Intermediate Daily Total Exposure = Short-term and Intermediate Daily Dermal Dose/70 kg. body weight

b Chronic Daily Total Exposure = Chronic Daily Dermal Dose/70 kg. body weight. Note for chronic exposure, the daily dermal dose was adjusted with a dermal absorption factor of 10% (0.1).

Note: MOE = NOEL /daily dose. where short-term and intermediate-term NOEL = 200 mg/kg/day; chronic NOEL = 20 mg/kg.

b. Homeowner Handler Risks

Margins of exposure (MOEs) for primary and secondary homeowner handlers were calculated for short-term (1-7 days) exposure and intermediate-term (one week to several months) exposure. Chronic exposure (several months to lifetime) and risks are not applicable for homeowner handlers. The calculations indicate that MOEs of above 100 occurred for all primary and secondary homeowner scenarios for which there were data. See Table 5 for a detailed breakdown of the MOE calculations for primary and secondary homeowner handlers. The Agency does not consider MOEs above 100 to be of concern.

Risk From Post-Application Exposures

Above, the Agency gives examples of potential post-application exposure situations to IPBC applications and/or treated products. However, the Agency currently has no data available to estimate such exposures.

Data Requirements

Mixer/Loader/Applicator Exposure Data Requirements:
Guideline Numbers 231, 232, 233 and 234

Data are required for wood product use (i.e., industrial handlers who operate the wood protection treatment process for the milled forest products solution supply system, dip tanks, or drive forklifts or carrier trucks to dip lumber). Data are also required for workers applying IPBC products to HVAC ducts and equipment, and for occupational (non-industrial) workers and homeowners applying wood treatments by methods other than brush, roller, and airless or compressed air sprayer. Methods for which there are currently no exposure data available include dipping wood (e.g., shingles), using a pad, and using any type of sprayer other than airless or compressed air. Risk assessments will be conducted upon the receipt and evaluation of the required data.

Guideline Numbers 133-3 and 133-4

Data are required for the wood product use [i.e., workers who handle wet wood which has been treated (graders, lumber pullers, etc.); workers who handle dry treated wood; workers who perform maintenance on any part of the treatment system or machinery]. Data are also required to characterize exposure to occupants of areas where HVAC ducts/systems have been treated, and to workers handling and consumers using textiles such as carpets, drapes, shower curtains, and canvas to which IPBC has been applied.

c. Other Considerations

The Food Quality Protection Act of 1996 amends both the FFDCFA and FIFRA by setting a new safety standard for the establishment of tolerances. In determining whether or not a

tolerance meets the new safety standard, FQPA directs EPA to consider information concerning: the susceptibility of infants and children to pesticide residues in food; the potential for aggregate exposure from dietary as well as non-occupational sources, such as pesticide uses in and around the home; and the potential for cumulative effects from a pesticide and other substances that have a common mechanism of toxicity.

Because IPBC has no food uses, and therefore no tolerances have been established, the specific considerations outlined in FQPA are not required for this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, the potential for aggregate exposures and cumulative effects is prudent for IPBC because children and other individuals could be exposed to this compound in non-occupational settings.

Potential Risks to Infants and Children

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

Based on current data requirements, only one developmental study is usually required for non-food use chemicals. However, for the purposes of assessing the pre- and post-natal toxicity of IPBC, two developmental and one reproduction study were available and have been evaluated by EPA. The effects observed in the IPBC developmental and reproduction studies can be summarized as follows:

The developmental toxicity of IPBC was assessed in pregnant Sprague-Dawley rats on gestation days six through 15 by oral administration of the test chemical at doses of 0, 20, 50, and 125 mg/kg/day. Maternal toxicity as reduced body weight gain during dosing was observed at the 125 mg/kg/day dose level. Developmental toxicity consisted of an increased incidence of skeletal abnormalities at the 125 mg/kg/day dose level. The maternal toxicity NOEL was determined to be 50 mg/kg/day, and the maternal toxicity LEL was determined to be 125 mg/kg/day, based on reduced body weight gain. The developmental toxicity NOEL was determined to be 50 mg/kg/day, and the developmental toxicity LEL was determined to be 125 mg/kg/day, based on incompletely ossified frontal skull bones and pelvic girdles.

A developmental toxicity study was conducted in female New Zealand white rabbits, in which pregnant rabbits received oral doses of 0, 2, 20, and 50 mg/kg/day IPBC on gestation days 6 through 19 inclusive. At 50 mg/kg/day, maternal toxicity in the form of increased mortality and abortion was observed. Although changes in cesarean section observations were reported at the 50 mg/kg/day dose level, these changes are likely a secondary effect of maternal toxicity, and not a primary effect of test chemical. The maternal toxicity NOEL was determined to be 20 mg/kg/day, and the maternal toxicity LEL was determined to be 50 mg/kg/day, based on increased mortality, clinical signs, and decreased body weight gain. The developmental toxicity

NOEL was determined to be >50 mg/kg/day, and the developmental toxicity LEL was determined to be >50 mg/kg/day.

A 2-generation reproductive toxicity study was conducted in male and female Sprague-Dawley rats. IPBC technical was administered over two generations at doses of 0, 120, 300, and 750 ppm (0, 6, 15, and 37.5 mg/kg/day). Reduced body weight and food consumption was observed for P1 and F1 males during the premating period at the 37.5 mg/kg/day dose. A decreased mean live birth index was reported for P1 and F1, generations without an effect on viability and development of pups. No adverse effects on reproductive indices or mating performance were observed at any dose level. The parental toxicity NOEL was determined to be 15 mg/kg/day, and the parental toxicity LEL was determined to be 37.5 mg/kg/day, based on decreased body weight and food consumption during premating for P1 and F1 males, and decreased mean live birth index for the P1 and F1 generations. The reproductive toxicity NOEL was determined to be >37.5 mg/kg/day, and the reproductive toxicity LEL was determined to be >37.5 mg/kg/day.

The developmental data for IPBC indicate developmental effects occurred at doses that were the same as or higher than doses which cause maternal toxicity. The Agency would generally be concerned when developmental/reproductive effects are seen at doses lower than those which cause maternal effects. No adverse effects on reproductive indices or mating performance were observed in the two generation rat study. The developmental studies in conjunction with the reproduction study do not indicate any additional sensitivity of young organisms to IPBC. Therefore, the Agency concludes that an additional uncertainty factor need not be applied to the NOELs selected for the IPBC risk assessments at this time.

Aggregate Exposure

In examining aggregate exposure, EPA takes into account available information concerning exposures from the pesticide residue in food and other exposures for which there is reliable information. These other sources of exposure can include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home.

There are no food uses for IPBC, therefore, exposure to IPBC in the diet is not expected. Laboratory data indicate that IPBC is mobile but non-persistent in soil and aquatic environments, so IPBC should not be a threat to surface and ground water. Because it rapidly degrades, it is not likely to occur in drinking water. Therefore, residential uses are the only sources of exposure which could be aggregated for IPBC. The Agency has identified several potential exposure scenarios for homeowners including handling and applying IPBC-containing paints and wood stains (wood protection treatments), and handling and using IPBC-treated products, such as wood. EPA currently does not have data to estimate exposure from all potential sources of IPBC in and around the home, e.g., dipping wood and using treated textiles such as carpets and drapes. However, the Agency is actively working with industry to augment the use/exposure data base.

The Agency assumes that the reasonable worst case exposure scenario for homeowners would be handling and applying paint containing IPBC. Homeowner handlers could be exposed for more than 7 days per year. Therefore, the exposure/risk assessment for homeowner handlers considers both short-term (less than 7 days per year) and intermediate-term (7 or more days per year) exposure scenarios. No chronic exposure to homeowners or children is anticipated. Because of the low volatility of IPBC, inhalation exposure is expected to be minimal.

Table 6. Residential Handler/Applicator Risk from Exposure to IPBC

Exposure Scenario	Daily Total Exposure (mg/kg/day) ^a	MOE ^b
Paint Brush	0.30 (H)	667 (H)
Paint Roller	No data	No data
Airless Sprayer	0.33 (H)	606 (H)

(H) = homeowner

a Daily total exposure = daily dermal exposure + daily inhalation dose/60 kg.

b MOE = NOEL (short-term and intermediate-term NOEL = 200 mg/kg/day) / daily total exposure.

Note: EPA assumes that exposure from roller application is no greater than exposure from brush application.

The Agency does not have chemical-specific post-application data to quantitatively determine the amount of IPBC to which a person/child re-entering a painted room or other treated area would be exposed. However, the Agency believes it is reasonable to assume that such exposures would not be significant compared to exposures associated with handling and applying IPBC-containing products.

Based on the high MOEs for homeowner applicators (see Table 6), EPA believes that aggregate exposures to IPBC in the home are not likely to be of concern.

Cumulative Effects

Consideration has been given to cumulative effects of IPBC and other substances that have a common mode of toxicity. IPBC is a carbamate. Carbamates can exhibit a variety of modes/mechanisms of toxicity including the inhibition of the enzyme cholinesterase (ChE). Some carbamates which may have a similar mode of toxicity to IPBC include carbaryl, methomyl, carbofuran, aldicarb, oxamyl, thiodicarb, methiocarb, aminocarb, propoxur, and bendiocarb.

The Agency has not yet made a determination regarding whether it is appropriate to consider exposure from these other carbamates with IPBC in order to address potential cumulative effects.

However, based on the high MOEs for homeowner applicators (see Table 6), the lack of food uses, unlikelihood of residues in drinking water, the low concentration of IPBC in paints, and the high NOEL for dermal exposure (200 mg/kg/day NOEL from subchronic dermal study)

the Agency believes that the contribution of IPBC to the risks from other carbamate pesticides is likely to be minimal considering currently registered IPBC uses.

D. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the toxicity of IPBC to nontarget organisms. Data for IPBC are outlined below.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of a microbiocide to birds, the following tests are required using technical-grade material: an avian single-dose oral (LD₅₀) study on one species (preferably mallard or bobwhite quail); one subacute dietary study (LC₅₀) on one species of waterfowl (preferably the mallard duck) or one species of upland game bird (preferably bobwhite quail).

Table 7: Avian Acute Oral Toxicity Findings

Species	% A.I.	LD ₅₀ (mg/kg)	MRID No.	Toxicity Category	Fulfills Guideline Requirement *
Northern Bobwhite Quail	98.2 %	749 mg a.i./kg	42430901	Slightly toxic	Y
Northern Bobwhite Quail	97.5 %	970 mg a.i./kg	43491806	Slightly toxic	Y

*Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed)
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

Table 8: Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC ₅₀ (ppm)	MRID No.	Toxicity Category	Fulfills Guideline Requirement*
Northern Bobwhite Quail	97.5 %	>5620	43491807	practically nontoxic	Y
Northern Bobwhite Quail	98.2 %	>3881	42430902	practically nontoxic	Y
Mallard Duck	98.2 %	>5620	42430903	practically nontoxic	S
Mallard Duck	97.5 %	>5620	43491808	practically nontoxic	Y

*Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur

Results are adequate to indicate that IPBC is slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRIDs 42430901, 42430902, 42430903, 43491806, 43491807, 43491808)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. These conditions do not apply to IPBC. Avian reproduction testing is not required.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD₅₀ from the Agency's toxicology database is used to determine toxicity to mammals. For IPBC, the LD50 is reported below.

Table 9: Mammalian Acute Oral Toxicity Findings

Species	% A.I.	LD ₅₀ (mg/kg)	MRID	Fulfills Guideline Requirement*
Rat (small mammal surrogate)		1795 mg/kg (male) 1065 mg/kg (female) 1470 mg/kg (male & female)	00148277	Y

*Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur

Results show that IPBC is slightly toxic to small mammals on an acute oral basis. The guideline requirements are fulfilled. (MRID 00148277)

(4) Insects

A honey bee acute contact LD₅₀ study is required if the proposed use will result in honey bee exposure. Because applications of IPBC are not likely to result in exposure to honey bees, data are not required.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a microbiocide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish acute toxicity study. The study should be conducted with either a cold-water species (preferably the rainbow trout) or a warm-water species (preferably the bluegill sunfish). Data for IPBC are presented in the table below.

Table 10: Freshwater Fish Acute Toxicity Findings

Freshwater Fish Acute Toxicity Findings					
Species	% A.I.	LC ₅₀ (ppm)	MRID	Toxicity Category	Fulfills guideline requirement*
Rainbow trout	97.5%	0.072	43530209	very highly toxic	S
Rainbow trout	97.7%	0.067	41627107	very highly toxic	Y
Bluegill sunfish	97.7%	0.226	41627106	highly toxic	Y
Fathead minnow	97.5%	0.2	43530208	highly toxic	S

*Y=Acceptable (Study satisfied Guideline)/Concur
 P=Partial (Study partially fulfilled Guideline but additional information is needed)
 S=Supplemental (Study provided useful information but Guideline was not satisfied)
 N=Unacceptable (Study was rejected)/Nonconcur

The results of the 96-hour acute toxicity studies indicate that IPBC is very highly toxic to cold-water fish and highly toxic to warm-water fish. The guideline requirements are fulfilled. (MRIDs 41627106, 41627107, 43530208, 43530209)

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a microbiocide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Data for IPBC are presented in the table below.

Table 11: Freshwater Invertebrate Toxicity Findings

Freshwater Invertebrate Toxicity Findings					
Species	% A.I.	EC ₅₀ (ppm)	MRID	Toxicity Category	Fulfills guideline requirement*
<i>Daphnia magna</i>	98.7%	0.956	41627108	highly toxic	Y
<i>Daphnia magna</i>	97.5%	0.16	43530210	highly toxic	Y

*Y=Acceptable (Study satisfied Guideline)/Concur P=Partial (Study partially fulfilled Guideline but additional information is needed)
S=Supplemental (Study provided useful information but Guideline was not satisfied) N=Unacceptable (Study was rejected)/Nonconcur

There is sufficient information to characterize IPBC as highly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 41627108; 43530210)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Because of the use sites and nature of this product, exposure of IPBC to marine/estuarine organisms is possible through industrial effluent. Results of the data submitted are given below.

Table 12: Estuarine/marine Invertebrate Toxicity Findings

Estuarine/marine Invertebrate Toxicity Findings					
Species	% A.I.	EC ₅₀ (ppm)	MRID No. (Author/Year)	Toxicity Category	Fulfills guideline requirement*
<i>Eastern oyster shell deposition</i>	97.25%	0.028	42168202	very highly toxic	S
Pink Shrimp	97.25%	0.103	42168204	highly toxic	Y
Sheepshead minnow	97.25%	0.18	42168203	highly toxic	Y

Y=Acceptable (Study satisfied Guideline)/Concur P=Partial (Study partially fulfilled Guideline but additional information is needed)
S=Supplemental (Study provided useful information but Guideline was not satisfied) N=Unacceptable (Study was rejected)/Nonconcur

There is sufficient information to characterize IPBC as highly toxic to estuarine/marine fish and highly to very highly toxic to estuarine/marine invertebrates. (MRIDs 42168202, 42168203, 42168204)

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial non-food/feed or aquatic non-food (except residential) use patterns and which have endangered or threatened plant species associated with the site of application. These conditions do not apply for IPBC. Phytotoxicity tests are not required.

2. Environmental Fate

a. Environmental Fate Assessment

A qualitative environmental fate assessment can be made for IPBC from existing acceptable and supplemental environmental fate and transport data.

The reported laboratory data suggest that IPBC is non-persistent and mobile in soil and aquatic environments. IPBC should not be a threat to surface and ground water because it rapidly degrades. The dissipation of IPBC in terrestrial and aquatic environments appears to be dependent on alkaline catalyzed hydrolysis, microbial-mediated oxidative mineralization, and leaching. IPBC was rapidly hydrolyzed ($t_{1/2} = 0.947$ days) in pH 9 buffer solution; however, it was stable ($t_{1/2} > 30$ days) in pH 5 and 7 buffer solutions. IPBC was rapidly degraded ($t_{1/2} < 3$ hours) in aerobic mineral soil and anaerobic aquatic environments. IPBC is expected to be very mobile to mobile ($K_{ad} < 2.64$ ml/g) in mineral soils.

The primary degradate of IPBC was isopropargyl butyl carbamate (PBC). This degradate was detected in hydrolysis, aerobic soil, and anaerobic aquatic metabolism studies. PBC was rapidly degraded ($t_{1/2} < 13$ days) in aerobic soil and anaerobic aquatic environments. Degradates of PBC in anaerobic aquatic environments were identified as 2-propenyl-butylcarbamate (2-PBC) and minor unidentified degradates. No mobility data are available for degradates of IPBC.

b. Environmental Fate and Transport

(1) Degradation

The hydrolysis (guideline 161-1) study provides marginally acceptable data because the study was conducted in non-sterile buffer solutions. The interpretation of the hydrolysis data is not affected by non-sterile conditions because minimal microbial contamination was observed in the buffer solutions.

Radiolabeled IPBC was stable ($k=0.0064$ day⁻¹) in pH 5 buffer solution, had a half life of 139 days ($k=0.0049$ day⁻¹) in pH 7 buffer solution, and 0.947 days ($k=0.732$ day⁻¹) in pH 9

buffer solution. Propargyl butyl carbamate (PBC) was identified as the only hydrolysis degradate. The guideline requirement is fulfilled. (MRID 42329301)

In an Aerobic Soil Metabolism (guideline 162-1) study, radiolabeled IPBC, at 1 µg/g, had a half-life of 2.13 hours ($k=0.326$ hours) in a non-sterile, Blackoar loam soil at 22°C. The half-life of IPBC was 8.60 days ($k=0.081$ hours) in a nonsterile, Blackoar loam soil at 5°C. The primary degradate of IPBC was identified as PBC. The aerobic soil metabolism half-life of PBC was 4.31 days ($k=0.161$ days) in nonsterile Blackoar soil at 22°C. The degradate PBC degrades to form CO₂, bound soil residues, and an unidentified metabolite. The guideline requirement is fulfilled. (MRID 42329302)

Marginally acceptable data for Anaerobic Soil Metabolism (guideline 162-2) and Anaerobic Aquatic Metabolism (guideline 162-3) were provided. The data are deemed marginally acceptable because low material balances were detected at later sampling intervals. The interpretation of anaerobic aquatic data is not affected by low material balance because supplemental information was provided to quantify and identify non-trappable volatile degradates.

Radiolabeled IPBC, at 6 µg/g, had a half-life of 1.5 hours ($k=0.464$ hours) in a non-sterile, static, anaerobic ($pe^1+pH < 7$) sediment water test system at 22°C. The anaerobic aquatic metabolism half-life of IPBC was 13.3 hours ($k=0.052$ hours) in a sterile, static, sediment-water test system. Radiolabeled residues were predominantly detected (80% of applied IPBC) in the water phase of sediment-water systems. The primary degradate of IPBC was PBC. The half-life of PBC was 11.5 days ($k=0.060$ days) in the nonsterile, static, anaerobic aquatic system. Secondary degradates of IPBC were 2-propenyl-butylcarbamate (2-PBC) and two unidentified compounds. Volatile degradates were identified as PBC, 2-PBC, CO₂ and possibly CH₄. The guideline requirement is fulfilled. (MRID 42481601)

(2) Mobility

Marginally acceptable data for unaged portion of the Adsorption/Desorption (guideline 163-1) data requirement were provided. The data are deemed marginally acceptable because IPBC degradation was observed during equilibration. The interpretation of mobility is not affected by IPBC degradation because the Freundlich adsorption coefficients for IPBC are low. Low Freundlich coefficients indicate a worst-case mobility assessment (*e.g.*, high mobility in soil and aquatic environments) for IPBC. The mobility of IPBC degradates cannot be determined at this time because no aged soil column leaching data or batch equilibrium data for individual degradates were provided.

Radiolabeled IPBC had Freundlich adsorption coefficients of 0.67 to 2.46 ml/g in a Hanford sandy loam, Centhan sand, Blackoar loam, Mexico silty clay, and an Evesboro sand. Freundlich desorption coefficients ranged from 3.4 to 31 ml/g. Degradation of IPBC was

*

PE is a measure of the redox potential. It varies indirectly with the pH.

observed in the equilibration solutions. The major degradate of IPBC was PCB. IPBC adsorption was not correlated to organic matter content, clay content, and cation exchange capacity of soil. The guideline requirement is partially fulfilled. (MRID 41975207)

c. Water Resources

A preliminary assessment based on laboratory data only indicates that IPBC should not pose a threat to surface waters and ground waters because it degrades rapidly. A leaching assessment for degradates is not possible at this time because no data on mobility of degradates has been provided.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

(1) Exposure and Risk to Nontarget Terrestrial Animals

The Agency requires only a limited set of ecotoxicology and environmental fate data for microbiocides. The available data classify IPBC as slightly toxic to practically nontoxic to birds and very highly toxic to highly toxic to freshwater fish and aquatic invertebrates.

While the hazard to aquatic organisms from IPBC has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from the microbiocide use of this chemical are regulated under the NPDES permitting program of EPA's Office of Water. Labels for all IPBC products must require that discharges to aquatic environments comply with an NPDES permit.

Because the outdoor use of IPBC is limited to terrestrial wood pressure/protection treatment of forest products, exposure of wildlife is not expected to be significant.

(2) Endangered Species

Based on the registered use patterns for IPBC, risks to endangered species are not anticipated from direct application of products.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data to support reregistration of products containing IPBC 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 IPBC except those containing uses for industrial wood protection treatment to milled forest products, HVAC uses, textile uses, and certain non-industrial applications to wood, under the conditions specified in the RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of IPBC, 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 IPBC and to determine that IPBC with modifications as specified in this document, and with the exception of industrial wood protection treatment to milled forest products, HVAC uses, textile uses, and certain non-industrial applications to wood, can be used without resulting in unreasonable adverse effects to humans and the environment if used according to the label as amended by this RED. The Agency therefore finds that all products containing IPBC as the active ingredient, except those labelled for industrial wood protection treatment to milled forest products, HVAC uses, textile uses and certain non-industrial applications to wood, are eligible for reregistration under the conditions specified in this RED. 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. The Agency has found that all uses of IPBC, except the industrial wood protection treatment to milled forest products, HVAC uses, textile uses, and certain non-industrial applications to wood, are eligible for reregistration under the conditions specified in this RED. However, it should be understood that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing IPBC, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

Because IPBC currently has no food uses and no tolerances have been established, the specific determinations outlined in FQPA are not required for this chemical. Nevertheless, EPA has considered available data relating to the special sensitivity of infants and children, the potential for aggregate exposures and cumulative effects in its risk management decisions for IPBC because children and other individuals could be exposed to this compound in non-occupational settings.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient IPBC, the Agency has sufficient information on the health effects of IPBC, and on its potential for causing adverse effects in fish and wildlife and the environment, for all uses except industrial wood protection treatments to milled forest products, textile uses, HVAC uses, and certain non-industrial

applications to wood. The Agency has determined that IPBC products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment, and that products containing IPBC, with the exceptions noted below, are eligible for reregistration.

2. Eligible and Ineligible Uses

In reaching eligibility decisions the Agency makes every effort to use available exposure data. However, in some cases existing exposure data were not an appropriate surrogate for currently labeled uses. EPA does not have adequate or sufficient data at this time to make eligibility decisions for uses involving the following exposure scenarios:

- workers exposed during industrial treatments to milled forest products, including post application exposures to workers handling or processing treated wood products;
- workers applying IPBC products to heating, ventilation and air conditioning (HVAC) ducts or filters, and post application exposure to occupants of areas where HVAC systems have been treated;
- post application exposure to persons handling and using textiles, such as carpets, drapes, shower curtains, and canvas, to which IPBC has been applied;

and

- non-industrial workers and homeowners applying IPBC products to wood by dipping, using a pad, or any method other than a brush, roller or airless or compressed air sprayer.

Eligibility decisions on products containing the industrial treatments to milled forest products use, HVAC use, textile uses, and non-industrial wood treatments using methods other than brush, roller and airless or compressed air sprayer, will be made after the exposure data specified in section V.A.1 are received and evaluated. Products containing these uses are not eligible for reregistration at this time.

The Agency has determined that all other uses, except those specifically noted above, are eligible for reregistration.

C. Regulatory Position

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

1. Potential Risks to Infants and Children/Aggregate Exposure/Cumulative Effects

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

Based on the current data requirements, IPBC has a complete data base for developmental and reproductive toxicity. In the developmental studies, developmental effects were seen at doses that were the same as or higher than doses which cause maternal toxicity. No adverse effects on reproductive indices or mating performance were observed in the two generation rat reproduction study. The developmental studies in conjunction with the reproductive study do not indicate any special sensitivity of young organisms to IPBC. Therefore, the Agency has concluded that an additional uncertainty factor need not be applied to the short- and intermediate-term NOELs used for the IPBC risk assessments.

In examining aggregate exposure, EPA takes into account available information concerning exposures from the pesticide residue in food and other exposures for which there is reliable information. These other sources of exposure can include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home.

No dietary exposure is expected since there are no food uses of IPBC. IPBC is not likely to be found in drinking water because it degrades rapidly both in soil and aquatic environments. Thus, residential uses are the only sources of exposure that could be aggregated for IPBC. EPA assumes that handling and applying paint would be the reasonable worst case exposure scenario for homeowners. Because the MOEs for this worst case exposure are high (> 600), EPA believes that aggregate exposures to other sources of IPBC in the home are not likely to be of concern.

The Agency has not yet made a determination regarding whether it is appropriate to consider exposure from other carbamates with IPBC in order to address potential cumulative effects. However, based on the high MOEs for homeowner applicators, the lack of food uses, unlikely residues in drinking water, and the high NOEL for dermal exposure, the Agency believes that it is reasonable to assume that the contribution of IPBC exposure to the risks from other carbamate pesticides is likely to be minimal considering currently registered IPBC uses.

2. Occupational and Residential Labeling Rationale/Risk Mitigation

a. Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

- If the Agency determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent the Agency guidelines.
- If the Agency determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):
 - In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
 - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
 - The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for IPBC.

b. Primary Occupational Handlers

The exposure data upon which the risks were assessed were based on studies where the handlers wore chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes, and socks. Therefore, for the following uses chemical-resistant gloves will be required in addition to the baseline requirements of long-sleeve shirt, long pants, shoes, and socks:

- oil-well mud-packer fluids, oil-recovery drilling muds, secondary-oil recovery injection water, and oil-well injection fluids;
- preservative uses, including oil/latex paint manufacturing, industrial adhesives, industrial coatings, resin/latex/polymer emulsions; plastic manufacturing, textile manufacturing, ink manufacturing, and canvas manufacturing;
- paper coating, and
- metalworking fluids.

NOTE: No personal protective equipment is being recommended at this time for wood products manufacturing (no data available). This will be added if risk mitigation measures are needed for this use.

c. Secondary Occupational Handlers

The data for occupational painters using airless or compressed air sprayers indicate the MOEs are less than 100 (71 for subchronic and 61 for chronic exposure) unless PPE (long-sleeve shirt, long pants, shoes, socks and chemical-resistant gloves) is used. EPA's regulatory authority does not encompass requiring label statements for paints, and consequently, the Agency would not be able to enforce the use of PPE by occupational painters. However, EPA assumes that occupational painters are likely to wear appropriate PPE. Furthermore, the MOE calculations use worst case exposure assumptions that are not likely to occur. For example, an occupational painter is not likely to use only paints containing IPBC, nor is he/she likely to apply paints only with an airless or compressed air sprayer.

d. Homeowner-Use Products

There are no homeowner uses of concentrated IPBC. However, for IPBC treated paints, the MOEs for secondary homeowner handlers (i.e., painters) are not of concern. The Agency is not establishing entry restrictions at this time for products containing IPBC, such as paints and adhesives, that are intended primarily for homeowner use, since the anticipated frequency, duration, and degree of dermal exposure after homeowner applications do not warrant special risk mitigation measures.

e. Post-Application/Entry Restrictions

The Agency is not establishing entry restrictions at this time for occupational uses of IPBC end-use products or treated products, since the anticipated frequency, duration, and degree of exposure following occupational applications do not warrant special risk mitigation measures. The Agency may revisit this issue upon receipt and evaluation of the wood treatment and other exposure data.

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

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 IPBC has been reviewed and determined to be substantially complete, except that information is needed to fulfill guidelines 81-8 and 82-7 to further characterize the potential for IPBC to cause neurological effects. The Agency is issuing a DCI concurrent with this RED to IPBC (technical) registrants for these neurotoxicity data. Additional exposure data are also required for guidelines 133-3, 133-4, 231, 232, 233, and 234 to characterize exposure to IPBC during wood protection treatment to milled forest products and subsequent handling of treated lumber, exposure to workers during and to occupants after application of IPBC to HVAC ducts/systems, exposure to persons handling textiles treated with IPBC, and exposure to occupational (non-industrial) workers and homeowners applying IPBC to wood by methods other than brush, roller and airless or compressed air sprayer. However, because much of the exposure data needed for IPBC is generic in nature and will also be required for other antimicrobial chemicals with similar characteristics and the same uses, EPA is developing a generic exposure DCI. IPBC registrants will receive the generic exposure DCI at the same time as registrants of other chemicals with similar uses.

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 Agency regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."

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)."

All products distributed or sold by **registrants and distributors (supplemental registrants)** should bear labeling that is consistent with this notice by **March 30, 1998** and all products distributed or sold by **persons other than registrants or supplemental registrants** after **September 30, 1998** should bear correct labeling.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain IPBC, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain IPBC, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

(1) Products Intended Primarily for Occupational Use

(a) Minimum (Baseline) PPE/Engineering Control Requirements

Although the Agency is not establishing minimum (baseline) engineering controls for occupational uses of IPBC end-use products, the Agency is establishing minimum (baseline) personal protective equipment for occupational uses of IPBC end-use products. The minimum (baseline) PPE for all occupational uses of IPBC end-use products is:

"Applicators and other handlers must wear:

--long-sleeve shirt and long pants,

--chemical-resistant gloves*,

--shoes plus socks.

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

(b) Determining PPE Requirements for End-use Product Labels

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

NOTE: All end-use products are required to specify a long-sleeved shirt, long pants, socks and shoes as minimum work attire for all handlers. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

(c) Placement in Labeling

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

(2) Products Intended Primarily for Homeowner Use

(a) Determining PPE Requirements for End-Use Product Labels

The Agency is not establishing active-ingredient-based minimum (baseline) handler PPE for IPBC end-use products that are intended primarily for homeowner use. Any necessary PPE for each IPBC end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

(b) Placement in Labeling

The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

b. Entry Restrictions

For sole-active-ingredient end-use products that contain IPBC the product labeling must be revised to remove any entry restrictions on the current labeling.

For multiple-active-ingredient end-use products that contain IPBC the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

c. Other Labeling Requirements

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

(1) Application Restrictions

"Do not apply this product in a way that will contact workers or other persons."

"This product is toxic to fish. Do not discharge effluent containing this product into

lakes, streams, ponds, estuaries, oceans or other water unless in accord with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

For home use products, add:

- "Do not apply this product in a way that will contact any person or pet."

(2) User Safety Requirements for Occupational Use Products

Add the following statement:

- "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

If coveralls are required for pesticide handlers, add the following:

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

(3) User Safety Recommendations for All Products

Include the following recommendations to all end-use product labels.

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove personnel protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly." (For occupational use products only.)

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 [add chemical names here] 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

Applicable., Not applicable for this use.

RTU

NA

.2383 lb 1K sq.ft

* NS

NS

NS

NS

NS

NS

CAU

label., Pad.

label., Sprayer.

RTU

NA

.2383 lb 1K sq.ft

* NS

NS

NS

NS

NS

NS

CAU

RTU

NA

.3435 lb 1K sq.ft

* NS

NS

NS

NS

NS

NS

C93

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 3-iodo-2-propynyl butyl carbamate (IPBC) covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 3-iodo-2-propynyl butyl carbamate (IPBC) in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of IPBC

REQUIREMENT	USE PATTERN	CITATION(S)	
<u>PRODUCT CHEMISTRY</u>			
61-1	Chemical Identity	All	41722901
61-2A	Start. Mat. & Mnfg. Process	All	41722901
61-2B	Formation of Impurities	All	41722901
62-1	Preliminary Analysis	All	41722901
62-2	Certification of limits	All	41722901
62-3	Analytical Method	All	41722901
63-2	Color	All	41722901
63-3	Physical State	All	41722901
63-4	Odor	All	41722901
63-5	Melting Point	All	41802601
63-6	Boiling Point	All	N/A
63-7	Density	All	41802501
63-8	Solubility	All	Data Gap
63-9	Vapor Pressure	All	42389802

* Indicates that this study has been classified as supplemental by the Agency. Additional confirmatory data may be required from the registrant to satisfy this guideline requirement.

Data Supporting Guideline Requirements for the Reregistration of IPBC

REQUIREMENT	USE PATTERN	CITATION(S)
63-10 Dissociation Constant	All	N/A
63-11 Octanol/Water Partition	All	N/A
63-12 pH	All	41802601, 42257901
63-13 Stability	All	Data Gap

* Indicates that this study has been classified as supplemental by the Agency. Additional confirmatory data may be required from the registrant to satisfy this guideline requirement.

Data Supporting Guideline Requirements for the Reregistration of IPBC

REQUIREMENT	USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>		
71-1A	Acute Avian Oral - Quail/Duck	C,K,M,O 42430901, 43491806
71-2A	Avian Dietary - Quail	C,K,M,O 43491807, 42430902
71-2B	Avian Dietary - Duck	C,K,M,O 42430903*, 43491808
71-3	Wild Mammal Toxicity	C,K,M,O 00148277
72-1A	Fish Toxicity Bluegill	C,K,M,O 41627106, 43530208*
72-1C	Fish Toxicity Rainbow Trout	C,K,M,O 43530209*, 41627107
72-2A	Invertebrate Toxicity	C,K,M,O 41627108, 43530210
72-3A	Estuarine/Marine Toxicity - Fish	C,K,M,O 42168203
72-3B	Estuarine/Marine Toxicity - Mollusk	C,K,M,O 42168202*
72-3C	Estuarine/Marine Toxicity - Shrimp	C,K,M,O 42168204
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Rat	C,K,M,O 00148277
81-2	Acute Dermal Toxicity - Rabbit/Rat	C,K,M,O 42135501
81-3	Acute Inhalation Toxicity - Rat	C,K,M,O 42204301
81-4	Primary Eye Irritation - Rabbit	C,K,M,O 41627109
81-5	Primary Dermal Irritation - Rabbit	C,K,M,O 41627110

* Indicates that this study has been classified as supplemental by the Agency. Additional confirmatory data may be required from the registrant to satisfy this guideline requirement.

Data Supporting Guideline Requirements for the Reregistration of IPBC

REQUIREMENT	USE PATTERN	CITATION(S)
81-6	Dermal Sensitization - Guinea Pig	C,K,M,O 43005701
81-8	Acute Rat Neurotoxicity with cholinesterase	C,K,M,O Data gap
82-1A	90-Day Feeding - Rodent	C,K,M,O 40947401*
82-3	90-Day Dermal - Rodent	C,K,M,O 42168201
82-7	90-day Rat Neurotoxicity with cholinesterase	C,K,M,O Data gap
83-1A	Chronic Feeding Toxicity - Rodent	C,K,M,O 42008206
83-2A	Oncogenicity - Rat	C,K,M,O 42008206, 42008202
83-2B	Oncogenicity - Mouse	C,K,M,O 43819001
83-3A	Developmental Toxicity - Rat	C,K,M,O 40990401
83-3B	Developmental Toxicity - Rabbit	C,K,M,O 42481604
83-4	2-Generation Reproduction - Rat	C,K,M,O 40990402
84-2A	Gene Mutation (Ames Test)	C,K,M,O 41975206
84-2B	Structural Chromosomal Aberration	C,K,M,O 40990404
84-4	Other Genotoxic Effects	C,K,M,O 40990403
85-1	General Metabolism	C,K,M,O 40947404, 43570701

* Indicates that this study has been classified as supplemental by the Agency. Additional confirmatory data may be required from the registrant to satisfy this guideline requirement.

Data Supporting Guideline Requirements for the Reregistration of IPBC

REQUIREMENT	USE PATTERN	CITATION(S)
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>		
133-3 Dermal Passive Dosimetry Exposure	C,K,M,O	41412201, 41742601, 42587501
<u>ENVIRONMENTAL FATE</u>		
161-1 Hydrolysis	C,K,M,O	42329301
162-1 Aerobic Soil Metabolism	C,K,M,O	42329302
162-2 Anaerobic Soil Metabolism	C,K,M,O	42481601
162-3 Anaerobic Aquatic Metabolism	C,K,M,O	42481601
163-1 Leaching/Adsorption/Desorption	C,K,M,O	41975207

* Indicates that this study has been classified as supplemental by the Agency. Additional confirmatory data may be required from the registrant to satisfy this guideline requirement.

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

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

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

3-IODO-2-PROPYNL BUTYL CARBAMATE (IPBC) DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing **3-iodo-2-propynyl butyl carbamate**.

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 3-iodo-2-propynyl butyl carbamate (IPBC). 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 3-iodo-2-propynyl butyl carbamate (IPBC) 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 3-iodo-2-propynyl butyl carbamate are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 3-iodo-2-propynyl butyl carbamate 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 3-iodo-2-propynyl butyl carbamate products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Richard J. Gebken at (703) 308-8591.

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

Richard J. Gebken
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Division
Mail Code - 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: **2725**

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.

The draft copy of part A for the Product Specific DCI is inserted here.

**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.

Page 1 of the sample Product Specific DCI (part b) is inserted here.

Page 2 of the sample Product Specific DCI (part b) is inserted here.

Page 3 of the sample Product Specific DCI (part b) is inserted here.

Page 4 of the sample Product Specific DCI (part b) is inserted here.

EPA'S BATCHING OF PRODUCTS CONTAINING 3-IODO-2-PROPYNYL BUTYL CARBAMATE AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient 3-Iodo-2-propynyl butylcarbamate the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), 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. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. The citation of data conducted on any new formulations (that were presented to the Agency after the publication of the RED) must be approved if these data are to be used to cover other products in a batch. 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.

Table 1 displays the batches for the active ingredient 3-Iodo-2-propynyl butylcarbamate

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	1258-1219	3-Iodo-2-propynyl butylcarbamate ... 97%	solid
	5383-50	3-Iodo-2-propynyl butylcarbamate ... 97%	solid
2	1022-575	3-Iodo-2-propynyl butylcarbamate ... 40%	liquid
	5383-63	3-Iodo-2-propynyl butylcarbamate ... 40%	liquid
3	577-543	3-Iodo-2-propynyl butylcarbamate ... 0.50%	liquid
	577-547	3-Iodo-2-propynyl butylcarbamate ... 0.50%	liquid
4	1022-550	3-Iodo-2-propynyl butylcarbamate ... 7.60% didecyl dimethyl ammonium chloride ... 64.80%	liquid
	60061-27	3-Iodo-2-propynyl butylcarbamate ... 7.60% didecyl dimethyl ammonium chloride ... 64.80%	liquid
	60061-78	3-Iodo-2-propynyl butylcarbamate ... 7.55% didecyl dimethyl ammonium chloride ... 64.34% 5-chloro-2-methyl-4-isothiazolin-3-one ... 0.06% 2-methyl-4-isothiazolin-3-one ... 0.02%	liquid
5	5383-80	3-Iodo-2-propynyl butylcarbamate ... 1.3%	liquid
	5383-81	3-Iodo-2-propynyl butylcarbamate ... 1.3%	liquid

Table 2 lists the products the Agency was unable to batch. These products were not batched because they were not considered to be similar to other products in terms of acute toxicity. Registrants of these products are responsible for meeting the acute toxicity data requirements for

each product individually. These products may not cite acute toxicity/ irritation data derived from any other products in this RED. The registrant may cite preexisting data conducted on their individual product if it exists and it meets current Agency standards.

Table 2.

Registration Number	Percent Active Ingredient	Form
200-125	3-Iodo-2-propynyl butylcarbamate ... 0.53%	liquid
341-46	3-Iodo-2-propynyl butylcarbamate ... 0.50%	liquid
748-277	3-Iodo-2-propynyl butylcarbamate ... 0.50%	liquid
748-292	3-Iodo-2-propynyl butylcarbamate ... 2.5%	liquid
1022-516	3-Iodo-2-propynyl butylcarbamate ... 6.0%	liquid
1022-540	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
1409-50	3-Iodo-2-propynyl butylcarbamate ... 2.4%	liquid
1409-51	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
1409-59	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
1719-41	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
1719-42	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
4091-9	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
5383-18	3-Iodo-2-propynyl butylcarbamate ... 40%	liquid
5383-51	3-Iodo-2-propynyl butylcarbamate ... 80%	solid
5383-52	3-Iodo-2-propynyl butylcarbamate ... 40%	solid
5383-55	3-Iodo-2-propynyl butylcarbamate ... 17%	liquid
5383-73	3-Iodo-2-propynyl butylcarbamate ... 15%	liquid
5383-74	3-Iodo-2-propynyl butylcarbamate ... 20%	liquid
5383-75	3-Iodo-2-propynyl butylcarbamate ... 10%	liquid
5383-76	3-Iodo-2-propynyl butylcarbamate ... 20%	solid
5383-78	3-Iodo-2-propynyl butylcarbamate ... 0.1% Bis (tributyl) oxide ... 0.5%	liquid
5383-79	3-Iodo-2-propynyl butylcarbamate ... 0.2% Bis (tributyl) oxide ... 0.5%	liquid
5383-83	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
6836-200	3-Iodo-2-propynyl butylcarbamate 4.5% 1,3-Bis(hydroxymethyl)-5,5-dimethyl- hydantoin ... 87% Hydroxymethyl-5,5-dimethyl- hydantoin ... 0.4%	liquid
8177-71	3-Iodo-2-propynyl butylcarbamate 0.05% Bis (tributyl) Oxide 0.30%	liquid
8177-72	3-Iodo-2-propynyl butylcarbamate 0.63%	liquid

Registration Number	Percent Active Ingredient	Form
8177-73	3-Iodo-2-propynyl butylcarbamate ... 0.57%	liquid
11599-2	3-Iodo-2-propynyl butylcarbamate 0.4%	liquid
39492-47	3-Iodo-2-propynyl butylcarbamate ... 0.8%	liquid
42768-8	3-Iodo-2-propynyl butylcarbamate ... 0.8%	liquid
46614-1	3-Iodo-2-propynyl butylcarbamate ... 0.53%	liquid
51578-1	3-Iodo-2-propynyl butylcarbamate ... 0.58%	liquid
52782-1	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
53354-1	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
56601-2	3-Iodo-2-propynyl butylcarbamate ... 0.23%	liquid
60061-21	3-Iodo-2-propynyl butylcarbamate ... 5.97%	liquid
60061-28	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
60061-30	3-Iodo-2-propynyl butylcarbamate ... 2.5%	liquid
60061-88	3-Iodo-2-propynyl butylcarbamate ... 4.0%	liquid
60061-89	3-Iodo-2-propynyl butylcarbamate ... 0.5%	liquid
60061-90	3-Iodo-2-propynyl butylcarbamate ... 3.09%	liquid
60061-91	3-Iodo-2-propynyl butylcarbamate ... 2.4%	liquid
63836-1	3-Iodo-2-propynyl butylcarbamate ... 0.16% Barium metaborate ... 9.0%	liquid

The placing of two products into a batch means that these products are able to share acute toxicity data interchangeably. However, bridging means that one product (a) should be able to cite data from another product (b), but the other product (b) is not allowed to cite data on the first product (a). In doing so, product (a) must not change a toxicity category from a I to a II, III or IV. Product (a) must also not change a toxicity category III or IV to a I or II. It is also assumed that product (a) will be no more likely to be a dermal sensitizer. At times, the Agency will allow a registrant to bridge data from a product while having to conduct one or two studies to cover studies were the Agency is concerned about potential differences in toxicity categories.

Table 3 presents products which may bridge acute toxicity data from the technical products in batch #1 with the exception of the primary eye irritation study:

Table 3.

Registration Number	Percent Active Ingredient	Form
5383-51	3-Iodo-2-propynyl butylcarbamate ... 80%	solid
5383-52	3-Iodo-2-propynyl butylcarbamate ... 40%	solid

Again, the registrant of these two products may not cite the primary eye irritation study conducted on the technical product to cover these two products, but may cite technical data of the other five

acute toxicity/ irritation studies. The data cited on the technical product must be acceptable by Agency standards and guidelines.

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.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all 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.



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
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Product Name	EPA Reg. No.
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I Certify that:

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

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



**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

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:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(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)

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

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Dee Henderson at (703)-308-8167.

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 IPBC.

The following documents are part of the Administrative Record for IPBC 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