

US EPA ARCHIVE DOCUMENT



## 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 ortho-benzyl-para-chlorophenol which includes the active ingredients potassium 2-benzyl-4-para-chlorophenate and sodium 2-benzyl-4-chlorophenate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in the tolerance is necessary, that tolerance, too, will be reassessed in the future pursuant to the requirements of FQPA. Also note, this signed and dated letter supercedes the signed but undated letter included at the beginning of the bound document.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Nancy Tompkins at (703) 308-8172. Address any questions on required generic data to the Special Review and Reregistration Division representative Veronica Dutch at 703-308-8585.

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**

**ORTHO-BENZYL-P-CHLOROPHENOL**

**LIST B**

**CASE 2045**

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**O-benzyl-p-chlorophenol 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	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	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 <sub>50</sub>	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 <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

## GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
$Q_1^*$	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## EXECUTIVE SUMMARY

The Agency has determined that the uses of the active ingredient, ortho-benzyl-para-chlorophenol (2-benzyl-4-chlorophenol), and its salts, potassium 2 benzyl-para-chlorophenate and sodium 2-benzyl-4-chlorophenate, as prescribed in this document except the enclosed area fogging application will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration. The Agency is requiring handler exposure data on the fogging application and cannot make an eligibility decision on this method until these data are generated.

Ortho-benzyl-para-chlorophenol and its salts, are broad-spectrum disinfectants/anti-microbials for controlling a variety of bacteria, fungi, algae, and viruses. The use patterns include: indoor medical, indoor nonfood, indoor residential, terrestrial nonfood crop, and aquatic nonfood industrial and residential. Outdoor use sites include swimming pool water related surfaces such as decks, and other hard surface areas surrounding swimming pools for the acid and both salts, refuse/solid waste sites for the acid, air washer water systems for the sodium salt, evaporative condenser water systems and industrial processing water for the potassium salt, and commercial/industrial water cooling systems for both salts.

Ortho-benzyl-para-chlorophenol and its salts are also registered for use as disinfectants for farm premises, poultry houses, food processing plants, eating establishments, and federally inspected meat and poultry processing plants. Dietary exposure is not expected from these use patterns. Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants in food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment. Phenolic-based products recommended for use as disinfectants on food contact surfaces in eating establishments and homes are limited to sites such as counter tops, stoves, and refrigerators, which followed by a potable water rinse would allow their classification as a nonfood use. Application of these products as disinfectants on eating utensils, glassware, and similar items would be considered a food use and would require a tolerance or an exemption from the requirements of a tolerance prior to approval. Specific label directions are provided in Section V, "Actions Required of Registrants", which result in the classification of farm premise and poultry house disinfectants as non-food use products.

Ortho-benzyl-para-chlorophenol and its salts when registered for use as sanitizers on food-processing equipment and utensils, and on other food-contact articles are under the purview of FDA (21 CFR Part 178.1010 (20)). EPA accepts FDA's approval and acceptance of the chemical(s) use pattern.

The product chemistry data base for ortho-benzyl-para-chlorophenol is adequate for reregistration. However, product chemistry data on the inorganic salts are required.

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. The chemical, ortho-benzyl-para-chlorophenol, is nontoxic to birds and highly toxic to freshwater fish and aquatic invertebrates. While the hazard to aquatic organisms from

ortho-benzyl-para-chlorophenol has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from the uses of ortho-benzyl-para-chlorophenol are regulated under the NPDES permitting program of the Office of Water. The Agency currently requires that labels for all ortho-benzyl --para-chlorophenol products require that discharges to aquatic environments comply with a NPDES permit. Because terrestrial use of ortho-benzyl- para-chlorophenol and its potassium and sodium salts is limited to refuse/solid waste sites, exposure to wildlife is not expected to be significant.

The environmental fate data indicate that the two salts rapidly degrade into the acid in the environment. Therefore, the data supporting the acid also can be used to support the potassium and sodium salts.

Ortho-benzyl-para-chlorophenol is Category III for acute oral and dermal toxicity, and Category IV for acute inhalation toxicity. Ortho-benzyl-para-chlorophenol is severely irritating to the eye (Category I), and is corrosive with repeated contact to the skin. The requirement for a dermal sensitization study was waived due to the corrosive nature of ortho-benzyl-para-chlorophenol. In chronic studies, ortho-benzyl-para-chlorophenol induces increases in kidney nephropathy and has been classified as a Group C, possible human carcinogen.

There is a data gap for mutagenicity testing. Under the new mutagenicity guidelines, a mammalian cells in culture forward assay (specifically a mouse lymphoma assay) is needed in order to completely satisfy the mutagenicity testing requirements.

The Agency has determined that regulatory action regarding the establishment of active ingredient-based minimum PPE requirements for occupational handlers must be taken for ortho-benzyl-para-chlorophenol. The Chemical Manufacturers Association (CMA) exposure data used to assess the risk resulting from three of the use-scenarios were based on the handlers in these use-scenarios wearing chemical-resistant gloves. Therefore, chemical-resistant gloves shall be required for occupational handlers of ortho-benzyl-para-chlorophenol for the following use-scenarios: mixing and pouring a soluble liquid, transferring (pumping) liquid, and pouring powdered or flaked solid product. Since the chronic MOE for hand-wiping (ungloved) was less than 300, chemical resistant gloves are required to reduce/mitigate the potential risk to applicators. For exposures related to indoor fogging applications, EPA is requiring the use of a full-face canister-style respirator to mitigate ocular and inhalation concerns.

The high-pressure spray application use-scenario, which is an intermediate exposure scenario, had an MOE of less than 100. Since the CMA exposure data used to assess the risk from this use-scenario was based, in some replicates, on the handlers wearing chemical-resistant gloves and rainsuits, there are no additional PPE options available that would adequately mitigate the risk. Furthermore, there are no practicable engineering controls for this use-scenario. However, due to uncertainties in the data used to calculate exposure, the Agency will consider the high pressure spray scenario conditionally acceptable until new exposure data are available.

At this time, EPA is not establishing active-ingredient-based minimum (baseline) PPE for occupational handlers for the following scenarios: (4) low-pressure spraying and (5) mopping. The estimated exposures to and resulting risk from ortho-benzyl-para-chlorophenol in these occupational use-scenarios do not warrant establishing such PPE requirements.

The dermal and inhalation studies are required on handlers during fogging and high-pressure spray applications in enclosed areas.

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





## I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of ortho-benzyl-para-chlorophenol (the acid) which includes the active ingredients potassium and sodium 2-benzyl-4-chlorophenate (the salts). The document consists of six sections. Section I is the introduction. Section II describes ortho-benzyl-para-chlorophenol and the salts, 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 ortho-benzyl-para-chlorophenol. Section V discusses the reregistration requirements for ortho-benzyl-para-chlorophenol. 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 ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Ortho-benzyl-para-chlorophenol/Chlorophen
- **Chemical Name:** 2-benzyl-4-chlorophenol
- **CAS Registry Number:** 120-32-1
- **OPP Chemical Code:** 62201
- **Empirical Formula:** C<sub>13</sub>H<sub>11</sub>ClO
- **Trade and Other Names:** Preventol BP Technical
- **Basic Manufacturer(s):** Bayer Inc. and NIPA Laboratories, Inc.

- **Chemical Name:** Potassium 2-benzyl-4-para-chlorophenate
- **CAS Registry Number:** 35471-49-9
- **OPP Chemical Code:** 62202
- **Empirical Formula:** C<sub>13</sub>H<sub>11</sub>Cl O K

- **Chemical Name:** Sodium 2-benzyl-4-chlorophenate
- **CAS Registry Number:** 3184-65-4
- **OPP Chemical Code:** 62203
- **Empirical Formula:** C<sub>13</sub>H<sub>11</sub>Cl O Na

### B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of ortho-benzyl-para-chlorophenol and salts is in Appendix A.

#### For ortho-benzyl-para-chlorophenol:

#### TYPE OF PESTICIDE:

Disinfectant (limited, general, or medical), Tuberculocide, Virucide, Sanitizer, Fungicide (mold/mildew), Fungicide/fungistat (Trichophyton), Microbiocide/microbiostat (slime-forming bacteria, slime-forming fungi), Bacteriostat.

**USE SITES:****INDOOR NON-FOOD:**

- + Agricultural/Farm Premises
- + Agricultural/Farm Structures/Buildings and Equipment
- Animal Kennels/Sleeping Quarters (Commercial)
- \* Animals (Laboratory/Research)
- + Barns/Barnyards/Auction Barns
- \*+ Calves
- Carpets (Commercial Sanitizer)
- Commercial Transportation Facilities - Nonfeed/Nonfood
- Commercial/Institutional/Industrial Floors
- Commercial/Institutional/Industrial Premises/Equipment (Indoor)
- \*+ Dairy Cattle (Lactating or Unspecified)
- \*+ Dairy Cattle (Non-lactating)
- # Dairy Farm Milk Handling Facilities/Equipment
- # Eating Establishments
- # Eating Establishments Equipment/Utensils (Food Contact)
- # Eating Establishments Food Handling Areas (Food Contact)
- Eating Establishments Food Handling Areas (Nonfood Contact)
- # Eating Establishments Food Serving Areas (Food Contact)
- Eating Establishments Food Serving Areas (Nonfood Contact)
- Egg Handling Equipment (Hatching)
- # Egg Packing Plants (Commercial)
- Egg Plants/Hatcheries/Brooder Rooms/Shoe Baths (Hatching)
- Egg Washing Treatments (Hatching)
- # Food Dispensing Equipment/Vending Machines
- # Food/Grocery/Marketing/Storage/Distribution Facility Premise
- # Food Marketing/Storage/Distribution Equipment/Utensils (Food Contact)
- # Food Processing Plant Equipment (Food Contact)
- # Food Processing Plant Premises (Nonfood Contact)
- \*+ Hog/Pig/Swine (Meat)
- \*Horses (Show/Race/Special/Ponies)
- # Household Domestic Dwellings Indoor Food Handling Areas
- # Human Drinking Water Systems (water-related surfaces)
- Laundry (Commercial)
- Laundry Equipment
- Leather/Leather Products
- \*+ Livestock

- \* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.
- + See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.
- # Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

#Meat Processing Plant Equipment (Food Contact)  
 #Meat Processing Plant Premises (Nonfood Contact)  
 Metalworking Cutting Fluids  
 \*+ Poultry (Egg/Meat)  
 \*+ Poultry (Meat)  
 #Poultry Processing Plant Equipment (Food Contact)  
 Poultry Processing Plant Premises (Nonfood Contact)  
 Refuse/Solid Waste Containers (Garbage Cans)  
 Rubber Products  
 \*Specialized Animals  
 Textiles/Textile Fibers/Cordage

#### INDOOR MEDICAL:

Barber/Beauty Shop Instruments (Shavers/Scissors)  
 Carpets (Hospital Sanitizer)  
 Diapers (Hospital Laundry)  
 Hospital Conductive Floors  
 Hospital Critical Items (Surgical Instruments/Pacemakers)  
 Hospital Noncritical Items (Bedpans/Furniture)  
 Hospital Semicritical Items (Catheters/Inhalation Equipment)  
 Hospital/Medical Institutions Non-conductive Floors  
 Hospitals/Medical Institutions Critical Premises (Burn Wards)  
 Hospitals/Medical Institutions Patient Premises  
 Hospitals/Medical Institutions Premises (Human/Veterinary)  
 Household Sickrooms Premises/Contents/Utensils  
 Human Waste (Typhoid Stools/Feces/Urine)  
 Laundry (Hospital)

#### INDOOR RESIDENTIAL:

Bathroom Premises/Hard Surfaces  
 \*Birds  
 Carpets (Household Sanitizer)  
 Diaper Pails (Empty)  
 Household/Domestic Dwellings  
 Household/Domestic Dwellings Contents  
 Household/Domestic Dwellings Indoor Premises  
 Human Grooming Instruments (Brushes, Combs)  
 Laundry (Household/Coin-operated)

- \* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.
- + See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.
- # Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

Pet Living/Sleeping Quarters  
 Refuse/Solid Waste Containers (Garbage Cans)  
 Refuse/Solid Waste Sites (Indoor)  
 Refuse/Solid Waste Transportation Facilities/Handling Equipment  
 Residential Floors  
 Toilet Bowls (Interior Surfaces)  
 Toilet Tanks/Water Closets Water  
 Urinals (Interior Surfaces)

AQUATIC NON-FOOD RESIDENTIAL:  
 Swimming Pool Water Related Surface Treatment

TERRESTRIAL NON-FOOD CROP:  
 Refuse/Solid Waste Sites (Outdoor)

### PESTS:

#### Bacteria:

*Mycobacterium tuberculosis*, *Mycobacterium bovis*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Pseudomonas cepacia*, *Pseudomonas maltophilia*, *Salmonella arizonae*, *Salmonella enteritidis*, *Salmonella gallinarum*, *Salmonella pullorum*, *Salmonella sonnei*, *Salmonella paratyphi*, *Salmonella schottmuelleri*, *Salmonella typhi* (*Salmonella typhosa*), *Salmonella typhimurium*, *Shigella dysenteriae*, *Shigella flexneri*, *Staphylococcus epidermis*, *Staphylococcus hyicus*, *Enterobacter aerogenes*, *Enterococcus sp.*, *Enterococci group D sp.*, *Enterococcus faecalis*, *Enterobacter chloacae*, *Escherichia coli*, *Proteus vulgaris*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Neisseria catarrhalis*, *Neisseria elongata*, *Serratia marcescens*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Streptococcus hemolyticus*, *Streptococcus equi*, *Streptococcus suis*, *Taylorella equigenitalis*, *Diplococcus pneumoniae*, *Corynebacterium diphtheriae*, *Providencia rettgeri*, *Alcaligenes faecalis*, *Bordetella bronchiseptica*, *Mycoplasma synoviae*, *Mycoplasma gallisepticum*, *Pasteurella anatipestifer*, *Pasturella multocida*, *Rhodococcus equi*, *Brevibacterium ammoniagenes*, odor-causing bacteria, slime-forming bacteria, ammonia-producing bacteria.

#### Fungi:

*Trichophyton interdigitales*, *Trichophyton mentagrophytes*, *Trichophyton equinarum*, *Candida albicans*, *Microsporum canis*, *Microsporum gypseum*, *Aspergillus niger*, *Aspergillus fumigatus*, *Penicillium glaucum*, slime-forming fungi, mold and mildew.

#### Viruses:

Polio I virus, Rhinovirus, Feline Picornavirus, Avian Reovirus, Mouse Hepatitis virus, Vaccinia

- \* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.
- + See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.
- # Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

virus, Herpes simplex Type 1, Herpes simplex Type 2, Pseudorabies, avian infectious bronchitis, Avian Adenovirus, avian influenza, Avian Rotavirus, porcine transmissible gastroenteritis, Porcine Rotavirus, Influenza Type A/Mich, Influenza A<sub>2</sub>/England, Influenza A<sub>2</sub> (Japan, Asian, Hong Kong), Newcastle disease, mumps virus, HIV-1 (AIDS virus), Human Rhinovirus Type 38, Feline Leukemia virus, Rubella, equine arteritis, Avian Laryngotracheitis virus, Parainfluenza virus, Adenovirus Type 2, Canine Parvovirus, duck enteritis, Equine Herpes virus, Equine Rotavirus, Feline Calicivirus, Feline Rhinotracheitis.

#### **FORMULATION TYPES REGISTERED:**

TYPE: Technical grade active ingredient, Manufacturing use, End use.

FORM: Emulsifiable concentrate, Soluble concentrate/liquid, Liquid - ready to use, Pressurized liquid.

#### **METHODS AND RATES OF APPLICATION:**

##### TYPES OF TREATMENT:

Additive treatment, Animal feeding-watering equipment, Barrier treatment, Brush-on, Conveyor treatment, Disposal treatment, Equipment treatment, Flush treatment, Fog, Heat treatment, Immersion, Manual brush treatment, Mop, Pour-on, Indoor premise treatment, Premise treatment, Rinse, Scrub, Shampoo, Sprinkle, Soak, Sponge-on, Spray, Surface treatment, Indoor general surface treatment, Swab, Transportation vehicle treatment, Wash, Water related surface treatment, Wipe-on.

##### EQUIPMENT:

Aerosol can, Bowl mop, Brush, Cloth, Foaming apparatus, Mop, Pad, Mechanical scrubber, Scrubber, Shampoo machine, Sponge, Sprayer, Compact sprayer, Mechanical sprayer, Pump spray bottle, Swab, Tank, Washing machine.

TIMING: Final rinse, when needed.

##### RATE OF APPLICATION:

###### Indoor Non-food

Disinfectant for hard surfaces - 43 ppm to 2941 ppm active ingredient by volume, 97 ppm to 2657 ppm active ingredient by weight.

- \* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.
- + See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.
- # Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

Sanitizer for laundry - 233 ppm active ingredient by volume, 102 ppm to 278 ppm active ingredient by weight.

Residual bacteriostatic activity for odor-causing bacteria in laundry - 0.3 ppm active ingredient by weight.

Carpet sanitizer - 180 ppm to 1438 ppm active ingredient by volume.

Fungicide (mold/mildew) - 18,000 ppm active ingredient by weight.

#### Indoor Medical

Disinfectant for hard surfaces - 202 ppm to 3820 ppm active ingredient by volume, 97 ppm to 3713 ppm active ingredient by weight.

Diaper sanitizer - 102 ppm active ingredient by weight.

Carpet sanitizer - 523 ppm active ingredient by volume.

Sanitary disposal of human waste - 769 ppm active ingredient by volume.

#### Indoor Residential

Disinfectant for hard surfaces - 202 ppm to 2941 ppm active ingredient by volume, 97 ppm to 2657 ppm active ingredient by weight. [Toilet bowls and urinals (interior surfaces) 2.3 ppm to 26,000 ppm active ingredient by weight.]

Laundry sanitizer - 105 ppm to 209 ppm active ingredient by volume.

#### Aquatic Non-food Residential

Disinfectant for water-related hard surfaces - 769 ppm - 1409 ppm active ingredient by volume, 1400 ppm active ingredient by weight.

#### Terrestrial Non-food

Disinfectant for refuse/waste sites (outdoor) - 623 ppm active ingredient by volume.

- \* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.
- + See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.
- # Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.



**For ortho-benzyl-para-chlorophenol, potassium salt:**

**TYPE OF PESTICIDE:**

Bacteriostat, General disinfectant, Limited disinfectant, Medical disinfectant, Fungicide, Fungicide/fungistat, Microbiocide/microbiostat (slime-forming bacteria and algae), Sanitizer, Sanitizer (non-food use), Tuberculocide, Virucide.

**USE SITES:**

**INDOOR NON-FOOD:**

Agricultural/Farm Equipment/Shoe Baths

+ Agricultural/Farm Premises

+ Agricultural/Farm Structures/Buildings and Equipment

Animal Kennels/Sleeping Quarters

\* Animals (Laboratory/Research) (Commercial)

+ Barns/Barnyards/Auction Barns

\*+ Beef/Range/Feeder Cattle (Meat)

Commercial Transportation Facilities-Nonfeed/Nonfood

Commercial/Institutional/Industrial Premises/Equipment (Indoor)

\*+ Dairy Cattle (Lactating or Unspecified)

\*+ Dairy Cattle (Non-Lactating)

#Eating Establishments

#Eating Establishments Equipment/Utensils (Food Contact)

#Eating Establishments Food Handling Areas (Food Contact)

Eating Establishments Food Handling Areas (Nonfood Contact)

#Eating Establishments Food Serving Areas (Food Contact)

Eating Establishments Food Serving Areas (Nonfood Contact)

Egg Handling Equipment (Hatching)

Egg Handling Rooms (Hatching)

Egg Plants/Hatcheries/Brooder Rooms/Shoe Baths (Hatching)

#Food Marketing/Storage/Distribution Equipment/Utensils (Food Contact)

Greenhouse-Empty

\*+ Hog/Pig/Swine (Meat)

\*Horses (Show/Race/Special/Ponies)

Laundry (Commercial)

\*+ Livestock

#Meat Processing Plant Equipment (Food Contact)

#Meat Processing Plant Premises (Nonfood Contact)

\* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, or Transportation vehicle treatment.

+ See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.

# Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

Mushroom Houses-Empty Premises/Equipment

\*+ Poultry (Egg/Meat)

\*+ Poultry (Meat)

#Poultry Processing Plant Equipment (Food Contact)

#Poultry Processing Plant Premises (Nonfood Contact)

INDOOR MEDICAL:

Hospital Conductive Floors

Hospital Critical Items (Surgical Instruments/Pacemakers)

Hospital Janitorial Equipment

Hospital Noncritical Items (Bedpans/Furniture)

Hospital Semicritical Items (Catheters/Inhalation Equipment)

Hospital/Medical Institutions Non-Conductive Floors

Hospitals/Medical Institutions Critical Premises (Burn Wards)

Hospitals/Medical Institutions Noncritical Premises

Hospitals/Medical Institutions Patient Premises

Hospitals/Medical Institutions Premises (Human/Veterinary)

Laundry (Hospital)

Morgues/Mortuaries/Autopsy/Embalming Equipment

Morgues/Mortuaries/Autopsy/Embalming Room Premises

Vomit

INDOOR RESIDENTIAL:

Bathroom Premises/Hard Surfaces

Household/Domestic Dwellings Indoor Premises

Human Footwear

Refuse/Solid Waste Containers (Garbage Cans)

Toilet Bowls (Interior Surfaces)

Urinals (Interior Surfaces)

AQUATIC NON-FOOD INDUSTRIAL:

Commercial/Industrial Water Cooling Systems

Evaporative Condenser Water Systems

Industrial Processing Water

## AQUATIC NON-FOOD RESIDENTIAL:

### Swimming Pool Water Related Surface Treatment

#### PESTS:

##### Bacteria:

*Pseudomonas aeruginosa*, *Pseudomonas cichorii*, *Pseudomonas fluorescens* (Biotype G), *Pseudomonas fragi*, *Pseudomonas putida*, *Pseudomonas solanacearum*, *Escherichia coli*, *Erwinia caratovora*, *Erwinia chrysanthemi*, *Klebsiella pneumoniae*, *Mycobacterium tuberculosis* var. *bovis* BCG, *Salmonella choleraesuis*, *Salmonella enteritidis*, *Salmonella pullorum*, *Salmonella gallinarum*, *Salmonella schottmuelleri*, *Salmonella typhosa*, *Sarcina lutea*, *Aerobacter aerogenes*, *Serratia marcescens*, *Shigella dysenteriae*, *Shigella flexneri*, *Streptococcus pyogenes*, *Agrobacterium tumefaciens*, *Bordetella avium*, *Pasteurella multocida*, *Staphylococcus aureus*, *Mycoplasma synoviae*, *Mycoplasma gallisepticum*, *Xanthomonas pelargoni*, *Xanthomonas campestris*, slime-forming bacteria, odor-causing bacteria.

##### Fungi:

*Trichophyton mentagrophytes*, *Trichophyton interdigitale*, *Verticillium fungicola*, *Verticillium albo-atrum*, *Mycogone perniciosa*, *Tricoderma viride*, *Dactylium dendroides*, *Botrytis cinerea*, *Fusarium oxysporum*, *Phytophthora cinnamomi*, *Phthium ultimum*, *Rhizoctonia solani*, mold and mildew.

##### Algae:

Slime-forming algae.

##### Viruses:

HIV-1 (AIDS Virus), Avian Influenza virus, Avian Bronchitis virus, Avian laryngotracheitis virus, Influenza A2/Hong Kong, Herpes simplex Type 1, Herpes simplex Type 2, Vaccinia virus, Adenovirus Type 2, Adenovirus Type 3, Hog cholera virus.

\* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, and/or Transportation vehicle treatment.

+ See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.

# Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

**FORMULATION TYPES REGISTERED:**

TYPE: End use.

FORM: Granular, Wettable powder, Emulsifiable concentrate, Soluble concentrate/liquid.

**METHODS AND RATES OF APPLICATION:**

## TYPES OF TREATMENT:

Water treatment (recirculating system), Water related surface treatment, Wipe-on/wiper treatment, Shoe bath treatment, Surface treatment, Conveyor treatment, Equipment treatment, Premise treatment, Animal feeding/watering equipment, Equipment treatment, Transportation vehicle treatment, Contact and/or surface treatment, Fog, Sprinkle, Mop, Scrub, Sponge-on, Spray, Swab, Brush-on, Immersion, Soak, Wash.

## EQUIPMENT:

Mop, High pressure sprayer, Mechanical sprayer, Pressure sprayer, Hand held sprayer, Cloth, Automatic scrubber, Brush, Scrubber, Sponge, Sprayer, Sprinkler can, Fogger, Bath, Bowl mop, Fogger.

## TIMING:

Initial, Subsequent/maintenance, Not specified.

## RATE OF APPLICATION:

Indoor Non-Food

Disinfectant for hard surfaces - 224 to 1075 ppm active ingredient by volume, 15 to 1345 ppm active ingredient by weight.

Disinfectant for commercial laundry - 520 ppm active ingredient by weight.

Sanitizing fog for hatcheries and incubators - 340 to 4085 ppm active ingredient by weight.

\* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, and/or Transportation vehicle treatment.

+ See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.

# Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

Sanitizing fog for hatchery rooms - 14371 ppm active ingredient by weight.

Sanitizing fog for hard surfaces of livestock premises and equipment - 26767 ppm active ingredient by volume.

Shoebath sanitizer - 224 ppm active ingredient by volume, 269 ppm active ingredient by weight.

#### Indoor Medical

Disinfectant for hard surfaces - 310 to 813 ppm active ingredient by volume, 15 to 1345 ppm active ingredient by weight.

Disinfectant for hospital laundry - 989 ppm active ingredient by volume, 623 to 1031 ppm active ingredient by weight.

Bacteriostat for vomitus - 5760 ppm active ingredient by weight.

#### Indoor Residential

Disinfectant for hard surfaces - 310 to 1075 ppm active ingredient by volume, 15 to 1345 ppm active ingredient by weight.

Shoe sanitizer - 520 to 1031 ppm active ingredient by weight.

Disinfectant for toilet bowls - 1078 ppm active ingredient by volume, 4000 to 24000 ppm active ingredient by weight.

#### Aquatic Non-Food Industrial

Microbiocide/microbiostat - 13 to 53 ppm active ingredient by weight.

#### Aquatic Non-Food Residential

Disinfectant for water-related hard surfaces - 813 ppm active ingredient by volume.

\* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, and/or Transportation vehicle treatment.

+ See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.

# Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

**For ortho-benzyl-para-chlorophenol, sodium salt:**

**TYPE OF PESTICIDE:**

Medical disinfectant, General disinfectant, Fungicide/fungistat, Tuberculocide, Virucide, Sanitizer, Fungicide, Microbiocide/microbiostat (slime-forming bacteria, fungi and algae), Bacteriostat.

**USE SITES:**

**INDOOR NON-FOOD**

Agricultural/Farm Equipment/Shoe Baths

+ Agricultural/Farm Premises

Animal Kennels/Sleeping Quarters (Commercial)

\* Animals (Laboratory/Research)

\*+ Beef/Range/Feeder Cattle (Meat)

Carpets (Commercial Sanitizer)

Commercial/Institutional/Industrial Floors

Commercial/Institutional/Industrial Premises/Equip. (Indoor)

\*+ Dairy Cattle (Lactating or Unspecified)

\*+ Dairy Cattle (Non-Lactating)

#Eating Establishments

#Eating Establishments Equipment/Utensils (Food Contact)

#Eating Establishments Food Handling Areas (Food Contact)

#Eating Establishments Food Serving Areas (Food Contact) Egg Handling Equipment (Hatching)

Egg Handling Rooms (Hatching)

Egg Plants/Hatcheries/Brooder Rooms/Shoe Baths (Hatching)

#Feed Mills/Feed Processing Plants

#Food Processing Plant Equipment (Food Contact)

#Food Processing Plant Premises (Nonfood Contact)

Greenhouse-Empty

\*+ Hog/Pig/Swine (Meat)

\*Horses (Show/Race/Special/Ponies)

\*+ Livestock

#Meat Processing Plant Equipment (Food Contact)

\* Indicates Premise treatment, Animal feeding/watering equipment treatment, Equipment treatment, and/or Transportation vehicle treatment.

+ See Section V, "Actions for Registrants", for labeling requirements to permit classification of this site as a non-food use.

# Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants on food contact surfaces of food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment.

#Meat Processing Plant Premises (Nonfood Contact)  
Mushroom Houses-Empty Premises/Equipment  
\*+ Poultry (Egg/Meat)  
#Poultry Processing Plant Equipment (Food Contact)  
#Poultry Processing Plant Premises (Nonfood Contact)  
\*Specialized Animals  
Textiles/Textile Fibers/Cordage  
Upholstery (Hospital/Commercial)

#### INDOOR MEDICAL

Carpets (Hospital Sanitizer)  
Hospital Conductive Floors  
Hospital Critical Items (Surgical Instruments/Pacemakers)  
Hospital Noncritical Items (Bedpans/Furniture)  
Hospital/Medical Institutions Non-Conductive Floors  
Hospitals/Medical Institutions Critical Premises (Burn Wards)  
Hospitals/Medical Institutions Noncritical Premises  
Hospitals/Medical Institutions Patient Premises  
Hospitals/Medical Institutions Premises (Human/Veterinary)  
Household Sickrooms Premises/Contents/Utensils  
Laundry (Hospital)

#### INDOOR RESIDENTIAL

Bathroom Premises/Hard Surfaces  
Filters (Air/Air Conditioner/Furnace)/Air Ducts  
Household/Domestic Dwellings Contents  
Household/Domestic Dwellings Indoor Premises  
Refuse/Solid Waste Containers (Garbage Cans)  
Refuse/Solid Waste Sites (Indoor)  
Toilet Bowls (Interior Surfaces)  
Toilet Tanks/Water Closets Water  
Urinals (Interior Surfaces)

#### AQUATIC NON-FOOD INDUSTRIAL

Air Washer Water Systems  
Commercial/Industrial Water Cooling Systems

#### AQUATIC NON-FOOD RESIDENTIAL

Swimming Pool Water Related Surface Treatment

**PESTS:**

## Bacteria:

*Alcaligenes sp.*, *Diplococcus pneumoniae* Type 1, *Escherichia coli*, *Lactobacillus delbrueckii* subspecies *lactis*, *Neisseria catarrhalis*, *Proteus vulgaris*, *Pasteurella multocida*, *Salmonella schottmuelleri*, *Salmonella typhimurium*, *Serratia marcescens*, *Shigella flexneri*, *Shigella sonnei*, *Streptococcus hemolyticus*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Mycobacterium bovis*, *Pseudomonas fluorescens* (biotype B), *Pseudomonas solanacearum*, *Pseudomonas cichorii*, *Erwinia caratovora*, *Erwinia chrysantemi*, *Agrobacterium tumefaciens*, *Xanthomonas campestris*, *Mycobacterium tuberculosis*, *Aeromonas hydrophila*, *Bordetella avium*, *Corynebacterium sepeidonicum*, *Klebsiella pneumoniae*, *Mycoplasma gallisepticum*, *Pasteurella multocida*, *Salmonella enteritidis*, *Salmonella pullorum*, Gram positive and gram negative bacteria, Slime-forming bacteria.

## Fungi:

*Trichophyton mentagrophytes*, *Verticillium fungicola*, *Mycogone perniciosus*, *Trichoderma viride*, *Dactylium dendroides*, *Botrytis cinerea*, *Phytophthora cinnamomi*, *Phthium ultimum*, *Rhizoctonia solani*, *Verticillium albo-atrum*, Slime-forming fungi.

## Algae:

Slime-forming algae.

## Yeasts:

*Candida albicans*, *Saccharomyces cerevisiae*.

## Viruses:

Avian influenza Virus, Avian Bronchitis Virus, Avian Laryngotracheitis Virus, Avian Herpes Virus 2, Hog Cholera Virus, Pseudorabies Virus, Influenza A<sub>2</sub>, Herpes Simplex, Adenovirus Type 2, Vaccinia Virus, Adenovirus Type 5, HIV-1, Influenza A3/Hong Kong, Herpes Simplex Type 2, Adenovirus Type 4, Herpes simplex WI-38.

**FORMULATION TYPES REGISTERED:**

TYPE: End use

FORM: Emulsifiable concentrate, Soluble concentrate/liquid, Liquid-Ready to use



**METHODS AND RATES OF APPLICATION:****TYPES OF TREATMENT:**

Mop, Sponge-on, Spray, Wipe-on/wiper treatment, Animal feeding/watering equipment treatment, Equipment treatment, Premise treatment, Transportation vehicle treatment, Scrub, Surface treatment, Brush-on, Soak, Rinse, Swab, Water treatment, Wash, Shampoo, Water treatment (recirculating system), Indoor premise treatment, Shoe bath treatment, Immersion, Water related surface treatment, Padding treatment.

**EQUIPMENT:**

Mop, Sponge, Sprayer, Cloth, Pressure sprayer, Brush, Bowl mop, Rag, Mechanical sprayer, Carpet shampooer, Bath, By hand, Shampoo machine, Swab, Not specified.

**TIMING:**

Intermittent (slug) (initial), Intermittent (slug) (subsequent), Not specified.

**RATE OF APPLICATION:**Indoor Non-food

341 to 4220 ppm active ingredient by volume, 329 to 2254 ppm active ingredient by weight.

Textiles/textile fibers/cordage-300,000 ppm active ingredient by weight.

Indoor Medical

341 to 1274 ppm active ingredient by volume, 176 to 2254 ppm of active ingredient by weight.

Indoor Residential

341 to 4000 ppm active ingredient by volume, 176 to 2395 ppm active ingredient by weight.

Aquatic Non-food Industrial

50 to 99 ppm active ingredient by volume.

Aquatic Non-food Residential

Water related surface treatment-494 ppm active ingredient by weight.

**C. Estimated Usage of Pesticide**

There are no non-proprietary data available regarding the usage of ortho-benzyl-para-chlorophenol and its salts. Ortho-benzyl-para-chlorophenol and its salts account for a substantial share of household disinfectant products used in the mid-1980s.

#### **D. Data Requirements**

The Agency issued a Data Call-In Notice (DCI) in 1987 to registrants for Subchronic and Chronic Toxicological Data for Antimicrobial Active Ingredients. On June 10, 1991 a DCI Notice for ortho-benzyl-para-chlorophenol was issued under Phase IV of the reregistration program and required submission of additional product chemistry data. The DCI Notices for potassium 2-benzyl-4-para-chlorophenate and sodium 2-benzyl-4-chlorophenate were issued on August 25, 1994 under Phase IV of the reregistration program and required submission of additional product chemistry, environmental fate and toxicity data.

#### **E. Regulatory History**

The active ingredients ortho-benzyl-para-chlorophenol, and potassium and sodium 2-benzyl-4-chlorophenate salts were first registered in the United States in 1948 as disinfectants. They are currently registered as disinfectants, bacteriostats, sanitizers and microbiocides for commercial/industrial water cooling systems, swimming pool water related surfaces such as decks, and other hard surface areas surrounding swimming pools, food-preparation, storage and serving areas, nonfood areas such as restroom facilities, and medical/veterinary settings. Additionally, the salts are currently registered for use as tuberculocides, virucides and fungicides on agricultural farm premises, and in mushroom houses and hospital/medical institutions.

There are currently 143 products registered by the Environmental Protection Agency containing ortho-benzyl-para-chlorophenol active ingredients.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

##### CHEMICAL IDENTITY:

Chemical Name:	2-benzyl-4-chlorophenol
Classification:	Disinfectant
PPC #:	062201
Common Names:	Ortho-benzyl-para-chlorophenol/Chlorophen
Trade Name:	Preventol BP Technical
Company:	Bayer Inc. and NIPA Laboratories, Inc.
CAS Reg. No.:	120-32-1
Molecular Formula:	C <sub>13</sub> H <sub>11</sub> ClO
Molecular Weight:	218.7
Structural Formula:	
Nominal Concentration...	98.0%
Upper Certified Limit.	100.0%
Lower Certified Limit...	95.0%

##### PHYSICAL AND CHEMICAL CHARACTERISTICS:

Color:	White to light gray.
Physical State:	Solid
Odor :	Slightly phenolic
Melting Point:	49°C
Boiling Point:	175°C
Bulk Density:	30.5 lbs./ft <sup>3</sup>

Solubilities: Solvent grams solute/100

	<u>grams solvent</u>
Methyl ethyl ketone.	656
Ethyl alcohol.	644
Isopropyl alcohol	601
Ethylene glycol	422
Benzene	219
Carbon tetrachloride	92
Mineral oil	2.3
Water	0.007

Vapor Pressure: 0.1 mbar at 100°C

Dissociation Constant:  $pK = 10.8 \pm 0.2$  at 20°C,

Octanol/Water

Partition Coefficient:  $\text{Log } p = 4.3$  ;  $K_{ow} = 2 \times 10^4$

pH: 5.3 (in saturated aqueous solution)

Stability: Stable. Darkens with age. Non-corrosive to metals but complex reactions with transitional metals. Slow coloration under sunlight.

## B. Human Health Assessment

### 1. Toxicology Assessment

The toxicological data base for ortho-benzyl-para-chlorophenol follows the tiering pattern set forth for antimicrobials in the 1987 Data Call-In Notice for Subchronic and Chronic Toxicological Data for Antimicrobial Pesticide Active Ingredients. Due to concerns about the economic effects of imposing full toxicological data requirements (i.e., same as for a food use), the Agency uses a tiered approach in which Tier 1, and Tier 2 toxicity data alone, or in combination with exposure data, indicate the need for Tier 3 data. The available data will support reregistration eligibility. This document also serves as the decision on the need for not requiring Tier 3 data (chronic/carcinogenic study, reproductive study, and metabolism study).

**a. Acute Toxicity**

The requirement for a dermal sensitization study (GLN 81-6) was waived because of the corrosive nature of ortho-benzyl-para-chlorophenol. Of the five studies that were reviewed, only the acute inhalation study was classified as acceptable. Table 1 summarizes the results of the studies reviewed. (These data are Tier 1).

**Table 1: Acute Toxicity Studies**

STUDY	GLN/ MRID No.	RESULTS	CATEGORY
Acute Oral <sup>a</sup>	GLN 81-1/ 00131367	LD <sub>50</sub> males: 4462 mg/kg LD <sub>50</sub> females: 3852 mg/kg LD <sub>50</sub> combined: 4147 mg/kg	III
Acute Dermal <sup>a</sup>	GLN 81-2/ 00130937	LD <sub>50</sub> > 2000 mg/kg	III
Acute Inhalation	GLN 81-3/ 00130938	LC <sub>50</sub> males: 2.60 mg/L LC <sub>50</sub> females: 2.43 mg/L LC <sub>50</sub> combined: 2.50 mg/L	IV
Primary Eye Irritation <sup>a*</sup>	GLN 81-4/ 00131368	PIS score = 79 at 72 hours severely irritating	I
Primary Dermal Irritation <sup>a*</sup>	GLN 81-5/ 00131369	PDII = 1.0 at 72 hours slightly irritating	IV

<sup>a</sup> Each of these studies was classified as unacceptable, although the information available was sufficient to categorize the study. However, each study can be upgraded to acceptable upon receipt of the purity of the test material and the identity of the vehicle.

\* Data pertaining to acute eye irritation and dermal irritation are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

**b. Subchronic Toxicity**

Ortho-benzyl-para-chlorophenol was tested in subchronic gavage studies in both rats and mice (summarized in a single report). The animals were dosed 5 days/week for 13 weeks at the following dose levels: rats - 0 (control), 30, 60, 120, 240 or 480 mg/kg/day; mice- 0 (control), 500, 650, 800 or 1000 mg/kg/day.

In rats, the NOEL was set at 120 mg/kg/day. The LOEL was set at 240 mg/kg/day based on clinical signs of toxicity, changes in clinical chemistries, decreases in thymus weights, increases in kidney weights, chronic nephropathy and thymic lymphoid depletion.

In mice, a NOEL was not established because kidney lesions were present at the lowest dose tested (LDT), 500 mg/kg/day. The observed toxic effects included mortalities, clinical signs of toxicity, increases in liver weights, decreases in kidney weights, renal lesions (necrosis, casts, inflammation and regeneration of renal tubules) and necrosis of thymic lymphocytes.

Both studies were classified as core supplementary because only minimal summary data tables were provided to support the text of the report. The studies may be upgraded if the tables are provided with legends for clarification, and the individual animal data are provided. For the mouse study, neither clinical biochemistry studies nor urinalysis studies were conducted (GLN 82-1; MRID 40376301, 41248202, 41462401; this is Tier 2 data).

In a 21-day dermal study, ortho-benzyl-para-chlorophenol was tested on New Zealand rabbits at dose levels of 0 (control), 1, 5 or 25 mg/kg/day. The NOEL for systemic effects was set at 25 mg/kg/day, the highest dose tested (HDT). The NOEL for skin effects was set at 1 mg/kg/day, and the LOEL for skin effects was set at 5 mg/kg/day based on acanthosis, hyperkeratosis, parakeratosis, dermatitis, and scabs. There were some ulcerated areas in the 25 mg/kg/day dose group. (GLN 82-2; MRID 41248201; this is Tier 1 data).

### **c. Combined Chronic Toxicity and Carcinogenicity**

Technical ortho-benzyl-para-chlorophenol (97%) was tested in a two-year gavage study with corn oil as the vehicle in male and female F344/N rats at the following dose levels: 0 (control), 30, 60 or 120 mg/kg/day in males; 0 (control), 60, 120 or 240 mg/kg/day in females. Eighty rats/sex/dose level were used for the study from which 10/sex/dose were sacrificed at 3 months and 20/sex/dose were sacrificed at 15 months (10 of these were used for clinical chemistry only).

In males at dose levels of 30 mg/kg/day and higher, there were increases in urinary coproporphyrin (179-321 % of control, which increased with increasing dose); and increases in severity of nephropathy.

At dose levels of 60 mg/kg/day and higher, there were observed increases in urinary protein (251-285%), urinary alkaline phosphatase (185-225%), kidney weights (104-118%), hyperplasia of the parathyroid gland and fibrous osteodystrophy of the cranium and femur (although neither effect was considered to be statistically significant) in males. In females, there were increases in yellow staining of the urogenital area and decreases in urinary N-acetyl- $\beta$ -glucose amidase (32-59%, not dose-related) and galactosidase (9-42%, not dose-related) activities. The increase in hyperplasia of the parathyroid gland was attributed to renal secondary hyperparathyroidism and the slight increase in fibrous osteodystrophy of the cranium and femur were also ascribed to and

correlated with the increased severity of the nephropathy and the development of secondary hyperparathyroidism.

At dose levels of 120 mg/kg/day and higher, the following effects were observed in males: decreases in urinary N-acetyl- $\beta$ -glucose amidase (54-62%) and galactosidase (30-51%) activities, increased incidence of hyperplasia of the kidney tubule, and an increase in transitional cell hyperplasia of the kidney, which can occur in the renal pelvis epithelium as a component of severe nephropathy. In females there were increases in kidney weights (107-119%).

At 240 mg/kg/day (HDT), the following effects were observed in females: an increase in the number and severity of kidney nephropathy and an increase in transitional cell hyperplasia of the kidney (no statistics available).

The systemic NOEL could not be established because of the increased severity of kidney nephropathy in males at the lowest dose tested (30 mg/kg/day). There was also an increase in urinary coproporphyrin in males at this dose level. Therefore, the NOEL can be assumed to be less than 30 mg/kg/day. The LOEL was set at 30 mg/kg/day, the lowest dose tested.

Two transitional cell carcinomas of the kidneys were observed in females, one in the mid-dose group and one in the high dose group. These are considered to be rare tumors. None were observed in either the control group or in any of the males. None of these tumors were observed in any of 1,068 female historical controls.

Individual animal data were provided only for the neoplasms, making it difficult to verify the information provided in summary tables for the other parameters. Nevertheless, the study appeared to be adequately conducted and had been subjected to a number of peer reviews in connection with the National Toxicology Program (NTP). The study was classified as Core Supplementary for a chronic feeding study; however, this portion of the study is still acceptable for regulatory purposes. The study is classified as core minimum for the carcinogenicity portion of the study. (GLN 83-5 is considered to be satisfied, since the chronic study is considered acceptable for regulatory purposes. MRID 42279301; This is Tier 3 data which were not required by the Agency. This study was performed by NTP and submitted as 6(a)(2) data).

Technical ortho-benzyl-para-chlorophenol (97%) was tested in a two-year gavage study with corn oil as the vehicle in groups of 70 male and female B6C3F<sub>1</sub> mice at the following dose levels: 0 (control), 120 (low), 240 (mid), or 480 (high) mg/kg/day. Three and 15 month evaluations were included in the study design in which 10/sex/dose were sacrificed for evaluation. A systemic NOEL could not be set due to treatment-related effects at the lowest dose tested. There was a dose-related trend (an increase) in clinical findings. There was a statistically significant decreasing trend in survival for both sexes. However, a sufficient number of mice survived to termination to adequately determine the carcinogenic potential.

There appeared to be a definite effect on body weights at the high dose in both sexes (66% of the control value for males; and 70% of the control value for females by study termination). Dose-related decreases in either absolute and/or relative kidney weights were observed (62-90% of controls in males, 72-89% of controls in females) at all dose levels. These effects were more prevalent in males. Absolute and relative liver weights in females were increased at various times, most consistently at the highest dose level (7-20% over controls for absolute and 46-48% over controls for relative weights at 15 months and at termination). There were increases in the following treatment-related lesions at all dose levels in both sexes: incidence and severity of kidney nephropathy, hyperplasia and ulcer of the forestomach, mineralization of the glandular stomach mucosa and fibrous osteodystrophy. There were increases in the following at the mid- and high dose levels: myocardial degeneration and hyperplasia of the renal tubule in males, and ulcers of the small intestine in females. There were increases in the following at the high dose level: ulcers of the small intestines in males, and depletion of lymphoid and hematopoietic proliferation of the spleen as well as coagulative necrosis and inflammation in the liver in females.

Male mice had a significant dose-related increasing trend and significant pair-wise comparisons of all dose groups with the controls, for kidney renal tubule adenomas and/or adenocarcinomas combined. The incidences of these tumors in the study were above the historical control incidences for all dose levels (5%, 10% and 9% for the low, mid- and high dose groups, respectively, versus 0.4% in the male historical controls for adenoma or carcinoma). There was also a significant difference in the pair-wise comparison of the 120 mg/kg/day dose group with the controls for kidney renal tubule adenomas. The highest dose level in this study was considered to be excessive. (MRID 422793-02; this is Tier 3 data which were not required by the Agency. The study was performed by NTP and submitted as 6(a)(2) data).



#### **d. Developmental Toxicity**

In a rat developmental toxicity study, ortho-benzyl-para-chlorophenol was given to Sprague-Dawley rats at dose levels of 0 (control), 100, 300 or 900 mg/kg/day on days 6-15 of gestation. Statistically significant decreases in body weight were observed at all dose levels, decreases in mean food consumption were observed in the mid- and high dose groups and increased water intake was observed in the high dose group. Therefore, the maternal NOEL was considered to be less than 100 mg/kg/day, the lowest dose tested. No developmental effects were observed; therefore, the developmental NOEL was greater than 900 mg/kg/day. (MRID 00143775; this is Tier 1 data).

In the second rat developmental toxicity study, ortho-benzyl-para-chlorophenol was given by gavage to Wistar rats at dose levels of 0 (control), 15, 75 or 375 mg/kg/day on days 6 - 15 post coitum. At 375 mg/kg/day, 3 of the dams died. There was also decreased body weight gain (47%), and corrected body weight gain (40%) when compared to controls, as well as an increase in the number of animals with mucoid feces. The NOEL for maternal toxicity was set at 75 mg/kg/day. The LOEL was set at 375 mg/kg/day based on decreased body weight gain, mortality and the increase in mucoid feces. At 375 mg/kg/day, there was a decrease in mean fetal weight (94% of control). The NOEL for developmental toxicity was set at 75 mg/kg/day. The developmental LOEL was set at 375 mg/kg/day based on a decrease in mean fetal weight (MRID 00145836, 00161231; this is Tier 1 data).

In the rabbit study, ortho-benzyl-para-chlorophenol was tested in New Zealand White rabbits at the following dose levels: 0, 10, 30 or 100 mg/kg/day. (These levels were determined by a dose-finding study in which there was a 50% mortality rate in the 150 mg/kg/day dose group and a 100% mortality rate in the 200 and 300 mg/kg/day groups. Therefore, 100 mg/kg/day was considered to be an adequate dose.) No maternal toxicity was observed at any dose level. The maternal NOEL is therefore greater than 100 mg/kg/day, the HDT. An increase in post-implantation loss was observed in the high dose group when compared with controls, which was outside the range of the historical control data. However, the litter sizes were comparable between the control and the high dose group indicative of a minimal effect. The NOEL for developmental toxicity was set at 30 mg/kg/day and the LOEL was set at 100 mg/kg/day. (MRID 00143774, 40988201, 41003901; this is Tier 2 data).

**e. Reproductive Toxicity**

These Tier 3 data are not required based on the Agency's tiering approach for antimicrobials. A reproduction study is required if it is determined that "developmental toxicity and/or adverse effects on the reproductive organs were observed in the 90-day dermal or inhalation study". For ortho-benzyl-para-chlorophenol the available studies included three developmental toxicity studies, a 90-day subchronic feeding study and a 21-day dermal study. The 21-day dermal study showed dermal effects only. No systemic effects were observed. The 90 -day feeding study showed effects on the kidneys, thymus and liver. The developmental toxicity studies indicated possible developmental toxicity in the rabbit. There was a non-statistically significant increase in post-implantation loss in the high dose group when compared to controls. Although the NOEL for developmental toxicity was based on this observation, this is not considered to be an effect significant enough to request a reproduction study because the number of corpora lutea per doe, the number of implantation sites per dose and the litter size for all the treated groups, including the high dose group, were larger than the control group. In addition, there was no indication of any mutagenic effects for ortho-benzyl-para-chlorophenol under the conditions of the studies.

**f. Mutagenicity**

Ortho-benzyl-para-chlorophenol was tested for potential to induce reverse mutations in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100. The exogenous metabolic activation mixes were derived from either hamster or rat liver S9 homogenates (all strains were tested with each). The material was tested up to levels of cytotoxicity in all tested strains, ranging from 0.3 to 33 µg/plate without metabolic activation and from 1 to 100 µg/plate with metabolic activation. Ortho-benzyl-para-chlorophenol failed to induce a mutagenic response, either with or without metabolic activation (MRID 41287501; this is Tier 1 data).

Ortho-benzyl-para-chlorophenol was tested in an *in vivo* bone marrow micronucleus assay in mice at dosing levels up to and including 2000 mg/kg. The animals showed clear signs of toxicity, although there was only slight evidence that the test chemical reached the target organ. Ortho-benzyl-para-chlorophenol tested negatively under the conditions of the study (MRID 41572801; This is Tier 1 data).

Non-activated and S9-activated cultures of Chinese hamster ovary cells were exposed to ortho-benzyl-para-chlorophenol at concentrations of 0 (control), 4, 8, 15, 30 or 60 µg/ml (-S9), or 0 (control), 1.3, 2.5, 5, 10 or 20 µg/ml (+ S9). They were then examined for structural chromosome aberrations 20 hours after initiation of treatment. The highest dose tested (HDT) caused excessive toxicity (complete inhibition), but at no doses were there increased cytogenetic effects. (MRID 41287502; this is Tier 1 data).

There is a data gap for mutagenicity testing. Under the new mutagenicity guidelines, a mammalian cells in culture forward gene mutation assay (specifically a mouse lymphoma assay) is needed in order to completely satisfy the mutagenicity testing requirements (GLN 84).

**g. Metabolism**

These Tier 3 data are not required based on the Agency's tiering approach for antimicrobials. Metabolism studies are "required only if the Agency determines that additional information on the metabolism of the chemical is necessary to clarify unusual effects observed in chronic or reproduction studies or to clarify issues concerning structure activity relationships". For ortho-benzyl-para-chlorophenol, no issues were identified that warrant the need for metabolism data.

**h. Dermal Penetration**

A dermal absorption study on a 5% ortho-benzyl-para-chlorophenol formulation is available. This study has been classified as acceptable.

The absorption study indicates that ortho-benzyl-para-chlorophenol reacts in such a way that is typical of a chemical which destroys the integrity of the stratum corium of the skin (MRID 433134-01; this is Tier 2 data). Table 2 summarizes the results.

**Table 2: Dermal Absorption of ortho-benzyl-para-chlorophenol**

% Absorption of 5% Formulation From Several Dose Levels at Various Time Points			
DoseTime	5µg/cm <sup>2</sup>	50µg/cm <sup>2</sup>	500µg/cm <sup>2</sup>
1 hour	7.7%	6.19%	5.42%
4 hours	15.82%	14.69%	18.96%
10 hours	23.93%	26.31%	29.15%
168 hours <sup>a</sup>	26.10%	51.61%	41.45%

<sup>a</sup> Animals kept longer than 10 hours were washed at 10 hours.

The 168 hours, 50µg/cm<sup>2</sup> value was considered the most appropriate to use. Therefore, the dermal absorption is 51.6%.

### **i. Toxicological Endpoints of Concern Identified for Use in Risk Assessment**

There is no registered food use pattern for ortho-benzyl-para-chlorophenol. Should the use pattern change in the future, an RfD was determined to be 0.01 mg/kg/day by HED's RfD Peer Review Committee on March 23, 1995. This is based on the NOEL of less than 30 mg/kg/day from the chronic gavage/carcinogenicity study in the rat using a safety factor of 3000 (100 to account for interspecies extrapolation and intraspecies variability; 10 to account for the lack of a NOEL for rat study (using less than 30 mg/kg/day); and 3 to account for the lack of a reproduction study or a chronic dog study).

Ortho-benzyl-para-chlorophenol has not been reviewed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

The HED Carcinogenicity Peer Review Committee (CPRC) met on March 29, 1995 to discuss and evaluate the weight-of-the-evidence. The CPRC concluded that ortho-benzyl-para-chlorophenol should be classified as Group C, possible human carcinogen. This was based on increases in renal tubule combined adenomas/carcinomas in the male B6C3F1 mouse and in renal transitional cell carcinomas in the female F344/N rat. Renal tubular carcinomas in the mouse and renal transitional cell tumors in the rat are rare. The CPRC recommended the RfD approach for estimating risk.

The following endpoints were determined by HED's Less Than Lifetime Committee on 4/7/95:

An acute (1 day) dietary risk assessment is not required since there is no food use pattern for ortho-benzyl-para-chlorophenol.

A short term (1 - 7 days) occupational or residential risk assessment is not required since the results from the 21-day dermal study and the data from the other shorter term studies do not indicate a toxicological endpoint of concern which would suggest the need for a risk assessment for workers exposed dermally to formulations of the chemical. An intermediate term (1 week - several months) occupational or residential risk assessment is required based on a subchronic 90-day gavage study in rats (MRID 41248202). The NOEL was set at 120 mg/kg/day and the LOEL was set at 240 mg/kg/day based on clinical signs of toxicity, changes in clinical chemistries, decreases in thymus weights, increases in kidney weights, chronic nephropathy and thymic lymphoid depletion.

A chronic (longer than several months) occupational or residential risk assessment is required based on a chronic gavage study in rats (MRID 42279301). The NOEL was assumed to be less than 30 mg/kg/day. Therefore, a LOEL of 30 mg/kg/day (LTD) in the rat chronic feeding study will be used.

For the intermediate occupational or residential risk assessments, an MOE of 100 is generally considered acceptable when based on animal data.

However, for ortho-benzyl-para-chlorophenol an MOE of 300 shall be considered acceptable for chronic occupational or residential risk assessments due to the lack of a NOEL in the chronic rat gavage study.

The 10 fold factor (which is used when there are data gaps in setting the RfD) is not appropriate to include because there are no data gaps for ortho-benzyl-para-chlorophenol based on the tiering data pattern for antimicrobials. The 3 fold factor (which is used for lack of a NOEL in the RfD calculation) is appropriate to include.

The dermal absorption factor is 51.6%.

## **2. Exposure Assessment**

### **a. Dietary Exposure**

Dietary exposure is not expected from the currently registered use patterns of ortho-benzyl-para-chlorophenol and its salts. The U.S. Department of Agriculture and the EPA have determined that disinfectants always requiring a potable water rinse, when applied to

surfaces in federally inspected meat, poultry, and egg processing plants, do not present dietary exposure risks (USDA, FSIS publication #1419, "List of Proprietary Substances and Nonfood Compounds"). Labeling for these products, as well as for phenolic-based products used as disinfectants in food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment. Furthermore, phenolic based products recommended for use as disinfectants on food contact surfaces in eating establishments and homes are limited to sites such as counter tops, stoves, and refrigerators, which followed by a potable water rinse would allow their classification as non-food use. Application of these products as disinfectants on eating utensils, glassware, and similar items would be considered a food use and would require a tolerance or an exemption from the requirements of a tolerance prior to approval. Specific label directions are provided in Section V, "Actions Required of Registrants", to permit the classification of farm premise and poultry house disinfectants as non-food use products.

The Food and Drug Administration (FDA) and the EPA have agreed in a Memorandum of Understanding (MOU) dated 1972 (36 FR 24234) that FDA will have purview over pesticides used as food sanitizers on food-processing equipment and utensils, and on other food-contact articles and EPA will register the use pattern based on FDA's approval and acceptance (see 21 CFR Part 178.1010 (20)).

#### **b. Occupational and Residential**

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

Mixer/loader/applicator (M/L/A) exposure data for ortho-benzyl-para-chlorophenol were required by EPA as part of the reregistration process, since one toxicological criteria (i.e., 90-day oral toxicity study indicated chronic nephropathy and thymic lymphoid depletion) had been triggered. EPA has determined there are possible exposures to handlers during use practices associated with ortho-benzyl-para-chlorophenol. Specifically, EPA is concerned about exposures to mixers, loaders, and applicators at commercial and industrial sites and about exposure to homeowners who handle ortho-benzyl-para-chlorophenol-containing products.

The criteria for conducting an occupational/residential exposure assessment were met; therefore, an exposure/risk assessment was conducted using data obtained from CMA (Chemical Manufacturers Association).

### Occupational Exposure

Based on the use patterns and potential exposures, several major exposure scenarios were identified for ortho-benzyl-para-chlorophenol. These exposure scenarios are: (1) mixing and pouring a liquid which involved transferring the liquid from the original container to a smaller measuring and pouring container, (2) transferring (pumping) liquid products by metered or gravity flow, (3) use of a high pressure spray, (4) use of a low pressure spray (ungloved), (5) floor mopping (ungloved), (6) hand-wiping (ungloved) which often included the use of finger pump dispensers, (7) pouring powdered or flaked solid product from large shipping containers to smaller containers for measuring and pouring, and (8) fogging enclosed areas.

The exposure data submitted by CMA used for use-scenarios (1)-(7) in this assessment was obtained in response to an EPA Data Call-in. The CMA Antimicrobial Exposure Assessment (MRID 41412201, 41742601, 42587501) was designed to assess potential dermal and/or inhalation exposures to M/L/As. Various industrial, commercial, and consumer use sites and application methods were analyzed. However, fogging of enclosed areas was not considered in the CMA Study.

For use-scenarios (1)-(7) it was necessary to calculate the amount of active ingredient to which the M/L/A was exposed. Therefore, each scenario assumed the use of an existing product to create a reasonable worst-case exposure scenario. The dilution ratios/mixing ratios discussed in each scenario were taken from the product labels.

#### **Scenario 1: Mixing and Pouring a Soluble Liquid.**

The product assumed for this scenario was WRICO BGA with 23.5% active ingredient (EPA Reg. 1757-87). It was assumed that an operator treated an industrial recirculating water system. The initial dose was 25.6 fluid ounces of product per 1000 gallons of water. (The dose would be repeated until control was evident.) Assuming 20,000 gallons of water were treated per exposure, a total of 512 ounces (4 gallons) of product would be needed. Four gallons of product equals 8.85 pounds of active ingredient for this initial treatment (4 gallons x 0.235 (23.5%) x 9.42 lbs/gal = 8.85 lbs). It was assumed that the

treatment was performed 50 times per year (once a week less two weeks vacation) thus indicating an intermediate exposure scenario.

### **Scenario 2: Transferring (Pumping) Liquid Products**

The product assumed for this scenario is the same as that for Scenario 1. Therefore, the same assumptions were used.

### **Scenario 3: High Pressure Spray**

Exposure potential is considered to be high for this scenario due to dripping and generated spray. The product assumed for this scenario was MAGNA PHEN-100 which is 8.99% active ingredient. (This is the potassium salt of ortho-benzyl-para-chlorophenol; EPA Reg. 52779-15). One ounce of product was used per 3 gallons of water (1:400 dilution) for high pressure spray applications. If 50 gallons of diluted product were used per 1,000 square feet of surface area; then, 16.7 ounces of product were used per 50 gallons of water. Assuming a total of 10,000 square feet of a poultry house could be treated in a day, then a total of 167 ounces of product would be used in a day. The 167 ounces of formulated product equals 1.12 pounds of active ingredient handled. ( $167 \text{ oz}/128 \text{ oz per gallon} = 1.3 \text{ gallon of product needed}$ . The density is 9.6 lbs per gallon of product,  $1.3 \text{ gallons} \times 9.6 \text{ lbs/gal} \times 0.0899$  (8.99%) = 1.12 lb a.i. used.) It was assumed that the treatment was performed 50 times per year (once a week less two weeks vacation) thus indicating an intermediate exposure scenario.

### **Scenario 4: Low Pressure Spray (ungloved)**

The product assumed for this scenario was SANI-GLIDE with 1.4% active ingredient (EPA Reg. 1677-128). A 1% by volume (1 ¼ ounce to 1 gallon of water) dilution of product in water was sprayed through standard conveyor lubricant spray nozzles. If a total of 100 gallons of water were treated by adding 125 ounces of product, then 0.123 lbs a.i. are handled ( $125/128 \times 0.014$  (1.4%)  $\times 9 \text{ lbs/gal} = 0.123 \text{ lbs a.i. used}$ ). It was assumed that the treatment was performed 50 times per year (once a week less two weeks vacation) thus indicating an intermediate exposure scenario.

### **Scenario 5: Floor Mopping (ungloved)**

The product assumed for this scenario was Tek-Trol, a liquid concentrate with 10% active ingredient (EPA Reg. 11725-7). One-half ounce of product was used per gallon of water (1:256 dilution). Assuming an applicator used 10 gallons of diluted product, then a total of 5 ounces of product were used, which is 0.5 ounce of active ingredient. A total of 0.035 pounds a.i. ( $0.5 \text{ oz}/128 \text{ oz (gallon)} \times 9 \text{ lbs per gallon} = 0.035 \text{ lb a.i.}$ ) was used. It was assumed that mopping was



performed 250 times per year (each work day less two weeks vacation) thus indicating a chronic exposure scenario.

**Scenario 6: Hand-Wiping (ungloved)**

The product assumed for this scenario is the same as that for Scenario 5. Therefore, the same assumptions were used.

**Scenario 7: Pouring Powdered or Flaked Solid Product**

The product assumed for this scenario was TERGISYL with active ingredient 7.45%. This is the potassium salt of ortho-benzyl-parachlorophenol; (EPA Reg. 675-16). One ounce of powder in a pre-measured water soluble pouch was mixed with one gallon of water. Assuming 100 gallons of water were treated, then a total of 100 ounces (6.25 pounds) of product were used, which is (6.25 lbs x 0.0745) 0.47 lbs a.i. It was assumed that the treatment was performed 50 times per year (once a week less two weeks vacation) thus indicating an intermediate exposure scenario.

**Scenario 8: Fogging in Enclosed Areas**

The Agency does not have any exposure data for the fogging use-scenario. Fogging of enclosed areas was not considered in the CMA Study.

**Table 3A: Exposure Estimates for Ortho-Benzyl Para-Chlorphenol Intermediate Use Scenarios**

Scenario	Setting or Use	UE (ug/lb a.i.)	lb a.i./ use (each day)	Daily Exposure (ug/kg/day)	Adjusted DE (ug/kg/day)	Adjusted DE (mg/kg/day)
Mixing and Pouring a Liquid	Cooling Tower	10230	8.85	1293	667	0.667
Transferring (Pumping) Liquid Products	Cooling Tower	90	8.85	11	5.9	0.0059
High Pressure Spray	Disinfection	299680	1.12	4795	2474	2.474
Low Pressure Spray (ungloved)	Disinfection	190560	0.123	335	173	0.173
Pouring Powdered or Flaked Solid Product	Preservative	479	0.47	3	1.7	0.0017
Fogging in Enclosed Areas	Disinfection	No data	No data	No data	No data	No data

The Unit Exposure (UE) was derived from the CMA Study (Amended report, 1992). The UE is a combination of both dermal and inhalation exposure values. The dermal exposure component of the UE was derived from the sum of dermal deposition measurements that were taken at multiple body locations. Measurements that were less than the Level of Detection (non-detects) were included in the calculation at one-half of the LOD. However, attempts to measure the inhalation exposure component resulted in non-detectable values. Therefore, the inhalation exposure component was added to the dermal exposure component. The inhalation exposure component is considered to be very minimal in comparison to the dermal exposure for o-BCP.

In the CMA Study the clothing worn by workers was long sleeve shirts, long pants and gloves with the exception of the low pressure spray, wiping and mopping scenarios for which the workers did not wear gloves.

BW = Body Weight, which is 70 kg the default male value  
 DE (Daily Exposure, ug/kg/day) = (UE X lb ai/used) / BW  
 Adjusted DE = DE x the dermal exposure factor for ortho-benzyl-para-chlorophenol, which is 0.516

**Table 3B: Exposure Estimates for Ortho-Benzyl-Para-Chlorphenol Chronic Use Scenarios**

Scenario	Setting or Use	UE (ug/lb a.i.)	lb a.i./use (each day)	EF	BW (kg)	Daily Exposure (ug/kg/day)	ADD (ug/kg/day)	Adjusted ADD (ug/kg/day)	Adjusted ADD (mg/kg/day)
Floor Mopping (ungloved)	Disinfection	75280	0.035	250	70	38	26	13	0.013
Wiping (ungloved)	Disinfection	2922645	0.035	250	70	1461	1001	517	0.517

The Unit Exposure (UE) was derived from the CMA Study (Amended report, 1992). The UE is a combination of both dermal and inhalation exposure values. The dermal exposure component of the UE was derived from the sum of dermal deposition measurements that were taken at multiple body locations. Measurements that were less than the Level of Detection (non-detects) were included in the calculation at one-half of the LOD. However, attempts to measure the inhalation exposure component resulted in non-detectable values. Therefore, the inhalation exposure component was added to the dermal exposure component. The inhalation exposure component is considered to be minimal in comparison to the dermal exposure for o-BCP.

In the CMA Study the clothing worn by workers was long sleeve shirts, long pants and gloves with the exception of the low pressure

spray, wiping and mopping scenarios for which the workers did not wear gloves.

EF = Exposure Frequency, which is the number of exposures per year (For the purposes of this assessment, it was assumed that only one exposure occurs during any one day.)

BW = Body Weight, which is 70 kg the default male value

DE (Daily Exposure, ug/kg/day) = (UE X lb ai/used) / BW

ADD (Average Daily Dose, ug/kg/day) = ADE x EF / 365

Adjusted ADD = ADD x the dermal exposure factor for o-BCP, which is 0.516

### **Occupational Post-Application Exposure**

The Agency does not have the data necessary to estimate post application exposure to ortho-benzyl-para-chlorophenol by workers entering treated areas. However, the Agency, assumes that post application exposures, would be significantly less than that of handlers for use-scenarios (1),(2), (5), (6), and (7). The Agency also assumes that post-application exposures would be less than that of applicators for the high-pressure spray and low-pressure spray scenarios, provided entry into treated areas does not occur immediately following the application, i.e., until sprays have dried. However, the Agency has concerns about post-application dermal and inhalation exposures to ortho-benzyl-para-chlorophenol by workers entering enclosed areas following fogging applications.

### **Residential/Homeowner Exposure**

The two scenarios most applicable to the homeowner/residential scenario are: floor mopping (ungloved) and hand-wiping (ungloved). It was assumed that a homeowner would mop or wipe once or twice a week (52 or 104 times a year) which is less than the 250 times a year for an occupational handler. The diluted product that would be used by the homeowner would contain less of the active ingredient than the product used by an occupational handler. Additionally, a homeowner is likely to use less than ten gallons per day.

Therefore, the Agency assumes that exposures to homeowners who handle products containing ortho-benzyl-para-chlorophenol would be considerably less than the estimated exposures and would not, therefore, be significant.

The Agency assumes that post-application exposures for homeowners, such as walking on a mopped floor, would be even less than the above estimated/assumed exposures.

### 3. Risk Assessment

#### a. Dietary

Based on the current use patterns and exposure profiles for ortho-benzyl para-chlorophenol, residues in/on food and/or feed are not expected to occur. Therefore, a dietary risk characterization is not required.

#### b. Occupational and Residential

As previously stated, the toxicological endpoint of concern for an intermediate exposure is the NOEL from a subchronic/90 day gavage study, 120 mg/kg/day. The endpoint for a chronic exposure is the LOEL from a chronic gavage study, 30 mg/kg/day.

The Margin of Exposure (MOE) is a measure of how closely the estimated exposure comes to the NOEL. The MOE is calculated using the following formula:

$$MOE = \frac{NOEL}{EXPOSURE}$$

For calculating the intermediate MOE, the formula would be:

$$MOE = \frac{120 \text{ mg/kg/day}}{\text{Adjusted DE mg/kg/day}}$$

For calculating the chronic MOE, the formula would be:

$$MOE = \frac{30 \text{ mg/kg/day}}{\text{Adjusted ADD mg/kg/day}}$$

The MOEs calculated using the chronic formula can be considered to be slightly over-estimated since a LOEL is being used in the calculation. The NOEL, could not be determined, but would be less than 30 mg/kg/day, and therefore yielding slightly smaller MOEs. The risk could be considered as under-estimated; therefore for a chronic exposure an MOE of less than 300 could trigger a risk concern.

**Table 4: Occupational Margins of Exposure**

Scenario	Setting or Use	Intermediate MOE	Chronic MOE
Mixing and Pouring a liquid	Cooling Tower	180	N/A
Transferring (Pumping) Liquid Products	Cooling Tower	20,338	N/A
High Pressure Spray	Disinfection	48	N/A
Low Pressure Spray (ungloved)	Disinfection	694	N/A
Floor Mopping (ungloved)	Disinfection	N/A	2,255
Wiping (ungloved)	Disinfection	N/A	58
Wiping (gloved)	Disinfection	N/A	581
Pouring Powdered or Flaked Solid Product	Preservative	70,588	N/A
Fogging in Enclosed Areas	Disinfection	No data	No data

N/A - This is not the applicable scenario.

Of the chronic MOEs, hand-wiping (ungloved), is less than 300. The chronic MOE is considered to be the most appropriate estimate for the wiping and mopping scenarios since an exposure frequency of 250 was assumed. For the wiping scenario, gloves were not worn during the CMA Assessment Study. If chemical resistant gloves were to be worn while wiping, then the MOE (gloved) can be estimated as 581 assuming gloves provide a 90% protection factor.

All of these MOEs were calculated using the 70 kg default male value. If these MOE calculations were to be performed using the 60 kg default value for a female, then the MOEs would be slightly smaller. Since, all intermediate MOEs, except the high pressure spray, are greater than 100 and all chronic MOEs are greater than 300, then MOEs calculated using 60 kg should also exceed 100 for intermediate exposure (except the high pressure spray), and 300 for chronic exposure.

As previously stated all intermediate MOEs, except the high pressure spray, are greater than 100. The CMA Assessment Study indicated that some of the exposure data for the high pressure spray scenario was obtained from applicators that were wearing rainsuits. Therefore, protection factors cannot be applied to improve the MOE through the use of PPE. There are no engineering controls that are practicable.

However, the Agency believes that the MOE of 48 for the high pressure spray scenario can for the present be considered acceptable for the following reasons:

- (1) Use of the daily exposure value instead of an average daily dose could over-estimate exposure.
- (2) The Agency does not have an appropriately designed study which would yield a toxicological endpoint of concern that mimics a use-scenario which assumes product use of once a week for a year.
- (3) The toxicological effects that were demonstrated at the LOEL in the 90-day study cannot be considered severe.

Thus, the Agency will consider the high pressure spray scenario conditionally acceptable until new exposure data are available. New exposure data are needed because the current study references that "Some applicators wore rainsuits", thus indicating that the data were taken from both protected and unprotected applicators. Therefore, it is not possible to extract an accurate exposure level.

The CMA Study does not provide data for the fogging application scenario. Therefore, the Agency is requesting the registrant to provide applicator exposure data to confirm that application of this product in a fogging device does not pose unreasonable risks to workers, through dermal or inhalation exposures. In the interim, since the Agency is particularly concerned about inhalation and ocular exposures to applicators during fogging and other handlers who may enter the treated area before the fog has dissipated, full-face respiratory protection will be required for such situations.

### **Risk From Occupational Post-Application Exposures**

It was previously stated that occupational post-application exposure would be significantly less than that of handlers in many of the exposure scenarios, such as use-scenarios (1, (2), (5), (6), and (7)). The MOEs for occupational handlers are considered to be acceptable. Therefore, if the data were available to estimate the MOEs for post-application workers; these MOEs should be even higher, and therefore also acceptable.

The Agency also assumes that post application exposures would be significantly less than that of applicators for the high-pressure spray and low-pressure spray use-scenarios provided entry into treated areas does not occur immediately following the application, i.e., until sprays have dried. In these use-scenarios prolonged skin contact by entering workers with treated surfaces (such as walls, benches, and floors) is unlikely.

However, the Agency is concerned about post-application dermal and inhalation exposures to ortho-benzyl-para-chlorophenol by workers entering an enclosed area following fogging applications. To mitigate these risks, the Agency is requiring that the fog be completely dissipated and the enclosed area be thoroughly ventilated before entry (other than entry by trained and equipped handlers) is allowed.

### **Residential/Homeowner Risk**

As previously stated, the two scenarios most applicable to the homeowner/residential scenario are: floor mopping (ungloved) and hand-wiping (ungloved). Since EPA assumed that exposures to homeowners would be significantly less than the estimated exposures to occupational handlers, the MOEs for homeowner handlers should also be greater than 100 for these two exposure scenarios. Therefore, the Agency has determined that requiring homeowner users to wear chemical-resistant gloves while wiping surfaces by hand with ortho-benzyl-para-chlorophenol is not warranted. No active-ingredient based personal protective equipment will be required for end-use products primarily intended for homeowner use.

Since EPA assumes that post-application exposures to homeowners would be significantly less than the estimated exposures to occupational handlers or post-application workers, EPA estimates that homeowner post-application exposures to ortho-benzyl-para-chlorophenol would be acceptable without restrictions.

## **C. Environmental Assessment**

### **1. Ecological Toxicity Data**

The Agency has adequate data to assess the toxicity of the acid (ortho-benzyl-para-chlorophenol) to nontarget organisms. No toxicity data exist for either the potassium or sodium salts. The requirements for testing the inorganic salts are waived because environmental fate data indicate that the two salts rapidly degrade into the acid in the environment.

#### **a. Toxicity to Terrestrial Animals**

##### **(1) Birds, Acute and Subacute**

To establish the toxicity of a microbiocide to birds, the following tests are required using technical-grade material: an avian single-dose oral study (LD<sub>50</sub>) on one species, preferably

mallard or bobwhite quail; and one subacute dietary study (LC<sub>50</sub>). One study should use one species of waterfowl, preferably the mallard duck, and the other study should use one species of upland gamebird, preferably bobwhite quail. The registrant conducted these studies, required for the acid and both salts, only on the acid. The following tables present these study results.

Avian Acute Oral Toxicity Findings					
Species	% A.I.	LD <sub>50</sub> (mg/kg)	Accession No. (Author/Year)	Toxicity Category	Fulfills Guideline Requirement*
Northern Bobwhite Quail	95 (acid)	> 2510	252126 (Beavers 1983)	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

Avian Subacute Dietary Toxicity Findings					
Species	% A.I.	LC <sub>50</sub> (ppm)	Accession No. (Author/Year)	Toxicity Category	Fulfills Guideline Requirement*
Northern Bobwhite Quail	95 (acid)	> 5620	252303 (Beavers 1984)	practically nontoxic	Y
Mallard Duck	95 (acid)	> 5620	252304 (Beavers 1984)	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

These results suggest that ortho-benzyl-para-chlorophenol is practically nontoxic to avian species on an acute oral and subacute dietary basis. Because the environmental fate data indicate that the two salts rapidly degrade into the acid in the environment, the guideline requirements for avian testing with the inorganic salts are waived. Therefore, the guideline requirements are fulfilled.

**(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 ortho-benzyl-para-chlorophenol and its potassium and sodium salts. Avian reproduction testing is not required.



**(3) Mammals**

Wild mammal testing is required on a case-by-case basis, depending on several factors: results of the lower tier studies, such as acute and subacute testing; the intended use pattern; and pertinent environmental fate characteristics. In most cases, however, an acute oral LD<sub>50</sub> study is used to determine toxicity to mammals. For ortho-benzyl-para-chlorophenol and its potassium and sodium salts, no acute mammal data are available.

**(4) Insects**

A honey bee acute contact LD<sub>50</sub> study is required if the proposed use will result in honey bee exposure. Because applications of ortho-benzyl-para-chlorophenol and its potassium and sodium salts are not likely to result in exposure to honey bees, data are not required.

**b. Toxicity to Aquatic Animals**

**(1) Freshwater Fish**

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 are required for the acid and both inorganic salts.

Freshwater Fish Acute Toxicity Findings					
Species	% A.I.	LC <sub>50</sub> (ppm)	Accession No. (Author/Year)	Toxicity Category	Fulfills guideline requirement*
Rainbow trout	95 (acid)	0.72	251889 (Anonymous 1983)	highly toxic	Y
Bluegill sunfish	95 (acid)	0.33	251889 (Anonymous 1983)	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

The results of the 96-hour acute toxicity studies, using the acid as the test material, indicate that ortho-benzyl-para-

chlorophenol is highly toxic to cold- and warm-water fish. The requirements for testing the inorganic salts are waived because environmental fate data indicate that the two salts rapidly degrade into the acid in the environment.

**(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 are required for the acid and both inorganic salts. The table below shows the results of these tests.

Freshwater Invertebrate Toxicity Findings					
Species	% A.I.	EC <sub>50</sub> (ppm)	Accession No. (Author/Year)	Toxicity Category	Fulfills guideline requirement*
<i>Daphnia magna</i>	95 (acid)	0.59	251889 (Anonymous 1983)	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 are sufficient information to characterize the acid as highly toxic to aquatic invertebrates. The guideline requirement for testing the acid is fulfilled. The requirements for testing the inorganic salts are waived because environmental fate data indicate that the two salts rapidly degrade into the acid in the environment.

**(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 the products, exposure of ortho-benzyl-para-chlorophenol and its potassium and sodium salts to marine/ estuarine organisms is not expected. Therefore, data are not required.

**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 ortho-benzyl-para-chlorophenol and its potassium and sodium salts. Phytotoxicity tests are not required.

**2. Environmental Fate**

**a. Environmental Fate Assessment**

The environmental fate data base for ortho-benzyl-para-chlorophenol is adequate for reregistration. The environmental fate assessment for ortho-benzyl-para-chlorophenol applies to both the potassium (potassium 2-benzyl-4-chlorophenate) and sodium (sodium 2-benzyl-4-chlorophenate) salt because the salts can be expected to rapidly degrade to the acid (ortho-benzyl-para-chlorophenol) in the environment.

The registered uses of ortho-benzyl-para-chlorophenol should not result in significant exposure to the environment. Ortho-benzyl-para-chlorophenol is not expected to hydrolyze under environmental conditions and existing data indicate that microbial degradation is likely the predominant route of degradation.

**b. Environmental Chemistry, Fate, and Transport**

Phenolic compounds make up a major group of antimicrobial chemical agents. These compounds are thought to act primarily by denaturing cell proteins and damaging cell membranes. The antimicrobial activity of phenolics is reduced at an alkaline pH and by organic material. Low temperatures and the presence of soap also reduce antimicrobial activity.

Ortho-benzyl-para-chlorophenol has a melting point of 45°C and a vapor pressure of < 1 torr at 139°C. It has a solubility of 70 ppm in water and  $6 \times 10^6$  ppm in isopropanol. The octanol/water partition coefficient ( $\log K_{ow}$ ) was estimated by the registrant to be 4.4 using the method of Hansch and Leo, 1979.

Ortho-benzyl-para-chlorophenol is not expected to hydrolyze under environmental conditions and existing data indicate that microbial degradation is likely the predominant route of degradation. Therefore hydrolysis data are not required for this chemical. The potassium (potassium 2-benzyl-4-chlorophenate) and sodium (sodium 2-benzyl-4-chlorophenate) salts are expected to rapidly degrade to the acid (ortho-benzyl-para-chlorophenol) in the environment.

The biodegradation of ortho-benzyl-para-chlorophenol was reported by Monsanto Industrial Chemicals Co. in its Technical Bulletin No. IC/DP-502 for SANTOPHEN 1 (MRID #: 00130936). They examined the biodegradation in systems closely approximating those which would be encountered by the product in nature, such as river water, sewage and activated sludge. These systems would be the primary route for disposal of liquid disinfectant compounds. The results of the study indicated that ortho-benzyl-para-chlorophenol is readily biodegraded in river water, sewage and activated sludge.

SYSTEM	Ortho-Benzyl-para-Chlorophenol	100% DEGRADATION
River Water	0.1 mg/L	6 days
Sewage	0.5 mg/L	1 day
	1.0 mg/L	1 day
Activated Sludge	1.0 mg/L	8 hours (80%)
	1.0 mg/L	1 day

### 3. Exposure and Risk Characterization

#### a. Ecological Exposure and Risk Characterization

##### (1) Exposure and Risk to Nontarget Organisms

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. The chemical, ortho-benzyl-para-chlorophenol, is nontoxic to birds and highly toxic to freshwater fish and aquatic invertebrates.

The swimming pool water related surface use of ortho-benzyl-para-chlorophenol may result in minimal to no exposure based upon the infrequent draining of the pools.

While the hazard to aquatic organisms from 2-benzyl 4-chlorophenol has been characterized, a quantitative risk assessment has not been conducted. The Office of Pesticide Programs has established a policy that risks to aquatic

environments are best characterized and regulated under the NPDES permitting program of the Office of Water. The Agency currently requires that labels for all ortho-benzyl-para-chlorophenol products require that discharges to aquatic environments comply with a NPDES permit.

Because terrestrial use of ortho-benzyl-para-chlorophenol and its potassium and sodium salts is limited to refuse/solid waste sites, exposure to wildlife is not expected to be significant.

In addition, the environmental fate data indicate that the two salts rapidly degrade into the acid in the environment. Therefore, the data supporting the acid also can be used to support the potassium and sodium salts.

## **(2) Endangered Species**

Based on the registered use patterns for 2-benzyl-4-chlorophenol and the inorganic salts, risks to endangered species are not anticipated.

# **IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

## **A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing ortho-benzyl-para-chlorophenol active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing ortho-benzyl-para-chlorophenol. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of ortho-benzyl-para-chlorophenol, potassium-2-benzyl-4-chlorophenolate and sodium-2-benzyl-4-chlorophenolate list 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 ortho-benzyl-para-chlorophenol and salts to determine that ortho-benzyl-para-chlorophenol and salts can be used without resulting in unreasonable adverse effects to humans and the environment. Therefore, the Agency concludes that all products containing ortho-benzyl-para-chlorophenol and the active ingredients, for

all uses are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of ortho-benzyl-para-chlorophenol potassium 2-benzyl-4-chlorophenate and sodium-2-benzyl-4-chlorophenate are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing ortho-benzyl-para-chlorophenol and salts, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

## **B. Determination of Eligibility Decision**

### **1. Eligibility Decision**

Based on the reviews of the generic data for the active ingredient of ortho-benzyl-para-chlorophenol and its salts, the Agency has sufficient information on the health effects of ortho-benzyl-para-chlorophenol and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that products containing ortho-benzyl-para-chlorophenol and its salts labeled and used as specified in this Reregistration Eligibility Decision, except the enclosed area fogging application will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that all the uses of products containing ortho-benzyl-para-chlorophenol, potassium -2-benzyl-4-chlorophenate and sodium 2-benzyl-4-chlorophenate are eligible for reregistration. The Agency is requiring handler exposure data on the fogging application and cannot make an eligibility decision on this method until these data are generated.

### **2. Eligible and Ineligible Uses**

The Agency has determined that all uses of products containing ortho-benzyl-para-chlorophenol, potassium -2-benzyl-4-chlorophenate, and sodium-2-benzyl-4-chlorophenate are eligible for reregistration. The Agency is requiring handler exposure data on the fogging application and cannot make an eligibility decision on this method until these data are generated.

## **C. Regulatory Position**

The following is a summary of the regulatory positions and rationales for ortho-benzyl-para-chlorophenol, potassium-2-benzyl-4-chlorophenate and sodium-2-benzyl-4-

chlorophenate. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

## **1. Labeling Rationale**

### **a. Occupational and Residential Labeling Rationale/Risk Mitigation**

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

1. If the Agency has no special concerns about 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 EPA guidelines.
2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):
  - In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE 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.

**b. Personal Protective Equipment/Engineering Controls for Handlers**

**(1) Occupational-Use Products**

The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for ortho-benzyl-para-chlorophenol. Many of the CMA exposure studies used as data in this risk assessment were conducted with the handlers wearing chemical-resistant gloves. Therefore, chemical-resistant gloves are required for occupational handlers of ortho-benzyl para-chlorophenol in the following use-scenarios: Scenario (1) mixing and pouring a liquid, Scenario (2) transferring (meter-pumping) liquid, and Scenario (7) pouring powdered or flaked solid product formulations. Since the MOE for chronic exposures from ungloved hand-wiping applications (Scenario 6) was less than 300, chemical-resistant gloves are required to reduce/mitigate the potential risk to those applicators. Finally, inhalation and ocular protection is required for persons exposed to the fog during or immediately following applications (Scenario 8).

At this time, EPA is not establishing active-ingredient-based minimum (baseline) PPE for occupational handlers for the following scenarios: (Scenario 4) low-pressure spray and (Scenario 5) mopping applications. The estimated exposures to and resulting risks from ortho-benzyl-para-chlorophenol in these occupational use-scenarios do not warrant establishing such PPE requirements.

The MOE from intermediate-term exposures during high-pressure spray applications (Scenario 3) could not be mitigated with additional personal protective equipment or engineering controls. However, as previously discussed, the Agency will consider the high pressure spray scenario conditionally acceptable until new exposure data are available.

**(2) Homeowner-Use Products**

EPA is not establishing active-ingredient-based minimum (baseline) PPE for homeowner handlers at this time. The assumed exposures to ortho-benzyl-para-chlorophenol in the use-



scenarios appropriate for a residential setting do not warrant establishing such PPE requirements.

**c. Post-Application/Entry Restrictions**

**(1) Occupational-Use Products**

Since the Agency has concerns about post-application exposures to persons after some occupational uses of ortho-benzyl-para-chlorophenol, it is establishing entry restrictions for those occupational uses. For specific requirements, refer to Section V of this document.

**(2) Homeowner-Use Products**

EPA is not establishing entry restrictions at this time for homeowner uses of ortho-benzyl-para-chlorophenol end-use products, because of minimal exposure concerns.

**d. 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 ortho-benzyl-para-chlorophenol. 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 o-benzyl-p-chlorophenol for the above eligible uses has been reviewed and determined to be substantially complete for reregistration. The following data are required for the salts and are considered confirmatory:

- 61-1 Product Identity and Disclosure of Ingredients
- 61-2 Description of Beginning Materials and the Manufacturing Process
- 61-3 Discussion of the Formation of Impurities
- 62-1 Preliminary Analysis

- 62-2 Certification of Ingredient Limits
- 62-3 Analytical Methods to Verify Certified Limits
- 63-2 Color
- 63-3 Physical State
- 63-4 Odor
- 63-5 Melting Point
- 63-6 Boiling Point
- 63-7 Density
- 63-8 Solubility
- 63-9 Vapor Pressure
- 63-10 Dissociation Constant
- 63-11 Octanol/Water Partition Coefficient
- 63-12 pH
- 63-13 Stability

The product chemistry data are adequate to support reregistration, however the following confirmatory data are required on the potassium and sodium salts of ortho-benzyl-para-chlorophenol because it is expected that the chemical properties are very much like the parent material. An individual CSF is required for each product.

Information to upgrade the acute oral, acute dermal, primary eye irritation, and primary dermal irritation studies ( guidelines 81-1, 81-2, 81-4, and 81-5) to acceptable.

The following study is required to satisfy guideline 84:  
84-2(b) Mammalian cells in culture forward gene mutation assay (specifically a mouse lymphoma assay).

### **Additional Occupational/Residential Exposure Studies**

#### **Handler Studies**

All registrants must submit additional handler exposure studies. Requirements for such studies are addressed in subdivision U of the Pesticide Assessment Guidelines.

The required studies are necessary to provide data on handlers during fogging in enclosed areas. They are:

- a dermal exposure study (Guideline 231), and
- an inhalation exposure study (Guideline 232)

These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same handler and at the same site during each trial.

The required confirmatory studies for reregistration are necessary to provide data on handlers during high-pressure spray applications in enclosed areas. They are:

- a dermal exposure study (Guideline 231), and

- an inhalation exposure study (Guideline 232)

These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same handler and at the same site during each trial. Note: This requirement is waived if the registrant reduces the application rate to a level where the MOE for this exposure/risk scenario is greater than 100.

## **2. Labeling Requirements for Manufacturing-Use Products**

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

"Only for formulation into an [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)."

## **B. End-Use Products**

### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility

has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

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

## **2. Labeling Requirements for End-Use Products**

### **Worker Protection Standard**

None of the uses of ortho-benzyl-para-chlorophenol are within the scope of the Agricultural Worker Protection Standard (40 CFR part 170).

### **PPE/Engineering Control Requirements for Pesticide Handlers**

For **sole-active-ingredient** end-use products that contain ortho-benzyl-para-chlorophenol, 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 ortho-benzyl-para-chlorophenol, 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.

#### **a. Products Intended Primarily for Occupational Use**

##### **Minimum (Baseline) PPE/Engineering Control Requirements**

EPA is establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for ortho-benzyl-para-chlorophenol end-use products that are intended primarily for occupational use for the following use-scenarios: (1) mixing and pouring soluble liquids, (2) transferring (pumping) liquids, (6) hand-wiping, (7) pouring powdered or flaked formulations, and (8) applying fogs to enclosed areas. The minimum (baseline) PPE for such occupational uses of ortho-benzyl-para-chlorophenol end-use products are:

"Applicators and other handlers must wear:

- long-sleeve shirt and long pants,
- socks plus shoes, and
- chemical-resistant gloves\*.

"In addition, for applicators and other handlers exposed to the fog during fogging applications and until the fog has dissipated and the enclosed area has been thoroughly ventilated must wear:

- a full-face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)"

\*For the glove statement, use the statement established for ortho-benzyl-para-chlorophenol through the instructions in Supplement Three of PR Notice 93-7.

EPA is not establishing active-ingredient-based minimum (baseline) PPE for occupational handlers in the following use-scenarios: (4) low-pressure spray, and (5) mopping (ungloved).

### **Determining PPE Requirements for End-use Product Labels**

The PPE, if any, that would be established on the basis of the acute toxicity category of each 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: if the eye irritation potential of an end-use product is classified as toxicity category I or II, protective eyewear is required on the labeling for all handlers of that product.)

### **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.

#### **b. Products Intended Primarily for Homeowner Use**

##### **Minimum (Baseline) PPE Requirements**

EPA is not establishing active-ingredient-based minimum (baseline) PPE for homeowner handlers.

## Determining PPE Requirements for End-use Product Labels

The PPE, if any, that would be established on the basis of the acute toxicity category of each 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.

### Placement in Labeling

The personal protective equipment requirements, if any, 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.

### Entry Restrictions

For **sole-active-ingredient** end-use products that contain ortho-benzyl-para-chlorophenol, the product labeling must be revised to adopt the entry restrictions set forth below. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain ortho-benzyl-para-chlorophenol 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. Products Intended Primarily for Occupational Use

##### Entry restrictions:

For spray applications:

"Following application as a low-pressure or high-pressure spray, do not enter or allow others to enter the treated area until sprays have dried."

For fog applications:

"Thoroughly ventilate entire enclosed area following application. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and the fog has completely dissipated, all

persons must wear the personal protective equipment, including a full-face respirator, required in the precautionary statements section of this labeling for applicators and other handlers."

**d. Other Labeling Requirements**

**Products Intended Primarily for Occupational Use**

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

**Application Restrictions**

For all spray applications:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

For pour, pump, mop, and wipe applications:

"Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application."

"The type of food contact surface recommended for disinfection must be identified, e.g., counter tops, stoves, and refrigerators".

**User Safety Requirements**

{Registrants, add this requirement if the end-use product labeling contains PPE requirements other than long-sleeve shirt, long pants, socks, and shoes.}

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

**User Safety Recommendations**

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

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

{Registrants, add this recommendation if the end-use product labeling contains PPE requirements other than long-sleeve shirt, long pants, socks, and shoes.}

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

The following label directions are required for farm premises to permit their classification as non-food use products:

1. "Do not use in milking stalls, milking parlors, or milk houses" (for phenolics, cresylic acid, and pine oils recommended for livestock premises).
2. "Remove all animals, poultry, and feed from premises, vehicles, and enclosures."
3. "Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals or poultry."
4. "Empty all troughs, racks, and other feeding and watering appliances."
5. "Thoroughly clean all surfaces with soap or detergent and rinse with water."
6. "Saturate all surfaces with the recommended solution for a period of 10 minutes."
7. "Immerse all halters, ropes, and other types of equipment used in handling and restraining animals or poultry, as well as the cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solution."
8. "Ventilate buildings, cars, boats, and other closed spaces in which the product has been used. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried."



9. "Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse."

The following label directions are required for farm premises/poultry house disinfectants to permit their classification as non-food use products:

1. "Do not use in milking stalls, milking parlors, or milk houses" (for phenolics, cresylic acid, and pine oils recommended for livestock premises).
2. "Remove all animals, poultry, and feed from premises, vehicles, and enclosures."
3. "Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals or poultry."
4. "Empty all troughs, racks, and other feeding and watering appliances."
5. "Thoroughly clean all surfaces with soap or detergent and rinse with water."
6. "Saturate all surfaces with the recommended solution for a period of 10 minutes."
7. "Immerse all halters, ropes, and other types of equipment used in handling and restraining animals or poultry, as well as the cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solution."
8. "Ventilate buildings, cars, boats, and other closed spaces in which the product has been used. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried."
9. "Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse."

The following label directions are required for poultry house disinfectants to permit their classification as non-food use products:

1. "Remove all poultry and feed from premises, vehicles, and enclosures."
2. "Remove all litter and manure from floors, walls, and surfaces of facilities occupied or traversed by animals or poultry."
3. "Empty all troughs, racks, and other feeding and watering appliances."
4. "Thoroughly clean all surfaces with soap or detergent and rinse with water."
5. "Saturate all surfaces with the recommended solution for a period of 10 minutes."
6. "Immerse all types of equipment used in handling and restraining poultry, as well as the cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solution."
7. "Ventilate buildings, cars, boats, and other closed spaces in which the product has been used. Do not house poultry or employ equipment until treatment has been absorbed, set or dried."
8. "Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse."

### **Products Intended Primarily for Home Use**

#### **Application Restrictions**

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

#### **User Safety Recommendations**

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

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

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

### **Effluent Discharge Labeling Statements**

Refer to subsection A. above for labeling requirements for effluent discharge.

### **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 ortho-benzyl-p-chlorophenol products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

## **VI. APPENDICES**

**Appendix A (Table of Use Patterns Subject to Reregistration) is 631 pages in length. The Agency has not included this section as part of the published version of the RED document. The entire appendix A is available as outlined in Appendix E.**

## GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Ortho-Benzyl-P-Chlorophenol covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Ortho-Benzyl-P-Chlorophenol 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 ortho-benzyl-para-chlorophenol

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY</b>		
61-1	Chemical Identity	All 43019301, 40937402, 41728001
61-2A	Start. Mat. & Mnfg. Process	All 40937402, 41728001
61-2B	Formation of Impurities	All 40937402, 41728001
62-1	Preliminary Analysis	All 43019301, 41728001
62-2	Certification of limits	All 43019301, 41728001
62-3	Analytical Method	All 43019301, 41728001
63-2	Color	All 43019301, 40937402
63-3	Physical State	All 41728001
63-4	Odor	All 43019301, 4093742, 41728001
63-5	Melting Point	All 43019301, 40937402, 41728001
63-6	Boiling Point	All 43019301, 40937402, 41728001
63-7	Density	All 43019301, 42082901, 40937402, 41728001
63-8	Solubility	All 43019301, 42082901, 41728001
63-9	Vapor Pressure	All 43019301, 42082901, 41728900
63-10	Dissociation Constant	All 43019301, 41728001
63-11	Octanol/Water Partition	All 43019301, 41728001
63-12	pH	All 43019301, 41728001
63-13	Stability	All 40937402, 42082901, 41728001
63-15	Flammability	All 43019301



## Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol

REQUIREMENT	USE PATTERN	CITATION(S)
<b>63-16</b>	<b>Explodability</b>	43019301
<b>63-17</b>	<b>Storage stability</b>	43019301
<b>63-18</b>	<b>Viscosity</b>	43019301
<b>63-19</b>	<b>Miscibility</b>	43019301
<b>63-20</b>	<b>Corrosion characteristics</b>	43019301
<b><u>ECOLOGICAL EFFECTS</u></b>		
<b>71-1A</b>	<b>Acute Avian Oral - Quail/Duck</b>	138112
<b>71-2A</b>	<b>Avian Dietary - Quail</b>	138112,138887,138888
<b>71-2B</b>	<b>Avian Dietary - Duck</b>	138112, 138888
<b>71-4B</b>	<b>Avian Reproduction - Duck</b>	138112
<b>71-5B</b>	<b>Actual Field Study</b>	138112
<b>72-1B</b>	<b>Fish Toxicity Bluegill - TEP</b>	138112
<b>81-1</b>	<b>Acute Oral Toxicity - Rat</b>	131367
<b>81-2</b>	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	130937
<b>81-3</b>	<b>Acute Inhalation Toxicity - Rat</b>	130938
<b>81-4</b>	<b>Primary Eye Irritation - Rabbit</b>	131368, 130939
<b>81-5</b>	<b>Primary Dermal Irritation - Rabbit</b>	11369
<b>82-1A</b>	<b>90-Day Feeding - Rodent</b>	41248202, 41462401, 40376301
<b>82-2</b>	<b>21-Day Dermal - Rabbit/Rat</b>	41248201
<b>83-2A</b>	<b>Oncogenicity - Rat</b>	42279301
<b>83-2B</b>	<b>Oncogenicity - Mouse</b>	42279302

## Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol

REQUIREMENT	USE PATTERN	CITATION(S)
<b>83-3A</b> <b>Developmental Toxicity - Rat</b>		161231, 145836, 143775
<b>83-3B</b> <b>Developmental Toxicity - Rabbit</b>	ACDGHILMNO	143774, 40988201, 41003901
<b>84-2A</b> <b>Gene Mutation (Ames Test)</b>	ACDGHILMNO	41287501
<b>84-2B</b> <b>Structural Chromosomal Aberration</b>	ACDGHILMNO	41287502, 41572801, 43322901
<b>84-4</b> <b>Other Genotoxic Effects</b>	ACDGHILMNO	41636601
<b>85-2</b> <b>Dermal Penetration</b>		43313401
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>		
<b>133-3</b> <b>Dermal Passive Dosimetry Exposure</b>	ACDGHILMNO	41412201



# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, potassium salt

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

## **Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, potassium salt**

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b>ECOLOGICAL EFFECTS</b>		
<b>71-1A</b>	<b>Acute Avian Oral - Quail/Duck</b>	138112
<b>71-2A</b>	<b>Avian Dietary - Quail</b>	138112, 138887, 138888
<b>71-2B</b>	<b>Avian Dietary - Duck</b>	138112, 138888
<b>72-1A</b>	<b>Fish Toxicity Bluegill</b>	133334
<b>72-1B</b>	<b>Fish Toxicity Bluegill - TEP</b>	138112
<b>72-1C</b>	<b>Fish Toxicity Rainbow Trout</b>	138112, 133335
<b>72-2A</b>	<b>Invertebrate Toxicity</b>	138112, 133336
<b>81-1</b>	<b>Acute Oral Toxicity - Rat</b>	131367
<b>81-2</b>	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	130937
<b>81-3</b>	<b>Acute Inhalation Toxicity - Rat</b>	130938
<b>81-4</b>	<b>Primary Eye Irritation - Rabbit</b>	131368
<b>81-5</b>	<b>Primary Dermal Irritation - Rabbit</b>	131369
<b>82-1A</b>	<b>90-Day Feeding - Rodent</b>	41248202, 41462401
<b>82-1B</b>	<b>90-Day Feeding - Non- rodent</b>	41248202, 40376301, 41462401
<b>82-2</b>	<b>21-Day Dermal - Rabbit/Rat</b>	41248201
<b>83-3A</b>	<b>Developmental Toxicity - Rat</b>	143775, 145836, 161231
<b>83-3B</b>	<b>Developmental Toxicity - Rabbit</b>	143774, 40988201, 41003901

## **Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, potassium salt**

<b>REQUIREMENT</b>		<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b>84-4</b>	<b>Other Genotoxic Effects</b>	ACDGHILMNO	41636601
<b>85-2</b>	<b>Dermal Penetration</b>		43313401
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>			
<b>133-3</b>	<b>Dermal Passive Dosimetry Exposure</b>	ACDGHILMNO	41412201



# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, sodium salt

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



## Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, sodium salt

REQUIREMENT	USE PATTERN	CITATION(S)
<b>ECOLOGICAL EFFECTS</b>		
<b>71-1A</b>	<b>Acute Avian Oral - Quail/Duck</b>	138112
<b>71-1B</b>	<b>Acute Avian Oral -Quail/Duck TEP</b>	138112
<b>71-2A</b>	<b>Avian Dietary - Quail</b>	138112
<b>71-2B</b>	<b>Avian Dietary - Duck</b>	138112
<b>72-1A</b>	<b>Fish Toxicity Bluegill</b>	138112
<b>72-1C</b>	<b>Fish Toxicity Rainbow Trout</b>	138112
<b>72-2A</b>	<b>Invertebrate Toxicity</b>	138112
<b>81-1</b>	<b>Acute Oral Toxicity - Rat</b>	131367
<b>81-2</b>	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	130937
<b>81-3</b>	<b>Acute Inhalation Toxicity - Rat</b>	130938
<b>81-4</b>	<b>Primary Eye Irritation - Rabbit</b>	131368
<b>81-5</b>	<b>Primary Dermal Irritation - Rabbit</b>	131369
<b>82-1B</b>	<b>90-Day Feeding - Non-rodent</b>	41248202, 40376301, 41462401
<b>82-2</b>	<b>21-Day Dermal - Rabbit/Rat</b>	41248201
<b>83-3A</b>	<b>Developmental Toxicity - Rat</b>	143775, 145836, 161231
<b>83-3B</b>	<b>Developmental Toxicity - Rabbit</b>	143774, 40988201, 41003901
<b>84-4</b>	<b>Other Genotoxic Effects</b>	41636601
<b>85-2</b>	<b>Dermal Penetration</b>	43313401

**Data Supporting Guideline Requirements for the Reregistration of ortho-benzyl-para-chlorophenol, sodium salt**

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b>		
<b>133-3</b>	<b>Dermal Passive Dosimetry Exposure</b>	<b>ACDGHILMNO</b>
		<b>41412201</b>

## GUIDE TO APPENDIX C

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

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

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## DATA CALL-IN NOTICE

### CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

The Attachments to this Notice are:

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

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

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

### II-B. SCHEDULE FOR SUBMISSION OF DATA

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

## II-C. TESTING PROTOCOL

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

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

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

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

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

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

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

### III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

### III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

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

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

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

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May



1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

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

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

### III-D REQUESTS FOR DATA WAIVERS

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

#### IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

##### IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or

- c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

#### SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois 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



# **ORTHO-BENZYL-P-CHLOROPHENOL DATA CALL-IN CHEMICAL STATUS SHEET**

## INTRODUCTION

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

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

## INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 8585.

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

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

**RE: Ortho-Benzyl-P-Chlorophenol**



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.

**Remove this page and insert page 1 of the part A for the product specific DCI for 62201 (2-Benzyl-4-chlorophenol) 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.

**Remove this page and insert page 1 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**



**Remove this page and insert page 2 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**

**Remove this page and insert page 3 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**

**Remove this page and insert page 4 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**

**Remove this page and insert page 5 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**

**Remove this page and insert page 6 for Part B of the Product Specific DCI for 2-Benzyl-4-chlorophenol here.**

**Attachment 4. List of All Registrants Sent This Data Call-In (insert) Notice**

INSERT PAGE 1 OF THE LIST OF REGISTRANTS HERE.

INSERT PAGE 2 OF THE LIST OF REGISTRANTS HERE.



## **EPA'S BATCHING OF O-BENZYL-P-CHLOROPHENOL PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS**

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 o-benzyl-p-chlorophenol as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred and six products were found which contain o-benzyl-p-chlorophenol as an active ingredient. The products have been placed into fifteen batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation, pH and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

The requirement for acute oral, acute dermal and acute inhalation data has been waived for all products addressed in this RED (i.e., all batched and "no batch" products listed below), with the exception of products in batch 14. Registrants with products in batch 14 should submit or cite appropriate acute oral, acute dermal and acute inhalation data. The waiver of acute oral, dermal and inhalation requirement is based on the condition that category III labeling will be employed for these three routes of exposure. If a registrant is not willing to use category III labeling for these routes, product specific acute oral, dermal and inhalation studies are needed.

Furthermore, in accordance with 40CFR, any products which are corrosive to skin or have a pH above 11.5 or below 2.0 are not required to provide eye and skin irritation data. A category I placement will be required for such products on the basis of potential effects.

**Table 1**

Batch	EPA Reg. No.	% o-benzyl-p-chlorophenol	Formulation Type
1	39967-5	95	Solid
	49403-2	95	Solid
	49403-3	95	Solid
2	1685-39	4.7	Liq
	49403-4	6.9	Liq
3	2155-68	3.7	Liq
	4313-11	2.2	Liq
4	1203-7	4.7	Liq
	8047-1	2.8	Liq
5	1459-23	2.0	Liq
	5747-7	2.6	Liq
6	572-293	3.9	Liq
	2296-103	3.9	Liq
	2296-105	2.0	Liq
7	1677-130	7.4	Liq
	1677-135	6.5	Liq
8	675-19	2.7	Liq
	777-10	2.7	Liq
9	421-409	2.2	Liq
	48211-62	2.2	Liq
10	303-223	4.5	Liq
	63281-5	3.4	Liq
11	303-225	9.1	Liq
	47371-163	9.1	Liq
	63281-4	9.1	Liq
12	11725-9	3.0	Liq
	66171-2	3.0	Liq
13	2296-111	5.0	Liq
	49403-6	5.0	Liq
14	421-350	1.0	Liq
	421-349	0.15	Liq
	675-1	0.01	Liq
15	1270-232	0.09	Spray
	1270-233	0.09	Spray

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately.

**Table 2 (No Batch)**

EPA Reg. No.	% o-benzyl-p-chlorophenol	Formulation Type
211-26	4.3	Liq
303-26	6.1	Liq
334-25	3.7	Liq
402-96	3.9	Liq
402-113	3.0	Liq
421-16	4.9	Liq
541-243	2.0	Liq
675-15	0.2	Liq
675-27	7.8	Liq
675-43	5.0	Liq
675-46	7.2	Liq
777-15	4.5	Liq
875-127	0.8	Liq
875-133	3.6	Liq
892-26	0.03	Liq
1043-36	5.2	Liq
1270-24	5.0	Liq
1683-25	2.9	Liq
1769-72	4.0	Liq
1769-194	3.0	Liq
1964-11	3.5	Liq
9167-8	2.1	Liq
1043-19	0.08	Spray
1057-61	3.0	Liq
1270-238	5.7	Liq
1270-243	0.06	Spray
1459-18	3.4	Liq
1622-32	3.5	Liq
1677-128	1.4	Liq
1677-157	2.5	Solid
1683-24	1.2	Liq
1769-277	6.7	Liq
2296-102	3.6	Liq
2296-106	5.2	Liq
2311-4	4.6	Liq
3525-126	0.68	Liq
4029-3	5.0	Liq
4313-3	2.6	Liq
4313-21	4.9	Liq
4313-66	9.7	Liq
4822-109	4.7	Liq
5197-45	2.6	Liq
5741-22	0.07	Spray

EPA Reg. No.	% o-benzyl-p-chlorophenol	Formulation Type
5747-14	2.6	Liq
5813-32	3.0	Liq
6109-10	9.2	Liq
6484-4	0.85	Liq
8047-2	4.9	Liq
10693-4	3.14	Liq
10807-90	3.0	Liq
11725-7	10.0	Liq
11725-8	6.5	Liq
33176-6	0.08	Spray
34810-8	5.7	Liq
34810-17	6.0	Liq
34810-21 *	0.02	Liq
34810-28	8.6	Liq
39967-6	75.0	Liq
46851-1	5.0	Liq
46851-5	0.03	Liq
47371-162	2.9	Liq
48211-63	4.9	Liq
49403-5 **	4.0	Liq
49403-23	10.1	Liq
57125-9	0.14	Liq
63163-1	1.0	Liq
63281-1	0.1	Liq
63281-7	9.5	Liq
63281-8	4.7	Liq
65020-7	9.9	Liq
66171-1	6.0	Liq
67813-1	5.7	Liq

\* Can be supported by all category III or category IV acute data generated with EPA Reg. No. 34810-8.

\*\* Can be supported by all category III or category IV acute data generated with EPA Reg. No. 49403-6.

## Instructions for Completing the Confidential Statement of Formula

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

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.



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

**Confidential Statement of Formula**

A.  Basic Formulation  Alternate Formulation Page \_\_\_\_\_ of \_\_\_\_\_ See Instructions on Back

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr./Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)

11. Supplier Name & Address

12. EPA Reg. No.

13. Each Component in Formulation  
a. Amount \_\_\_\_\_ b. % by Weight \_\_\_\_\_

14. Certified Limits % by Weight  
Upper Limit a. \_\_\_\_\_ Lower Limit b. \_\_\_\_\_

15. Purpose in Formulation \_\_\_\_\_

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. (Include Area Code)

21. Date







United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106  
2070-0057

Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer
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Certification:

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

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

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

US EPA ARCHIVE DOCUMENT



**United States Environmental Protection Agency  
Washington, DC 20460**



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

**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:**

- 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.
- 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,"
- 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
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Name and Title (Please Type or Print)



The following is a list of available documents for Ortho-Benzyl-P-Chlorophenol 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 on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Veronica Dutch at (703)-8585.

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 Ortho-Benzyl-P-Chlorophenol.
5. Appendix A.

The following documents are part of the Administrative Record for Ortho-Benzyl-P-Chlorophenol and may be 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