United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7510C)

739-R-06-004
July 2006

Reregistration Eligibility Decision for 2-phenylphenol and Salts (Orthophenylphenol or OPP)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial 2-phenylphenol, or orthophenylphenol, and salts (hereafter referred to as OPP). The enclosed Reregistration Eligibility Decision (RED) document was approved on July 28, 2006. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for OPP and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for OPP are available to the public in EPA's Pesticide Docket **EPA-HQ-OPP-2006-0154** at: http://www.regulations.gov.

The OPP RED was developed through EPA's public participation process, published in the Federal Register on April 26, 2006, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision-making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the OPP risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to OPP alone. This document also contains both generic and product-specific data that the Agency intends to require in a Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90

days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that OPP will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by OPP. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Rebecca M. Miller, at (703) 305-0012.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
2-phenylphenol and Salts (OPP)
List B
CASE 2575

Approved By:

Frank T. Sanders
Director, Antimicrobials Division

Date: July 28, 2006

Attachment

Table of Contents

OPP Reregistration Team i
Glossary of Terms and Abbreviations ii
Abstract iv

I. Introduction 1
II. Chemical Overview 3
A. Regulatory History 3
B. Chemical Identification 3
C. Use Profile 5
III. Summary of OPP Risk Assessments 7
A. Human Health Risk Assessment 7
1. Toxicity of OPP 7
2. FQPA Safety 11
3. Population Adjusted Dose (PAD) 11
a. Acute PAD 12
b. Chronic PAD 12
4. Dietary Exposure Assumptions 12
5. Dietary (Food) Risk Assessment 13
a. Acute and Chronic Dietary Risk 13
b. Dietary Exposure and Risk for Inert Ingredient Uses 15
c. Dietary Risk from Drinking Water 16
6. Residential Risk for Active Ingredient Uses 17
a. Toxicity 17
b. Residential Handler Scenarios 19
i. Exposure Scenarios, Data and Assumptions 19
ii. Residential Handler Risk Estimates 20
iii. Residential Painter Inhalation Exposure and Risk 21
c. Residential Post-Application Exposure 21
i. Exposure Scenarios, Data and Assumptions 21
ii. Residential Post-Application Risk Estimates 22
7. Residential Risk for Inert Ingredient Uses 24
8. Aggregate Risk 25
a. Acute and Chronic Aggregate Risks 25
b. Short- and Intermediate- Term Aggregate Exposures and Risks 26
9. Occupational Risk 30
a. Occupational Toxicity 30
b. Occupational Handler Exposure 30
c. Occupational Handler Risk Summary 33
d. Occupational Post-Application Exposure and Risk 42
i. Fogging 43
ii. Metalworking Fluids: Machinist 44
iii. Wood Preservation 44
B. Environmental Risk Assessment 46
1. Environmental Fate and Transport 46
2. Ecological Risk 46

3. Listed Species Consideration 48
IV. Risk Management, Reregistration, and Tolerance Reassessment Decision 50
A. Determination of Reregistration Eligibility 50
B. Public Comments and Responses 50
C. Regulatory Position 51
1. Food Quality Protection Act Findings 51
a. "Risk Cup" Determination 51
b. Determination of Safety to U.S. Population 51
c. Determination of Safety to Infants and Children 52
d. Cumulative Risks 52
e. Endocrine Disruptor Effects 52
2. Tolerance Summary 53
a. Tolerances Currently Listed under 40 CFR 54
b. Codex Harmonization 55
D. Regulatory Rationale 55
1. Human Health Risk Management 55
a. Dietary (Food) Risk Mitigation 55
b. Drinking Water Risk Mitigation 55
c. Residential Risk Mitigation 55
d. Occupational Risk Mitigation 56
i. Handler Exposure 56
ii. Post-Application Risk Mitigation 57
2. Environmental Risk Management 57
3. Listed Species Considerations 58
a. The Endangered Species Program 58
b. General Risk Mitigation 59
V. What Registrants Need to Do 60
A. Manufacturing Use Products 61
1. Additional Generic Data Requirements 61
2. Labeling for Technical and Manufacturing Use Products 62
B. End-Use Products 62
1. Additional Product-Specific and Efficacy Data Requirements 62
2. Labeling for End-Use Products 63
a. Labeling Changes Summary Table 63
VI. Appendices 65
A. Table of Use Patterns for OPP and Salts 66
B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision 104
C. Technical Support Documents 115
D. Bibliography Citations 116
E. Generic Data Call-In 128
F. Product Specific Data Call-In 130
G. Batching of End-Use Products 132
H. List of All Registrants Sent the Data Call-In 142
I. List of Available Forms 143

OPP Reregistration Team

Health Effects Risk Assessment
Cassi Walls
Tim McMahon
Talia Milano
Bob Quick
Matthew Crowley
Dave Hrdy

Environmental Fate and Ecological Assessment
Najm Shamim
Kathryn Montague

Use Analysis
Rebecca Miller

Risk Management
Rebecca Miller

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for 2-phenylphenol (orthophenylphenol or OPP) and its salts and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of OPP and salts that pose risks of concern. As a result of this review, EPA has determined that OPP and salts-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for 2-phenylphenol and salts (also commonly called orthophenylphenol and salts or OPP).

OPP is a bacteriostat, microbiostat, nematicide, fumigant, and bactericide chemical. OPP is used in applications to hard surfaces, agricultural premises and equipment, air deodorization, commercial and institutional premises, medical premises, residential and public access premises (carpet, hard surfaces, crack and crevice treatment), and material preservatives (stains, and paints, metal working fluids, textiles, paper slurries and cement mixtures, glues, and adhesives, and consumer, household and institutional cleaning products). As a fungicide, tolerances have been established (40 CFR 180.129) for the combined residues of OPP and its sodium salt (sodium o-phenylphenate or Na-OPP) from postharvest application on citrus and pears. Tolerances for other commodities were established at the same time as those for citrus and pears, however those additional use sites have since been cancelled. The uses are not assessed in this RED and the tolerances are to be revoked.

Sodium o-phenylphenate (Na-OPP) is the only chemical in the RED case that is formulated as an inert ingredient. Sodium o-phenylphenate is formulated as inert ingredient in approximately 123 registered end-use products. The types of products that contain sodium o-phenylphenate as an inert ingredient include: turf insecticides and herbicides; garden and ornamental insecticides and herbicides; insect repellant for pets; and indoor/outdoor crack and crevice insecticides. These products are formulated as soluble concentrates, gels, flowable concentrates, ready to use liquids, granular, and bait traps. The vast majority of these products contain sodium o-phenylphenate as an inert ingredient in amounts less than 2% of the formulation. In these cases, the residues on food have an exemption from the requirement of a

tolerance under the 40 CFR §180.920 when used as an inert ingredient in pesticide formulations that are applied to growing crops.

The Agency has concluded that the special hazard-based FQPA safety factor be **reduced to 1x** for OPP based on the available data and because the risk assessment does not underestimate risks for infants and children. There are available developmental toxicity and reproductive toxicity studies for OPP that are considered acceptable and that show no evidence of increased toxicity to offspring at the same or lower doses as those causing parental/systemic toxicity or evidence of more severe toxicity relative to parental/systemic toxicity.

Risks summarized in this document are those that result from the use of the active ingredient OPP and salts in addition to the inert uses of Na-OPP only. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for OPP and any other substances. OPP does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that OPP has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of OPP. In an effort to simplify the RED, the information presented herein is summarized from more detailed information that can be found in the technical supporting documents for OPP referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of OPP, and its regulatory history. Section III, Summary of OPP Risk Assessments, gives an overview of the human health and environmental assessments based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

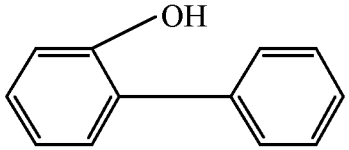
A. Regulatory History

The 2-phenylphenol reregistration case contains OPP and its sodium (Na-OPP) and potassium (K-OPP) salts. There are 120 active products containing OPP and salts as an active ingredient registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). There are 123 active products that have inert uses for Na-OPP.

B. Chemical Identification - Technical OPP, Na-OPP, and K-OPP

1. Chemical Identity of OPP:

Chemical Name: 2-phenylphenol
Chemical Family: Phenol
Common/Trade Name: Dowcide1, Preventol O Extra 1
CAS Number: 90-43-7
Molecular Formula: $C_{12}H_{20}O$
Chemical Structure:



Orthophenylphenol

Table 1. Chemical Characteristics for Technical Grade Active OPP

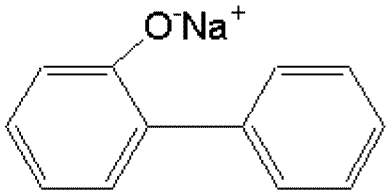
Molecular Weight	170.2
Color	Colorless
Physical State	Solid (flakes)
Specific Gravity	1.2
Dissociation Constant	9.9 at 25 ^{o} C
pH	6.1 in aqueous solution at 22.7 ^{o} C
Stability	Stable at normal conditions
Melting Point	56-58 ^{o} C
Boiling Point	286 ^{o} C
Water Solubility	700 mg/L at 25 ^{o} C
Octanol-Water Partition constant ($LogK_{OW}$)	3.3
Vapor Pressure	2 x 10^{-3} mm Hg at 25 ^{o} C

2. Chemical Identity of Na-OPP:

Chemical Name: Sodium orthophenylphenate
Chemical Family: Phenol
Common/Trade Names: Dowcide A, Preventol ON Extra

CAS Number: 132-27-4
Molecular Formula: $C_{12}H_{19}NaO$

Molecular Structure:



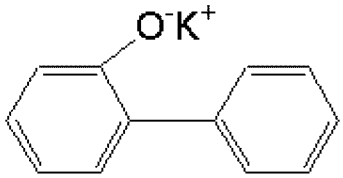
Na-OPP (Sodium orthophenylphenate)

Table 2. Chemical Characteristics for Technical Grade Active Na-OPP

Molecular Weight	192.19
Color	White to light buff
Physical State	Solid (flakes)
Specific Gravity	0.61 to 0.69
Dissociation Constant	10 at 20 ^{o} C
pH	12. 13.5
Stability	Stable under controlled conditions
Melting Point	298.5 ^{o} C
Boiling Point	N/A
Octanol-Water Partition Coefficient (Log K_{OW})	0.59
Water Solubility	60.6 g/100 mL, 53.37 % (w/w)
Vapor Pressure	1.8 x 10^{-9} mm Hg at 25 ^{o} C

3. Chemical Identity of K-OPP:

Chemical Name: Potassium orthophenylphenate
Chemical Family: Phenol
Common/Trade Name: Potassium salt
CAS Number: 13707-65-8
Molecular Formula: $C_{12}H_{19}KO$
Chemical Structure:



K-OPP (Potassium Orthophenylphenate)

Table 3. Chemical Characteristics for Technical Grade Active K-OPP

Molecular Weight	208.30
Color	White
Physical State	Solid
Specific Gravity	n/a
Dissociation Constant	n/a
PH	n/a
Stability	n/a
Melting Point	230.7 C
Boiling Point	n/a
Octanol-Water Partition Coefficient (Log K_{OW})	0.59
Water Solubility	Highly water soluble
Vapor Pressure	1.91×10^{-11} mm Hg at 25 C

C. Use Profile

The following is information on the currently registered uses of OPP products and an overview of use sites and application methods. A detailed table of the uses of OPP eligible for reregistration is contained in Appendix A.

Type of Pesticide: Fungicide/Fungistat
Bacteriostat
Sanitizer
Microbistat
Disinfectant (Bacteriocide)
Nematicide
Fumigant

Summary of Use:
Products containing OPP and salts as an active ingredient are intended for use in agricultural, food handling, commercial/institutional/ industrial, residential and public access, and medical settings (Use Site Categories I, II, III, IV and V, respectively), as well as a materials preservative for a variety of products (Use Site Category VII) and as a wood preservative (Use Site Category X). Some examples of uses are listed below, for a detailed use description please refer to Appendix A.

Agricultural: OPP is used in mushroom houses, in addition to cattle, swine and poultry farms and premises.

Commercial/Institutional/Industrial:
OPP is used to treat hard, non-porous industrial and institutional equipment and surfaces.

Food: OPP and salts is used as a post-harvest fungicide on citrus and pears.

Non-Food: Na-OPP is used as an inert ingredient in turf insecticides and herbicides; garden and ornamental insecticides and herbicides; insect repellant for pets; and indoor/outdoor crack and crevice insecticides.

Residential and Public Access:
OPP is used in applications to treat indoor and outdoor premises including decks, carpets, garbage cans, animal kennels, and bathrooms.

Materials Preservatives:
OPP is found in metalworking fluids, stains and paints, glues, building materials, glazes, paper, leather, and polymers.

Medical: OPP is used to treat hospital and dental office equipment and premises.

Wood Preservative:
OPP is used for sapstain control in freshly cut lumber.

Target Pests: Deterioration/spoilage bacteria, fungi (coatings, leather, metal working coolants), mildew, mold, pseudomonas spp., and sapstain.

Formulation Types of OPP and Salts:
Soluble concentrates, soluble powder, ready-to-use solutions, and impregnated wipes.

Method and Rates of Application:
The methods and rates of application for OPP-containing products vary greatly depending on use site. Please refer to Appendix A for more detailed application rates for each use site and methods of application.

III. Summary of OPP Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for OPP. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed at http://www.regulations.gov. Hard copies of these documents may be found in the Office of Pesticide Program's public docket under docket number HQ-EPA-OPP-2006-0154. The public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of OPP

The Agency's use of human studies in the OPP and salts risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26. A brief overview of the toxicity studies used for determining endpoints in the human health dietary risk assessments are outlined in Table 5. Further details on the toxicity of OPP can be found in the documents "Toxicology Disciplinary Chapter for the Re-Registration Eligibility Decision (RED) Risk Assessment," dated April 17, 2006 and "Ortho Phenylphenol, and its Sodium and Potassium Salts. Dietary Exposure Assessments for the Reregistration Eligibility Decision," dated April 10, 2006. These documents are available in the docket at http://www/regulations.gov.

The database is complete with the exception of acute dermal toxicity (870.1200), acute inhalation toxicity (870.1300), and primary eye irritation (870.2400). Acceptable acute toxicity studies for these guidelines must be submitted. The Agency has reviewed all toxicity studies submitted for OPP and found the database sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. 2-phenylphenol has a moderate order of acute toxicity via the oral route of exposure (Toxicity Category III). For dermal irritation, 2-phenylphenol and its sodium salt are severe (Toxicity Category I) and moderate to severe (Toxicity Category II) irritants, respectively. 2-phenylphenol and its sodium salt are not dermal sensitizers.

Table 4. Acute Toxicity Profile for 2-Phenylphenol and Salts

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral- Rat 2-phenylphenol purity (99.9%)	43334201	LD_{50} = 2733 mg/kg	III
870.1100 (§81-1)	Acute Oral- Rat 2-phenylphenol, sodium salt purity (99.1%)	43334204	LD_{50} = 846 mg/kg (male) LD_{50} = 591 mg/kg (female)	III

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1200 (§81-2)	Data Gap	NA	NA	NA
870.1300 (§81-3)	Data Gap	NA	NA	NA
870.2400 (§81-4)	Data Gap	NA	NA	NA
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit 2-phenylphenol purity (99.9%)	43334202	Primary Irritant	I
870.2600 (§81-6)	Dermal Sensitization - Guinea pig 2-phenylphenol purity (99.9%)	43334203	Not a sensitizer.	No
870.2600 (§81-6)	Dermal Sensitization - Guinea pig 2-phenylphenol, sodium salt purity (99.1%)	43334205	Not a sensitizer.	No

The doses and toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 5 below.

Table 5. Toxicological Doses and Endpoints for Ortho-Phenylphenol (Dietary)

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population and females 13-49)	No appropriate endpoints were identified that represent a single dose effect. Therefore, this risk assessment is not required.		
Chronic Dietary (all populations)	**NOAEL** = 39 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic RfD (cPAD)** = 0.39 mg/kg/day	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity.

UF = uncertainty factor, DB UF = data base uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure

General Toxicity Observations

Repeated dose (subchronic) oral toxicity testing with OPP by the oral route showed systemic toxicity (decreased body weight gain and food consumption; decreased hemoglobin and mean corpuscular hemoglobin concentration) only at doses in excess of a limit dose (approximately 1650 mg/kg). Repeated dose dermal toxicity testing (21-day toxicity test) showed no significant treatment-related systemic effects up to and including a limit dose (1000 mg/kg), but dermal irritation was observed at 500 mg/kg.

The Agency has concluded that there is not a concern for neurotoxicity resulting from exposure to OPP and salts. The available toxicology data on OPP show no significant neurotoxic effects from administration of the chemical in experimental animal studies.

Developmental toxicity studies for orthophenylphenol are available in both the rat and rabbit. The examination of these studies shows that adverse effects in offspring occurred at doses higher than those producing maternal toxicity. In addition, the effects on offspring were not considered more severe than those occurring in maternal animals. Therefore, there is no increased concern for developmental toxicity of orthophenylphenol when comparing effects in adult animals with those in offspring. This conclusion is similar to that reached by the UK's Department for Environment, Food and Rural Affairs of the Pesticides Safety Directorate in their 1993 publication on the Evaluation of 2-phenylphenol.

In a two-generation reproduction toxicity study, there were no toxicologically significant effects on reproductive parameters. Therefore, there is no increased concern for potential reproductive toxicity of orthophenylphenol.

Dietary: No appropriate endpoints were identified that represent a single dose effect therefore an acute assessment was not conducted. The chronic RfD is 0.39 mg/kg/day. This endpoint is based on a combined oral toxicity/carcinogenicity study in rats with a reported NOAEL of 39 mg/kg/day. This study indicated decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity at the LOAEL of 200 mg/kg/day. An uncertainty factor of 100 (10x for interspecies extrapolation, and 10x for intraspecies variability) was applied to the NOAEL to obtain the chronic RfD.

Incidental Oral: The short-term oral endpoint is 100 mg/kg/day and is based upon clinical observations of toxicity, decreased weight gain, food consumption and food efficiency at 300 mg/kg/day in maternal developmental toxicity studies in rats and rabbits. The intermediate-term oral endpoint is 39 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity at 200 mg/kg/day in a combined oral toxicity/carcinogenicity study in rats. The target MOE is 100 for residential and occupational exposure.

Dermal: The short-term dermal endpoint is 100 mg/kg/day and is based dermal irritation (erythema, scaling) at the site of test substance application at 500 mg/kg/day in a 21-day dermal toxicity study in rats. The target MOE is 100 for residential and occupations exposure. The intermediate- and long-term dermal endpoints are 39 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13

weeks in this study), increased clinical and gross pathological signs of toxicity at 200 mg/kg/day in a combined oral toxicity/carcinogenicity study in rats. The target MOE is 100.

Inhalation: The short-term inhalation endpoint is 100 mg/kg/day based upon clinical observations of toxicity, decreased weight gain, food consumption and food efficiency at 300 mg/kg/day in maternal developmental (gavage) toxicity studies in rats and rabbits. The intermediate- and long-term inhalation endpoints are 39 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13 weeks in this study), increased clinical and gross pathological signs of toxicity at 200 mg/kg/day in a combined oral toxicity/carcinogenicity study in rats. The target MOE is 100 for occupational and residential exposure; however if the resulting MOE is not greater than 1000, the Agency will generally require a repeat dose inhalation study of at least 28 days in duration. (The MOE of 1000 is based on the application of a 10X uncertainty factor for interspecies extrapolation, a 10X uncertainty for intraspecies variability and a 10X for the lack of an inhalation study).

Mutagenicity: All acceptable mutagenicity studies showed a negative mutagenic response for this chemical.

Carcinogenicity: In accordance with the EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005), the Agency used multiple descriptors for the classification of orthophenylphenol and sodium orthophenylphenol.

OPP and NA-OPP were classified as **"Not Likely to be Carcinogenic to Humans"** based on convincing evidence that carcinogenic effects are not likely below a defined dose range (i.e., below 200 mg/kg/day). This classification is based on convincing evidence that a non-linear mode of action for bladder tumors was established in rats. High doses of OPP lead to saturation of phase II detoxification enzyme pathways, resulting in increased amounts of the oxidative metabolites o-phenylhydroquinone (PHQ) and/or o-phenylbenzoquinone (PBQ). The generation of PBQ is considered dose-dependent, appearing in increased quantity only at higher doses of OPP (>200 mg/kg/day). The shift in biotransformation products with increased dose of OPP has been postulated to be associated with the non-linear response observed in tumorigenicity of the urinary bladder, involving oxidative damage to cells and subsequent regenerative hyperplasia. With continued exposure, this process leads to development of tumors. Evidence suggests that a non-genotoxic mode of action is operative.

OPP and NA-OPP were also classified as **"Likely to be Carcinogenic to Humans,"** based on the presence of urinary bladder tumors in rats and the presence of liver tumors in mice at doses above 200 mg/kg/day. This classification is based on the fact that insufficient data were provided to support a mode of action for the mouse liver tumors. Although the tumors were benign and observed only in one sex at high doses, more data are required for any conclusion to be drawn regarding the mode of action for these tumors.

The Agency notes that although both chemicals are classified as "Likely to be Carcinogenic to Humans" above a defined dose range, quantification of cancer risk is not required since the NOAEL selected for the chronic Reference Dose (39 mg/kg/day) is protective

of the precursor events leading to development of bladder tumors that occur at doses above 200 mg/kg/day and liver tumors that occur above 500 mg/kg/day.

Endocrine Disruption Potential: EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, OPP may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for orthophenylphenol and salts based on the available developmental toxicity and reproductive toxicity studies for OPP that are considered acceptable. These studies show no evidence of increased toxicity to offspring at the same or lower doses as those causing parental/systemic toxicity or evidence of more severe toxicity relative to parental/systemic toxicity. The FQPA Safety Factor assumes that the databases for food, drinking water, and residential exposures are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met for OPP and salts. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor was needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

As there is no acute dietary endpoint selected for OPP an acute dietary assessment was not performed for OPP.

b. Chronic PAD

Chronic dietary risk for OPP is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.39 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from a combined oral toxicity/carcinogenicity study in rats in which both the NOAEL (39 mg/kg/day) and the LOAEL (200 mg/kg/day) were determined based on decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity. The OPP cPAD is 0.39 mg/kg/day based on a reference dose of 0.39 mg/kg/day, which includes the incorporation of the FQPA safety factor (1X) for the overall U.S. population or any population subgroups.

4. Dietary Exposure Assumptions

Dietary exposure to OPP residues occurs from the antimicrobial uses as disinfectants and sanitizers in the following scenarios: counter tops, tables, refrigerators, preservative in papermaking, preservative in adhesive, mushroom premises, and in plastics and polymers. These are considered to be indirect food uses. The maximum rate of application for OPP in sanitizer end-use solutions is 400 ppm as indicated in 40 CFR 180.940. Review of current labels indicates that product application rates are much higher than the limit the Agency has set in the 40 CFR 180.940. The Agency has carried out the dietary assessment for all the scenarios listed above using the maximum application rate found on the labels, except for plastics and polymers which were not included in the quantitative assessment due to a lack of residue migration data. Exposures via this pathway are not expected to be greater than those from the assessed uses and should have limited impacts on the dietary exposure assessment. To confirm this, a plastics and polymers migration study is required. Chronic dietary exposure assessments were conducted using FDA's Center for Food Safety & Applied Nutrition's (CFSAN) screening-level approach as presented in "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations" dated April 2002. Using the maximum application rates and US FDA's default assumptions, "worst-case" dietary concentration values were calculated by the Agency.

FDA's method utilizes a number of general assumptions for calculating the amount of OPP and salts in food from contacting treated paper surfaces. These assumptions include the following: 1) the food contact can result from a one time use or a repeat use of the paper; 2) the consumption factor (CF or fraction of food that contacts the packaging surface) represents a ratio of the actual weight of food that comes into contact with the paper packaging to the total weight of the food packaged with the paper; 3) the CF varies based on type of packaging; and 4) 100% of the antimicrobial present in the packaging migrates into the food commodities.

Dietary exposure to active ingredient OPP residues, specifically Na-OPP, also occurs from the conventional (agricultural) use as a fungicide in post-harvest application on raw agricultural commodities (RAC) including citrus and pears. These uses are considered direct food uses. Tolerances (40 CFR Part 180.129) were established for the residues of orthophenylphenol and its sodium salt (46 FR Notice 27938, May 22, 1981 and its amendment 48 FR Notice 32015, July 13, 1983) for this use. The established tolerances are 25 ppm on pears and 10 ppm for citrus.

The direct food use portion of the non-cancer dietary risk assessment was carried out by the Agency using the Dietary Exposure Evaluation Model (DEEM- FDIC™), Version 2.03 as well as Lifeline Model Version 3.0 which uses food consumption data from the USDA's Continuing Surveys of Food Intake by Individuals (CSFII) from 1994-1996 and 1998. This assessment is tier 1, conservative (assumes 100% crop treatment) and uses a deterministic approach. As input parameters for modeling analyses, residue level tolerances (indicated above) were used as point estimates.

5. Dietary (Food) Risk Assessment

a. Acute and Chronic Dietary Risk

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's levels of concern. A summary of antimicrobial indirect food use chronic risk estimates are shown below in Table 6. Risk estimates are below the Agency's level of concern. For adults, the chronic dietary risk estimate is 19.68% of the chronic PAD. For children, the most highly exposed population subgroup, the chronic dietary risk estimate is 45.17% of the chronic PAD. Therefore, chronic dietary risk estimates are below the Agency's level of concern for all population subgroups. As there is no acute dietary endpoint selected for OPP an acute dietary assessment was not performed for OPP.

Table 6. Summary of Dietary Exposure and Risk for OPP from Indirect Food Uses

Use	Dietary Concentration (ppb)	Estimated Daily Intake (µg/person[1]/day)	Daily Dietary Dose (mg/kg/day)	% cPAD
Counter top/ disinfectant	280	840 (adult) 420 (child)	0.012 (adult) 0.028 (child)	3.0 7.0
Dishwashing/ disinfectant	91.5	274 (adult) 137.5 (child)	0.004 (adult) 0.0092 (child)	1.0 2.0
Paper slimicide use	1120	3360 (adult) 1680 (child)	0.048 (adult) 0.112 (child)	12.0 28.0
Paper Coating/ preservative	3200	960 (adult) 480 (child)	0.014 (adult) 0.032 (child)	3.6 8.0
Paper Adhesive preservative	7	21 (adult) 10.5 (child)	0.0003 (adult) 0.0007(child)	0.08 0.17
Cumulative	4698	5455 (adult) 2728 (child)	0.077 (adult) 0.181 (child)	19.68 45.17

[1] A 15 kg child is about 3 years old for both male and female. A 70 kg male is approximately 18-19 years old while a 60 kg female is approximately 17-19 years old.

A summary of direct food use chronic risk estimates are shown below in Table 7. For conventional direct food uses, the chronic analyses were below Agency's level of concern for the general US Population (4.4% of cPAD) and all other population subgroups (the most highly exposed being children 1-2 years old with a 15.8% of the cPAD).

Table 7. Summary of Dietary Exposure and Risk for OPP from Direct Food Uses

Total Exposure by Population Subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of cPAD
U.S. Population (total)	0.017272	4.4%
U.S. Population (spring season)	0.017159	4.4%
U.S. Population (summer season)	0.015500	4.0%
U.S. Population (autumn season)	0.017393	4.5%
U.S. Population (winter season)	0.019154	4.9%
Northeast region	0.022233	5.7%
Midwest region	0.016081	4.1%
Southern region	0.014734	3.8%
Western region	0.018139	4.7%
Hispanics	0.023028	5.9%
Non-hispanic whites	0.015798	4.1%
Non-hispanic blacks	0.018590	4.8%
Non-hisp/non-white/non-black	0.023932	6.1%
All infants (< 1 year)	0.032546	8.3%
Nursing infants	0.019018	4.9%
Non-nursing infants	0.037682	9.7%
Children 1-6 yrs	0.048971	12.6%
Children 7-12 yrs	0.025727	6.6%
Females 13-19 (not preg or nursing)	0.015235	3.9%
Females 20+ (not preg or nursing)	0.012330	3.2%
Females 13-50 yrs	0.013916	3.6%
Females 13+ (preg/not nursing)	0.015402	3.9%
Females 13+ (nursing)	0.016392	4.2%
Males 13-19 yrs	0.016401	4.2%
Males 20+ yrs	0.011248	2.9%
Seniors 55+	0.013104	3.4%

Children 1-2 yrs	0.061534	15.8%
Children 3-5 yrs	0.045373	11.6%
Children 6-12 yrs	0.027089	6.9%
Youth 13-19 yrs	0.015950	4.1%
Adults 20-49 yrs	0.011278	2.9%
Adults 50+ yrs	0.012849	3.3%
Females 13-49 yrs	0.012266	3.1%

b. Dietary Exposure and Risk for Inert Ingredient Uses

Included in this RED is the reassessment of sodium o-phenylphenate (Na-OPP) when used as an inert ingredient in agricultural pesticide products. Sodium o-phenylphenate is formulated as inert ingredient in approximately 123 registered end-use products and is used primarily as a materials preservative. The types of products that contain Na-OPP as an inert ingredient include: turf insecticides and herbicides; garden and ornamental insecticides and herbicides; insect repellant for pets; and indoor/outdoor crack and crevice insecticides. These products are formulated as soluble concentrates, gels, flowable concentrates, ready to use liquids, granular, and bait traps. The vast majority of these products contain Na-OPP as an inert ingredient in amounts less than 2% of the formulation.

When used as an inert ingredient in agricultural insecticide and herbicide products, Na-OPP residues on food have an exemption from the requirement of a tolerance under the 40 CFR §180.920. Based on the inert ingredient use patterns, it was determined that dietary (food and water) and residential non-dietary exposure assessments were required.

Inert Dietary Exposure Assumptions

A dietary exposure analysis was conducted for the inert ingredient of sodium o-phenylphenate used in agricultural pesticide products. This dietary assessment was conducted using the generic dietary screening model for estimating dietary exposure. The generic model's output was adjusted to reflect the tolerance exemption limitation given in 40 CFR §180.920 (i.e., no more than 0.1% of the pesticide formulation) and maximum application rates. Based on a review of the agricultural labels that contain sodium o-phenylphenate as an inert ingredient, it appears that the maximum application rate (in terms of the inert ingredient) is less than 0.05 lb/acre. The generic screening model does not specifically include an application rate input; rather it is based on tolerances for pesticide active ingredients with application rates generally ranging from 1 to 5 lb ai/acre. Therefore, to more accurately estimate residues resulting from the lower application rate of 0.05 lbs sodium o-phenylphenate /acre, the results from the generic model were adjusted by a factor of 20 (using the ratio of 1 lb. per acre ÷ 0.05 lbs per acre) and 100 (using the ratio of 5 lbs. per acre ÷ 0.05 lbs/acre).

It should be noted that the generic model output is unrefined and extremely conservative since it assumes that the inert ingredient is used on all commodities and that 100 percent of each crop is treated with the inert ingredient. Further, the model assumes finite residues for every consumed commodity (including meat, milk, poultry and eggs) that is included in the Dietary Exposure Evaluation Model (DEEM™). A complete explanation of the assumptions used in the

generic screening model for estimating inert ingredient dietary exposure is given in Appendix A of the 'Inert Ingredient Dietary and Non-dietary Risk Assessments for O-Phenylphenol and Salts Reregistration Eligibility Document (RED),' dated February 22, 2006.

Inert Dietary Risk from Food

The table below (Table 8) provides a summary of the results of chronic dietary risk estimates for the inert ingredient use of sodium o-phenylphenate. An acute dietary assessment was not conducted because no acute dietary endpoint was selected.

Table 8. Estimated Chronic Dietary Exposure and Risk from use of Na-OPP as an Inert Ingredient

Population Subgroup[1]	Generic Estimated Exposure[2] (mg/kg/day)	OPP/salts Estimated Exposure[3] (mg/kg/day)	%cPAD[3]
U.S. Population (total)	0.120	0.0012 - 0.006	0.31% - 1.5%
All infants (< 1 year)	0.245	0.0025 - 0.012	0.63% - 3.1%
Children (1-2 years)	0.422	0.0042 - 0.021	1.1% - 5.4%
Children (3-5 years)	0.310	0.0031 - 0.016	0.79% - 4.0%
Children (6-12 years)	0.174	0.0017 - 0.009	0.45% - 2.2%
Youth (13-19 years)	0.100	0.0010 - 0.005	0.26% - 1.3%
Adults (20-49 years)	0.087	0.00087 - 0.004	0.22% - 1.1%
Adults (50+ years)	0.086	0.00086 - 0.004	0.22% - 1.1%
Females (13-49 years)	0.087	0.00087 - 0.004	0.22% - 1.1%

[1] Only representative population subgroups are shown
[2] Exposure estimates are based on highest-tolerance-level residues of high-use active ingredients for all food forms, including meat, milk, poultry, and eggs
[3] Generic exposures based on application rates of 1 - 5 lb ai/acre were adjusted for the tolerance exemption limitation of 0.1% maximum formulation and maximum application rates (0.05 lb inert/acre); the generic exposures were divided by a factor of 20 (1/0.05) and 100 (5/0.05)
cPAD = 0.39 mg/kg/day

Based on the results of the screening level inert ingredient dietary exposure model, there are no concerns for risks associated with dietary (food) exposures since the estimated dietary exposures for the U.S. population and all population subgroups are well below 100% of the cPAD.

c. Dietary Risk from Drinking Water

Based on the environmental fate data, OPP and salts are stable and persistent in abiotic aqueous medium at a pH of 5, 7 and 9. It degrades completely in 14 days when exposed to sunlight and is therefore photolytically unstable in neutral aqueous medium. OPP degrades when exposed to UV light (253.7 nm). Its half-life (measured against hydroxyl radical) is 14 hours, and it is unstable in the atmosphere. It has a high K_{OC} value of 10,000, and is immobile in soils.

Its major degradation pathway appears to be through biodegradation under aerobic and anaerobic conditions. Even though it is likely to stay on soil surfaces, it biodegrades under aerobic and anaerobic soil conditions and is not likely to contaminate surface water (drinking water) or migrate into ground water.

Based on the outdoor use patterns of OPP and its salts and considering their tendency to degrade in the environment, and the small amount (0.05 lbs. per acre) that may be applied to crops via the inert use, sodium o-phenylphenate is not likely to be present in drinking water sources at substantial concentrations. Therefore a quantitative drinking water assessment was not necessary and drinking water risks are not of concern.

6. Residential Risk for Active Ingredient Uses

The residential risk assessment considers all potential non-occupational pesticide exposure, other than that due to residues from food and drinking water. OPP and OPP salts are registered for residential uses such as disinfectants and deodorizers. Exposure may occur during and after application to indoor and outdoor hard surfaces (e.g., floors, bathroom fixtures, trash cans, household contents), textiles (e.g., clothing, diapers, and bedding) and carpets. Additional residential uses include fogging and air deodorizing and a material preservative for homeowner-type products (e.g., plastics and paints, glues, paper, polymers, and paper). Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose. The percentage of OPP and OPP salts in various products currently range from 0.0137% to 99.5%. For additional info, please see 'Revised Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts.'

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for OPP and salts are listed in Table 9. A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the dermal, incidental oral and inhalation routes of exposure. The MOE of 100 includes a 10x for interspecies extrapolation, and an additional 10x for intraspecies variation.

Table 9. Toxicity Endpoints Selected for Assessing Occupational and Residential Risks for OPP and Salts

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1 - 30 days)	**NOAEL (maternal)** = 100 mg/kg/day	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental (gavage) toxicity studies in rats (MRID 00067616, 92154037) and rabbits (MRID 41925003; co-critical developmental toxicity study) Maternal LOAEL of 300 mg/kg/day based upon clinical observations of

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
			toxicity, decreased weight gain, food consumption and food efficiency observed in the rat developmental toxicity study.
Incidental Oral Intermediate-Term (1 - 6 months)	**NOAEL** = 39 mg/kg/day	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity.
Dermal Short-Term (1 - 30 days) (residential and occupational)	**NOAEL (dermal)** = 100 mg/kg/day (200 µg/cm^2)[a]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	21-Day Dermal toxicity study in rats (MRID 42881901) LOAEL (dermal) of 500 mg/kg/day based upon dermal irritation (erythema, scaling) at the site of test substance application.
Dermal Intermediate- and Long-Term (1 - 6 months and >6 months) (residential and occupational)	**NOAEL** = 39 mg/kg/day[b]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13 weeks in this study), increased clinical and gross pathological signs of toxicity.
Inhalation Short-Term (1 - 30 days) (residential and occupational)	**NOAEL (maternal)** = 100 mg/kg/day[c]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Note:** an additional 10x is necessary for route extrapolation. If results are below a MOE of 1,000, a confirmatory inhalation study may be required	Developmental (gavage) toxicity studies in rats (MRID 00067616, 92154037) and rabbits (MRID 41925003; co-critical developmental toxicity study) Maternal LOAEL of 300 mg/kg/day based upon clinical observations of toxicity, decreased weight gain, food consumption and food efficiency observed in the rat developmental toxicity study.

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
Inhalation Intermediate- and Long-Term (1 - 6 months and >6 months) (residential and occupational)	**NOAEL** = 39 mg/kg/day[c]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Note:** an additional 10x is necessary for route extrapolation to determine the need for inhalation data. If results are below a MOE of 1,000, a confirmatory inhalation study may be required	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13 weeks in this study), increased clinical and gross pathological signs of toxicity.
Cancer (oral, dermal, inhalation)	**Classification:** Orthophenylphenol is classified as 'Not likely to be carcinogenic below a specific dose range', without quantification of risk.		

UF = uncertainty factor, DB UF = data base uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure

[a] $\left(\frac{100\text{mg}}{\text{Kg rat}} \times \frac{0.200 \text{ kg rat}}{} \times \frac{1000\ \mu\text{g}}{\text{mg}}\right) / 100\ \text{cm}^2 \text{ area of rat dose} = 200\ \mu\text{g/cm}^2$

[b] A dermal absorption factor of 43% was chosen based on the results of a submitted study (Timchalk et al., 1996) in humans.

[c] The inhalation absorption factor of 100% (default value, assuming oral and inhalation absorption are equivalent) is used as an assumption since an oral endpoint was selected for the inhalation exposure scenarios.

b. Residential Handler Scenarios

i. Exposure Scenarios, Data and Assumptions

The following residential handler scenarios were assessed to determine dermal and inhalation exposures from applying OPP-containing products:

- to indoor hard surfaces via mopping, wiping, and aerosol foam spray;
- to outdoor hard surfaces via tank-type low pressure garden sprayer;
- to textiles via trigger pump spray;
- for air deodorization via aerosol spray; and
- while painting via brush/roller and airless sprayer.

The majority of the scenarios were assessed using Chemical Manufacturer Association (CMA) data. However, for handlers using paint, two approaches were used to determine inhalation

exposure. First, the Pesticides Handler Exposure Database (PHED) was used to determine inhalation exposure to aerosolized particles of paint (assessed below). Secondly, to assess the inhalation exposure to OPP vapor, EPA's Wall Paint Exposure Model (WPEM) was used. For specific assumptions used in this analysis, consult the 'Revised Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts.'

ii. Residential Handler Risk Estimates

The short-term dermal and aerosol portion of the inhalation exposures and MOEs for the representative residential handler scenarios are presented in Table 10. The calculated MOEs were above the target dermal and inhalation MOE of 100 for all scenarios.

Table 10. Short-Term OPP & Salts Residential Handlers Exposures and MOEs

Exposure Scenario	Method of Application	Unit Exposure (mg/lb ai)		Application Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)		MOE (ST)	
		Dermal[a]	Inhalation			Dermal[b]	Inhalation[c]	Dermal (Target = 100)[d]	Inhalation (Target = 100)[e]
Application to indoor hard surfaces	Mopping	71.6	2.38	0.126 lb ai/gallon	1 gallons	0.1289	0.0043	780	23,000
	Wiping	2870	67.3	0.126 lb ai/gallon	0.13 gallons	0.6716	0.0157	150	6,300
	Aerosol Foam Spray	220	2.4	0.42 % ai by weight	0.875 lbs	0.0116	0.0001	8,700	7.90×10^5
Application to outdoor hard surfaces (i.e. exterior of homes)	Tank Type Low Pressure Garden Sprayer	100	0.03	0.00104 lb ai/gallon	5 gallons	0.01	0.00016	13,000	4.5×10^7
Application to textiles	Trigger Pump Spray	220	2.4	0.0208 lb ai/gallon	0.13 gallons	0.085	0.0065	12,000	1.10×10^6
Air deodorization	Aerosol Spray	220	2.4	0.199% ai by weight	1.03 lbs	0.0064	0.0001	16,000	6.70×10^6
Painting	Brush/roller	230	0.284	0.56% ai by weight	20 lb s (2 gal)	0.368	0.0005	270	220,000
	Airless sprayer	79	0.83	0.56% ai by weight	150 lbs (15 gal)	0.948	0.01	110	10,000

a All dermal unit exposures represent ungloved replicates. The aerosol spray, tank-type garden sprayer (i.e., low pressure sprayer), trigger pump sprayer, brush/roller, and airless sprayer unit exposures represent short sleeve and short pant replicates. The mopping, wiping, and liquid pour represent long pant and long shirt replicates.

b Dermal Daily Dose (mg/kg/day) = [dermal unit exposure (mg/lb ai) * application rate * quantity handled / body weight (70 kg).

c Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * application rate * quantity handled / body weight (70 kg).

d Dermal MOE = NOAEL (100 mg/kg/day) / Daily Dose. Target dermal MOE is 100.

e Inhalation MOE = NOAEL (100 mg/kg/day) / Daily Dose. Target inhalation MOE is 100.

iii. Residential Painter Inhalation Exposure and Risk

For assessment of the vapor portion of the inhalation exposure of residential painters, EPA utilized the Wall Paint Exposure Model (WPEM) version 3.2 to estimate air concentrations resulting from the use of paint preserved with OPP. WPEM was developed to allow EPA to estimate potential air concentrations and consumer/worker exposures to chemicals emitted from wall paint which is applied using a roller or a brush. WPEM uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. The emission data can then be combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc,) to estimate exposure. Specific input parameters include: the type of paint (latex or alkyd) being assessed, density of the paint (default values available), and the chemical weight fraction, molecular weight, and vapor pressure. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure/docs/wpem.htm.

Results of the WPEM model calculated the short-term vapor inhalation MOE as 1500, which does not present a risk of concern for of residential painters.

c. Residential Post-Application Exposure

i. Exposure Scenarios, Data and Assumptions

Residential postapplication exposures result when adults or children come into contact with OPP in areas where pesticide end-use products have recently been applied (e.g., treated hard surfaces/floors), or when children incidentally ingest the pesticide residues through mouthing the treated products/treated articles (through hand-to-mouth or object-to-mouth contact). The residential post-application scenarios considered in this assessment are contacting treated hard surfaces/floors (dermal and incidental oral exposure to children), wearing treated clothing (dermal exposure to adults and children), wearing treated diapers (dermal exposure to infants), mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and mouthing treated plastic toys (incidental oral exposure to infants). Additionally, post-application/bystander inhalation exposures were assessed for use of the disinfecting/deodorizing products (vapor exposure to adults and children) and paints (vapor exposure to adults and children). Typically, most products used in a residential setting result in exposures occurring over a short-term time duration (1 to 30 days).

There is the potential for dermal exposure to toddlers crawling on treated floors and for incidental oral exposure from mouthing treated objects. To calculate incidental ingestion exposure to OPP due to hand-to-mouth transfer, the scenarios established in EPA's *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* were used.

OPP labels also include an application to textiles such as bedding, linens, and uniforms through aerosol spray, trigger pump spray, and immersion. To determine dermal and incidental oral exposure to treated clothing and textiles, the guidance provided in Agency SOP's for Residential Exposure Assessments (HED, 1997, 2000, 2001) was used to estimate direct skin

exposure contact from wearing treated clothes and oral exposure from mouthing or sucking on treated fabric.

ii. Residential Post-Application Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and incidental oral exposure assessments. A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the dermal, incidental oral and inhalation routes of exposure. The MOE of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variation.

For short-term dermal exposure of adults and children wearing treated clothing, the dermal MOEs for children were below the target MOE of 100, assuming the 100% transfer of residues (MOE < 1). The Agency also calculated the risks assuming a 5% transfer or residues, resulting in a MOE of 16. For adults, the dermal MOEs were also below the target MOE of 100 assuming 100% transfer, (MOE = 1). If assuming a 5% OPP transfer of residues to skin the resulting MOE is 25 and thus present risks of concern for this scenario. In addition to treated clothing, there is the potential for dermal exposure to infants wearing cloth diapers treated with a trigger-pump spray product containing OPP. Though it is likely that the diapers treated with this product would be washed prior to use, the label does not provide specific use instructions requiring washing. Therefore, a post-application assessment assuming no laundering was conducted as a conservative measure. Calculation of short-, intermediate-, and long-term dermal doses and a MOE for infants wearing treated cloth diapers showed all MOEs below the target of 100 assuming a transfer factor of either 100% or 5% of OPP onto skin.

All other results are as follows: for incidental oral exposures of children mouthing treated textiles or treated toys, calculation of incidental oral MOEs showed no risks of concern from these exposures. Short- and intermediate-term dermal incidental oral exposures of children contacting treated floors were also above the target MOE of 100 and thus are not of concern. For both adults and children, the calculated inhalation MOEs are greater than 100 and thus present no risk of concern from this use. Results of post-application inhalation exposures for entry into a room after fogging and paint showed all of the adult and child inhalation MOEs above 100 and thus are not of concern. A summary of the residential handler exposures and risks are presented in Table 11.

Table 11. Summary Table of Residential Postapplication Exposures to OPP and OPP Salts		
Exposure Scenario[a]	**Daily Dose (mg/kg/day)[b]**	**MOE (Target MOE = 100)[c,f]**
Dermal exposure from children contacting treated floors; residential settings	0.674	150
Dermal exposure from children contacting treated floors; daycare center	0.0421	930 (IT)
Incidental oral ingestion from children contacting treated floors; residential settings	0.0824	1200
Incidental oral ingestion from children contacting treated floors; daycare centers	0.0057	6900 (IT)
Dermal exposure to adults wearing treated clothing	79.34 (assuming 100% transfer) 3.97 (assuming 5% transfer)	1 25
Dermal exposure to children wearing treated clothing	124.24 (assuming 100% transfer) 6.21 (assuming 5% transfer)	<1 16
Dermal exposure to infants wearing treated cloth diapers assuming 100% transfer	182.2 (ST) 78.35 (IT/LT)	<1 (ST/IT/LT)
Dermal exposure to infants wearing treated cloth diapers assuming 5% transfer	9.11	11
	3.92	10 (IT/LT)
Incidental oral ingestion from children mouthing treated textiles	0.329	300
Incidental oral ingestion from children mouthing treated plastic toys	0.0425	2,400
Inhalation exposure for adults in areas treated with air deodorizers	2.67 x E-04	370,000
Inhalation exposure for children in areas treated with air deodorizers	9.53 x E-04	100,000
		41,000 (IT)[d]
Inhalation (vapor) exposures for adults in areas painted with preserved paint	0.168	600
Inhalation (vapor) exposures for children in areas painted with preserved paint	0.867	120

Inhalation Exposures for Adults and Children in Fogged Houses[e]				
Inhalation exposures for adults in fogged homes (re-entry interval = 0 hours)	EXPOSURE DURATION	2 hrs 4 hrs 24 hrs	0.075 0.127 0.245	1,300 790 410
Inhalation exposures for adults in fogged homes (re-entry interval = 4 hours)		2 hrs 4 hrs 24 hrs	0.037 0.062 0.119	2,700 1,600 840
Inhalation exposures for children in fogged homes (re-entry interval = 0 hours)		2 hrs 4 hrs 24 hrs	0.280 0.475 0.913	360 210 110
Inhalation exposures for children in fogged homes (re-entry interval = 4 hours)		2 hrs 4 hrs 24 hrs	0.136 0.231 0.445	730 430 230

a: Each exposure scenario is discussed in the Occupational and Residential Exposure chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts.
b: Scenario-specific methodologies were employed for the calculation of the daily dose. For a complete discussion of the methodology and assumptions, refer to the chapter referenced in footnote 'a.'
c: All MOEs represent **short term** exposure durations unless otherwise indicated. The Target MOE for all routes of exposure and all durations is 100. For the calculated inhalation MOEs <100, a confirmatory inhalation toxicity study may be requested by the Agency.
d: Intermediate term durations were assessed for this scenario because of the potential of air deodorizers being used in daycare centers.
e: For this specific exposure scenario, please refer to Table 4.12 of the Occupational and Residential Exposure chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts chapter for a complete discussion of the model output used to calculate exposure for the durations of 2, 4, or 24 hours/day.
f: Although the target MOE is also 100 for inhalation scenarios, the Agency may request a confirmatory inhalation toxicity study in cases where the inhalation MOEs are below a value of 1,000 since the inhalation endpoint is based on an oral study.
g: ST= short-term, IT= intermediate-term, LT= long-term

7. Residential Risk for Inert Ingredient Uses

Based on the inert ingredient use patterns of sodium o-phenylphenate, it was determined that residential non-dietary exposure assessments were necessary. An inert non-dietary exposure assessment was conducted for several high-end, representative residential products used in turf and garden products as well as insect repellant pet spray products. It should be noted that the non-dietary inert assessment did not specifically evaluate indoor/outdoor crack and crevice uses since it was anticipated the applicator exposures resulting from the outdoor lawn products would result in higher exposures based on the amount used per day. Additionally, it was also anticipated that post-application exposures resulting from the use of turf products would result in higher exposures than those from indoor/outdoor crack and crevice residues. This is due to the fact that exposure to residues on a lawn are much more accessible than residues applied in cracks/crevices and along baseboards.

U.S. EPA's Pesticide Inert Risk Assessment Tool (PiRat) was used to estimate applicator and post-application exposure and risk from the use of sodium o-phenylphenate as an inert ingredient in representative residential products. Background information for PiRat can be found at http://www.epa.gov/opptintr/exposure/docs/pirat.htm. All of PiRat's default values were used in each run. Based on a review of the confidential statements of formulas (CSFs) for various types of sodium o-phenylphenate inert products, 2% was selected as a high-end representative value and was used in all of the model simulations. As previously discussed, since sodium o-phenylphenate is used in numerous types of products, only exposures from representative high-end scenarios were estimated using PiRat. These scenarios include dermal and inhalation applicator exposures from liquid turf and garden products and post-application dermal and incidental ingestion exposures to toddlers from liquid turf products. It should be noted that the post-application inhalation exposure scenario was not assessed because sodium o-phenylphenate has a low vapor pressure (1.8×10^{-9} mm Hg @ 25 degrees C) and is not expected to result in inhalation exposure. Again, it is expected that the crack and crevice applicator and post-applicator exposure scenarios would result in lower exposures and higher MOEs. All of the MOEs were greater than or equal to the target MOE of 100 and therefore are not of concern.

As previously indicated, sodium o-phenylphenate is also used as an inert ingredient in pet insect repellant products. Therefore, applicator dermal and inhalation exposures as well as, toddler post-application dermal and incidental oral exposures were evaluated. All of the MOEs were greater than or equal to the target MOE of 100 and therefore are not of concern.

8. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

a. Acute and Chronic Aggregate Risks

In general, acute and chronic dietary aggregate risks are represented by dietary (direct, indirect, and inert exposures) and drinking water exposures. As there is no acute dietary endpoint selected for OPP and drinking water exposure is not of concern, an acute aggregate dietary assessment was not performed. Chronic exposure from the direct food, indirect food, and inert uses for OPP has been assessed. Exposure from direct food and inert uses was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 2.00, which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. Exposures from indirect food uses of OPP from counter top disinfectants, dishwashing disinfectants, paper slimicides, paper coatings, and paper adhesives were derived from FDA's methodology.

Total chronic aggregate dietary exposure and risk are shown below in Table 12 for direct, indirect, and inert uses of OPP. The results indicate that for adults, 28.9% of the cPAD is

occupied from all dietary exposure sources, while for children, 64.1% of the cPAD is occupied from all dietary sources. These percentages are below 100% of the cPAD and are thus not of concern to the Agency.

Table 12. Chronic Aggregate Dietary Exposures and Risks (direct, indirect, and inert uses)

Population	Direct Dietary Exposure (mg/kg/day)	Indirect Dietary Exposure (mg/kg/day)		cumulative % cPAD
	Active	Active	Inert	
Dose (mg/kg/day)				
U.S. Population	0.017	0.09	0.006	28.9
Children	0.049	0.18	0.021	64.1

b. Short- and Intermediate-Term Aggregate Exposures and Risks

Short- and intermediate-term aggregate exposures and risks were assessed for adults and children that could be exposed to OPP and OPP salt residues from the use of products in non-occupational environments. The following lists summarize all of the non-dietary, non-occupational potential sources of OPP and OPP salt exposures for adults and children:

Adult OPP and OPP salt exposure scenarios:

- Cleaning indoor hard surfaces via mopping, wiping, or spraying
- Cleaning outdoor hard surfaces via low pressure sprayer
- Applying textile products to clothes and diapers
- Applying air deodorizers in residential settings
- Applying of OPP preserved paint in residential settings
- Wearing treated clothing
- Post-application exposure to OPP vapors from foggers used in residential settings
- Post-application exposure to OPP vapors from air deodorizers used in residential settings
- Post-application exposure to OPP vapors from OPP preserved paint used in residential settings

Child OPP and OPP salt exposures sources:

- Post-application exposures to residues from cleaning products used on hard surfaces (i.e., floors)
- Wearing treated clothing and diapers
- Post-application exposure to OPP vapors from foggers used in residential settings
- Post-application exposure to OPP vapors from air deodorizers used in residential settings
- Post-application exposure to OPP vapors from OPP preserved paint used in residential settings
- Playing with OPP preserved plastic toys

The use patterns of the products and probability of co-occurrence must be considered when selecting scenarios for incorporation in the aggregate assessment. In the case of OPP and

OPP salts, it is anticipated that homeowner painting activities occur only once or twice a year. Furthermore, the use of fogger products occurs on an intermittent basis since they are used as a cleanup after water or smoke damage. Therefore the probability of co-occurrence and the potential for exposure to residues from these products on the same day is highly unlikely. However, it is possible that someone could clean the kitchen (mopping and wiping activities) as well as, use an air deodorizer containing OPP or OPP salts during the same day.

Cleaning activities in a residential setting occur on a short-term basis. However, the OPP and salts-containing cleaning products are also labeled for use in institutional settings such as day care facilities where cleaning activities can occur on an intermediate-term basis. Therefore, children could have exposure to cleaning product residues on a long-term basis in a day care facility thus, these post-application scenarios were included in the intermediate-term aggregate assessment. Table 13 summarizes the scenarios included in the short- and intermediate-term aggregate assessments.

Table 13. Exposure Scenarios Included in the Aggregate Assessments

	Short-term Aggregate	Intermediate-Term Aggregate
Adults	Dermal: • Mopping applicator • Wiping applicator • Air deodorizer applicator	Dermal + Oral + Inhalation: • No applicable exposures
	Oral + Inhalation: • Mopping applicator • Wiping applicator • Air deodorizer applicator • Post-app to air deodorizers	
Children	Dermal: • Dermal post-app exposure to residues from mopping activities	Dermal + Oral + Inhalation: • Inhalation post-app exposure to air deodorizer residues • Oral post-app exposure to residues from mopping activities • Dermal post-app exposure to residues from mopping activities
	Oral + Inhalation: • Inhalation post-app exposure to air deodorizer residues • Oral post-app exposure to residues from mopping activities	

Short- term aggregate exposures and risks were assessed for adults and children that could be exposed to OPP and OPP salt residues from the use of products in non-occupational environments. The short-term dermal toxicity endpoint (NOAEL of 100 mg/kg/day from a 21-day dermal toxicity study) was based on skin irritation. In comparison, the short-term oral and inhalation endpoints were based on systemic effects from the same study and toxic effect (NOAEL of 100 mg/kg/day from developmental toxicity studies). Therefore, short-term dermal exposures were aggregated in a separate analysis from the short-term inhalation and oral exposures.

For OPP, the short-term aggregate assessment includes average (chronic) dietary exposure and estimated exposures from incidental oral and inhalation exposure that are believed to co-occur. For short-term aggregate risk to adults, the average dietary exposure was aggregated with short-term oral and inhalation exposures that occur from mopping, wiping, and air deodorizer uses for the short-term incidental oral and inhalation residential exposures. The results showed no aggregate risks of concern to adults applying OPP through wiping, mopping, or air deodorizing activities (total MOE = 323). For short-term aggregate risk to children, the average dietary exposure was aggregated with short-term oral and inhalation exposures that occur from mopping, wiping, and air deodorizer uses for the short-term incidental oral and inhalation residential exposures The results showed no aggregate risks of concern to children exposed post-application to OPP through mopping, or air deodorizing activities (total MOE = 137). These results can be seen in Tables 14 and 15 below. Dermal aggregate risk is assessed separately as the effect was different for this route of exposure.

Table 14. Short-term Aggregate Exposures and Risks for Adults

Exposure Routes	Exposure (mg/kg/day)	Margin of Exposure	Total MOE
Dietary aggregate	0.113	345	**323**
Inhalation exposure -wiping -mopping -air deodorizer	 0.0157 0.0043 0.0001	 6400 23,000 1,000,000	
Inhalation post-app Air deodorozer	0.00026	375,000	

Aggregate MOE = 1/(1/MOEdiet) + (1/MOEwipe, app-inhal) + (1/MOEmop,app-inhal) + (1/MOEair deodorizer, app-inhal) + (1/MOEair deodorizer, post-inhal))

Table 15. Short-term Aggregate Exposures and Risks for Children

Exposure Routes	Exposure (mg/kg/day)	Margin of Exposure	Total MOE
Dietary aggregate	0.25	156	**137**
Inhalation exposure -mopping	0.0824	1200	
Inhalation post-app Air deodorozer	0.00095	105,000	

Aggregate MOE = 1/(1/MOEdiet) + (1/MOEmop,post- app:oral) + (1/MOEair deodorizer, post app: inhal))

Results of the short-term dermal aggregate assessment are presented in Table 16. Dermal exposure to adults also showed no risk of concern (total MOE = 141) as well as dermal exposure to children (MOE = 111).

Table 16. Short-term Aggregate Dermal Exposures and Risks

Exposure Routes	**Adults**		**Children**	
	Exposure (mg/kg/day)	Margin of Exposure	Exposure (mg/kg/day)	Margin of Exposure
Wiping	0.672	148	0.674	148
mopping	0.129	775	N/A	
Air deodorizer	0.0064	15625	**N/A**	
Pet product (inert use)	0.00052	192307	0.32	312
TOTAL MOE	0.807	**141**	0.99	**111**

Aggregate MOE = 1/((1/MOEwipe) + (1/MOEmop) + (1/MOEair deodorizer))

Intermediate-term aggregate risks are presented in Table 17. The intermediate-term toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same combined oral toxicity/carcinogenicity study in rats in which both the NOAEL (39 mg/kg/day) and the LOAEL (200 mg/kg/day) were determined based on decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity; therefore, all intermediate-term routes were aggregated together, as appropriate. There are no intermediate-term residential scenarios identified for adults. For children, intermediate-term scenarios were identified for post-application oral, inhalation, and dermal exposures from household cleaning, i.e., day care centers. Intermediate-term aggregate risk (children only) was calculated to be 130. This value is above the target MOE of 100 and are thus not of concern.

Dermal post-application exposures to adults and children from treated textiles are of concern to the Agency and, therefore, were not included into the aggregate assessment as this would make aggregate risk of concern. This exposure scenario will be mitigated in order to make exposure from this use of OPP not of concern.

Table 17. Intermediate-term Aggregate Exposures and Risks for Children

Exposure Routes	Exposure	Margin of Exposure
Dietary aggregate	0.25	156
Post-app incidental oral from mopping	0.0057	6800
Post-app dermal from mopping	0.0421	930
Incidental Oral pet product inert use	0.0039	10,000
Inhalation air deodorizer post-app	0.00095	41,000
Total	0.298	**130**

a: Aggregate MOE = 1/(1/MOEdiet) + (1/MOEinc. oral post-app) + (1/MOEdermal post-app) + (1/MOE inc.oral pet product) + (1/MOE inhalation air deodorizer)

9. Occupational Risk

Potential occupational handler exposure can occur in various use sites, which include; agricultural premises, food handling premises, commercial/institutional/industrial premises, and medical premises. Additionally, occupational exposure can occur during the preservation of materials that are used for household, institutional, and industrial uses, along with the preservation of wood. Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of OPP include formulated product handlers, material preservative handlers, and metal working fluids handlers. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of OPP, MOEs greater than 100 are not of concern to the Agency. This MOE includes the standard safety factors of 10X for intraspecies variability (i.e., differences among humans) and 10X for interspecies extrapolation (differences between humans and animals).

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve efficacious results. For additional information, please see 'Revised Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts.'

a. Occupational Toxicity

Please see Table 10, "Summary of Toxicological Doses and Endpoints for Orthophenylphenol for Use in Human Risk Assessments," as it provides a listing of the toxicological endpoints used in the occupational risk assessment for OPP.

b. Occupational Handler Exposure

<u>Formulated Product Handlers</u>:

EPA has assessed the exposure to handlers mixing/loading/applying products containing the active ingredients orthophenylphenol or its salts. The following handler exposure scenarios were assessed and represent the high end exposures to industrial uses of the formulated product.

- Direct application of the undiluted liquid product via a low-pressure hand wand, high-pressure spray, mopping, wiping, or trigger pump spray.
- Pouring the undiluted OPP or OPP-Salt containing liquid product into a fogging mechanism.
- Pouring the OPP or OPP-Salt containing liquid product into a mixture with water and then using the mixture for a low pressure hand wand, mopping, wiping, trigger pump spraying, or airless spraying application.
- Spraying the OPP or OPP-Salt containing product into the air through handling a can in which the contents are under pressure and are aerosolized.

- Pouring or pumping the OPP or OPP-Salt containing liquid biocide preservative into metalworking fluid.
- Pouring or pumping the OPP or OPP-Salt containing liquid biocide preservative into industrial process intermediate materials (dispersions, slurries, emulsions, solutions, etc. used to make paint and textiles)

Post application bystander exposure was also assessed for the fogging scenario. However, all of the industrial bystander post application inhalation exposures were not assessed because there is no data available and monitoring data is needed. There are no chemical-specific exposure data to assess primary handler applications, such that dermal and inhalation exposures were assessed using CMA surrogate exposure data as well as PHED data. In addition, product label maximum application rates, related use information, and Agency standard values were used to assess exposures.

Material Preservative Handlers:

EPA has assessed the exposure to handlers mixing/loading/applying products containing the active ingredient as a material preservative, not the formulated product (previously defined as "secondary" handlers). This includes those individuals exposed to the active ingredient as a direct result of its incorporation into an end use product (e.g., individuals using paint that in itself is not a registered product). The scenario assessed has been selected to represent the high end of exposure to these types of products.

Metal Working Fluids Handlers:

Potential inhalation and dermal exposure may exist when using treated metal working fluid. A screening-level long-term inhalation exposure estimate for treated metal working fluids has been developed using the OSHA PEL for oil mist. The Agency conducted the screening level assessment for metal working fluids using the USEPA/OPPTS Chemical Engineering Branch (CEB) model (U.S. EPA, 1991). The CEB model uses measured and/or assumed airborne oil mist concentrations for metal working operations. Since no measured concentrations are available for OPP and OPP salts, the high-end oil mist concentration is based on the OSHA's Permissible Exposure Limit (PEL) of 5 mg/m3 (NIOSH, 1998). Registered product labels indicate that 1.5% (i.e., 0.015) of the labeled product is added to metal working fluids and of that, 99.5% is the active ingredient (OPP Salt). Therefore, the upper bound air concentration dose of OPP salt that a worker is exposed to is 0.0107 mg/kg/day. Additionally, the following assumptions were made in the assessment: the inhalation rate for adults is 1.25 m3 /hr; the exposure duration is 8 hours; and body weight is 70 kg.

Wood Preservation Handlers:

OPP and OPP salts are used in products that are intended to preserve wood (non-pressure treatment). OPP Salt for wood preservation provides the temporary protection of freshly sawn lumber against staining and molding. The scenarios that were identified and assessed for wood preservation were extracted from a proprietary study submitted for Didecyl Dimethyl Ammonium Chloride (DDAC). The Agency used this study to establish potential exposure

pathways for this use. An individual is anticipated to come into contact with OPP whether they are the handlers of the wood preservative itself or via post application (e.g. handling treated wood or encountering areas where wood treatment occurred). Exposure is expected to occur through handling the wood preservative or via handling the treated wood itself.

The CMA unit exposure data were used to assess exposure and risks for the job function that involves blender/spray operators. The operators fill the blender/sprayer system for composite wood via closed-liquid pumping. The liquid pump preservative unit exposures for gloved workers were used. The quantity of the wood being treated was derived from standard Agency assumptions for wood slurry because no chemical specific data were available for OPP. Please refer to "Revised Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts," dated April 4, 2006 for more detail.

The CMA data were inadequate to represent all job functions associated with preservation of non-pressure treated wood, therefore, previously mentioned, surrogate data was obtained from a proprietary DDAC study for the following job functions: Chemical Operators, Graders, Millwrights, Clean-up Crews, and Trim Saw Operators. The Agency assessed short-, intermediate-, and long-term durations for these worker functions. Exposures to diptank operators were also assessed using surrogate data from the DDAC study (Bestari et al., 1999).

Not enough data exists to estimate the amount of exposure associated with construction workers who install treated wood. In particular, values for the transfer coefficient associated with a construction worker handling the wood could not be determined. However, it is believed that the construction worker using a trim saw will have larger dermal and inhalation exposures than the installer, due to the amount of sawdust generated and the greater amount of hand contact that would be necessary to handle the wood when using a saw compared to installing the wood.

Agricultural-Application Handlers:

OPP and NA-OPP are used as a conventional post-harvest fungicide for citrus and pears. Application rates range from 0.0066 to 0.264 lb ai/gallon solution (0.05 to 2% solution by weight). Approximately 3,000-10,000 lbs of fruit are treated per gallon of solution depending on the concentration of active ingredient. For example, the ready-to-use (RTU) thermo-fogging product has an application rate of 0.0633 lb ai/2200 lbs fruit. It is to be noted that in the absence of actual chemical specific data, the Agency utilizes data from the Pesticide Handler Exposure Database (PHED), Version 1.1 to assess handler exposures. The potential exists for dermal and/or inhalation exposure during the following occupational handler scenarios:

- Mixing/loading (M/L) liquid concentrate solutions for post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading RTU solutions for post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading RTU solution for thermo-fogging post-harvest treatment using an XEDA® Electrofogger; significant dermal and inhalation exposures are not expected for thermo-fogging applications – workers are not present within the storage rooms during the application process;

- Application of solutions by foaming, dipping, drenching, brushing, spraying for inhalation exposure only. *Note: this scenario is not a typical "applicator" scenario. The assessment for automated application estimates exposures and risks (inhalation exposure only – automated application process results in negligible dermal exposure) for workers in the vicinity of the application process.*

c. Occupational Handler Risk Summary

The results of the short-term MOE analysis for antimicrobial exposure scenarios are shown in Table 18. The results of the intermediate-, and long-term analyses are shown in Table 19. For additional information, please see 'Revised Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts.'

Table 18. Estimates of Short-term Risks to Occupational Handlers of OPP[a] and OPP Salt containing products

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Baseline Dermal MOE (Target MOE =100)	PPE Dermal MOE (Target MOE = 100)
Occupational Handler				
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **agricultural** premises	Indoor hard surfaces	56,000	200	NA[e]
Handling OPP-containing solutions using **high pressure spray** methods for cleaning in **agricultural** premises		80,000	NA	3,800
Handling OPP-containing solutions using **mopping** methods for cleaning in **agricultural** premises		80,000	2,700	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **agricultural premises**		22,000	510	NA
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **food handling** premises	Indoor hard surfaces	1.3 E 06	4,700	NA
Handling OPP-containing solutions using **mopping** methods for cleaning in **food handling** premises		380,000	13,000	NA

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Baseline Dermal MOE (Target MOE =100)	PPE Dermal MOE (Target MOE = 100)
Handling OPP-containing solutions using **wiping** methods for cleaning in **food handling** premises		100,000	2,400	NA
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **commercial/institutional** premises	Indoor Hard surfaces	280,000	1,000	NA
Handling OPP-containing solutions using **mopping** methods for cleaning in **commercial/institutional** premises		1,200	390	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **commercial/institutional** premises		3,200	**74**	NA
Handling OPP-containing solutions using **airless spraying** methods for cleaning in **commercial/institutional** premises	Outdoor hard surfaces	200,000	4,400	12,000
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **medical** premises	Indoor hard surfaces	280,000	1,000	NA
Handling OPP-containing solutions using **mopping** methods for cleaning in **medical** premises		2,800	**93**	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **medical** premises		17,000	400	NA
Handling OPP-containing **paints** via method of **brush/roller** applications	Painting [c]	89,000	140	1,000
Handling OPP-containing **paints** via method of **airless spraying** applications		3,000	**66**	180
Inhalation exposures to vapors as a result of handling	Painting	43	NA	NA

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Baseline Dermal MOE (Target MOE =100)	PPE Dermal MOE (Target MOE = 100)
OPP-preserved **paints**				
Handling OPP-containing **metalworking fluids** via hand immersion (machinist)	Metalworking fluids	9,300	**54**[d]	NA
Dipping or lowering wood into a OPP-containing solution[b]	Wood preservation	34,000	NA	520
Occupational Handlers (Formulated Product)				
Handling OPP-containing solutions using **trigger pump spray** methods for cleaning in **agricultural** premises	Indoor hard surfaces	1.1 E 06	7,700	18,000
Liquid pouring of OPP-containing products for fogging in **agricultural** premises	Fogger	2,200	NA	120
Application of OPP-containing products using **trigger pump spray** methods for cleaning in **food handling** premises	Indoor hard surfaces	6.1 E 06	42,000	98,000
Handling OPP-containing products using **trigger pump spray** methods for cleaning in **commercial/institutional** premises	Indoor hard surfaces	620,000	4,200	10,000
Handling OPP-containing products for via **aerosol** methods for cleaning in **commercial/institutional** premises	Air deodorization	900,000	6,200	14,000
Liquid pouring of OPP-containing products for fogging in **commercial/institutional** premises	Fogger	650,000	NA	270
Handling OPP-containing products using **trigger pump spray** methods for cleaning in **medical** premises	Indoor hard surfaces	620,000	4,200	10,000
Handling OPP-containing productsr via **aerosol** methods for cleaning in **medical** premises	Air deodorization	900,000	6,200	14,000
Mixing/loading/ OPP-containing biocides using	Metalworking fluids	5,800	NA	270

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Baseline Dermal MOE (Target MOE =100)	PPE Dermal MOE (Target MOE = 100)
liquid open pour methods for preservative products	Paint	180,000	NA	4,600
	Textiles	3,600	NA	**90**
Mixing/loading OPP-containing biocides using **liquid pump** methods for preservative products	Metalworking fluids	14,000	NA	160
	Paint	310,000	NA	20,000
	Paper pulp	6,900	NA	410
	Textiles	31,000	NA	2,000
Mixing/loading OPP-containing biocides using **liquid pump** methods for blender/spray operators treating wood [b]	Wood preservation	2,200	140	NA
Flushing and cleaning spray nozzles (**chemical operators**) in contact with OPP-containing biocides for treating wood [b]		1.0 E06	2,900	NA

a: References to OPP containing products can also mean OPP Salt containing products. For simplicity, since these actives are addressed in the same RED, they are generically referred to as OPP containing products.
b: For wood preservation, please see the OPP and OPP Salts ORE for a detailed discussion of the worker functions listed, and whether or not the data was based on gloved or ungloved monitoring. These were extracted from MRID 455243-04, "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)*" (Bestari et al., 1999). This is a proprietary task force study (task force # 73154) that includes the potential ways that the Agency believes an individual can come into contact with preserved wood.
c: Any risks associated with painting with OPP preserved paint can not be mitigated by the use of gloves. The reason for this is because the paint is the end-use product, which contains OPP or OPP Salt as a preservative.
d: The dermal exposure MOE for the machinist exposed to metalworking fluids treated with OPP was assessed as a baseline route. The reason for this is because the estimates were derived using the 2-hand immersion model from ChemSTEER. This is thoroughly discussed in the OPP and OPP Salts ORE chapter.
e: The text "NA" throughout the table indicates that no data was available.

Table 19. Estimates of Intermediate-term and Long-Term Risks to Occupational Handlers of OPP and OPP Salt containing products

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Baseline Dermal MOE (Target MOE =100)	PPE Dermal MOE (Target MOE = 100)	Total Baseline IT MOE (Target MOE = 100)	Total PPE IT MOE (Target MOE = 100)
Occupational Handler						
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **agricultural** premises	Indoor hard surfaces	22,000	200	NA	180	NA
Handling OPP-containing solutions using **high pressure spray** methods for cleaning in **agricultural** premises		31,000	NA	3,800	NA	3,100
Handling OPP-containing solutions using **mopping** methods for cleaning in **agricultural** premises		31,000	2,400	NA	2,200	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **agricultural premises**		85,000	460	NA	440	NA
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **food handling** premises	Indoor hard surfaces	510,000	4,300	NA	4,300	NA

Handling OPP-containing solutions using **mopping** methods for cleaning in **food handling** premises		150,000	11,000	NA	10,000	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **food handling** premises		40,000	2,200	NA	2,100	NA
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **commercial/institutional** premises	Indoor Hard surfaces	110,000	910	NA	900	NA
Handling OPP-containing solutions using **mopping** methods for cleaning in **commercial/institutional** premises		4,600	350	NA	330	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **commercial/institutional** premises		1,200	**68**	NA	**64**	NA
Handling OPP-containing solutions using **airless spraying** methods for cleaning in **commercial/institutional** premises	Outdoor hard surfaces	79,000	4,000	11,000	3,800	9,700
Handling OPP-containing solutions using **low pressure handwand** methods for cleaning in **medical** premises	Indoor hard surfaces	110,000	910	NA	902	NA

Handling OPP-containing solutions using **mopping** methods for cleaning in **medical** premises		1,100	**84**	NA	**78**	NA
Handling OPP-containing solutions using **wiping** methods for cleaning in **medical** premises		6,700	360	NA	340	NA
Handling OPP-containing **paints** via method of **brush/roller** applications	Painting [c]	NC	NC	NC	NC	NC
Handling OPP-containing **paints** via method of **airless spraying** applications		NC	NC	NC	NC	NC
Handling OPP-containing **metalworking fluids** via hand immersion (machinist)[d]	Metalworking fluids	3,600	290	NA	270	NA
Dipping or lowering wood into a OPP-containing solution[b]	Wood preservation	13,000	NA	470	NA	450
Occupational Handlers (Formulated Product)						
Handling OPP-containing solutions using **trigger pump spray** methods for cleaning in **agricultural** premises	Indoor hard surfaces	440,000	7,000	16,000	6,900	15,000
Liquid pouring of OPP-containing products for fogging in **agricultural** premises	Fogger	880	NA	110	NA	**98**

Application of OPP-containing products using **trigger pump spray** methods for cleaning in **food handling** premises	Indoor hard surfaces	2.4 E 06	89,000	38,000	37,000	86,000
Handling OPP-containing products using **trigger pump spray** methods for cleaning in **commercial/institutional** premises	Indoor hard surfaces	2.4E 05	3,800	9,000	3,700	8,700
Handling OPP-containing products for via **aerosol** methods for cleaning in **commercial/institutional** premises	Air deodorization	350,000	5,600	13,000	5,500	13,000
Liquid pouring of OPP-containing products for fogging in **commercial/institutional** premises	Fogger	25,000	NA	880	NA	28,000
Handling OPP-containing products using **trigger pump spray** methods for cleaning in **medical** premises	Indoor hard surfaces	240,000	3,800	9,000	3,700	8,700
Handling OPP-containing productsr via **aerosol** methods for cleaning in **medical** premises	Air deodorization	35,000	5,600	13,000	5,500	13,000
Mixing/loading/ OPP-containing biocides using **liquid open pour** methods for preservative products	Metalworking fluids	2,300	NA	240	NA	220
	Paint	70,000	NA	4,200	NA	4,000

	Textiles	1,400	NA	**83**	NA	**78**
Mixing/loading OPP-containing biocides using **liquid pump** methods for preservative products	Metalworking fluids	5,500	NA	140	NA	140
	Paint	120,000	NA	18,000	NA	16,000
	Paper pulp	2,700	NA	370	NA	330
	Textiles	12,000	NA	1,800	NA	1,600
Mixing/loading OPP-containing biocides using **liquid pump** methods for blender/spray operators treating wood [b]	Wood preservation	840	130	NA	110	NA
Flushing and cleaning spray nozzles (**chemical operators**) in contact with OPP-containing biocides for treating wood [b]		3.9 E05	2,400	NA	2,600	NA

a: References to OPP containing products can also mean OPP Salt containing products. For simplicity, since these actives are addressed in the same RED, they are generically referred to as OPP containing products.
b: For wood preservation, please see the OPP and OPP Salts ORE for a detailed discussion of the worker functions listed, and whether or not the data was based on gloved or ungloved monitoring. These were extracted from MRID 455243-04, "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)*" (Bestari et al., 1999). This is a proprietary task force study (task force # 73154) that includes the potential ways that the Agency believes an individual can come into contact with preserved wood.
c: Any risks associated with painting with OPP preserved paint can not be mitigated by the use of gloves. The reason for this is because the paint is the end-use product, which contains OPP or OPP Salt as a preservative.
d: The dermal exposure MOE for the machinist exposed to metalworking fluids treated with OPP was assessed as a baseline route. The reason for this is because the estimates were derived using the 2-hand immersion model from ChemSTEER. This is thoroughly discussed in the OPP and OPP Salts ORE chapter.
e: The text "NA" throughout the table indicates that no data was available. The text "NC" is applicable to the use of preserved paint. The reason for the IT durations of exposures not being assessed is because it is assumed that specifically OPP or OPP Salt treated paint is not used on a continuious basis by professional painters.

Antimicrobial Applications:

All MOEs in the occupational setting were above the target MOE of 100 for dermal, inhalation and total exposures, except for the following scenarios:

- Agricultural premises, fogging: intermediate-term PPE Total MOE = 98
- Commercial/Institutional premises, wiping: short-term baseline dermal MOE= 74, intermediate-term baseline dermal MOE = 68, and intermediate-term baseline Total MOE = 64.
- Medical premises, mopping: short-term baseline dermal MOE= 93, intermediate-term baseline dermal MOE = 84, and intermediate-term baseline Total MOE = 78.
- Materials Preservatives, liquid pour preservation of textiles: short-term PPE dermal MOE= 92, intermediate-term PPE dermal MOE = 83, and intermediate-term Total MOE = 78.
- Materials Preservatives, painter (applying paint post-preservation), airless sprayer: baseline dermal short-term MOE = 66.

It should be noted that although the target inhalation MOE is 100, if the MOE is below 1,000 the Agency may request a confirmatory inhalation toxicity study because the current inhalation endpoint is based on an oral NOAEL in animal studies. Further, given the low vapor pressure of OPP, route-to-route extrapolation becomes more uncertain. Therefore, the Agency will request an inhalation study. All of the occupational inhalation MOEs were above 1,000, except for the following scenarios:

- Agricultural equipment, fogger MOE = 880

Agricultural Applications:

With the use of chemical-resistant gloves, short-term dermal risks are not of concern for handlers. Short-term inhalation risks are not of concern without respiratory protection. Intermediate-/long-term dermal risks are not of concern when chemical-resistant gloves are used and intermediate-/long-term inhalation risks are not of concern.

d. Occupational Post-Application Exposure and Risk

Antimicrobial Applications:

Occupational post-application exposures were assessed for inhalation from fogging use and dermal and inhalation from metalworking fluid use. In addition, the potential for inhalation exposures to the vapor of OPP may occur to bystanders as a result of material preservative applications in industrial settings. Currently, no data are available to assess these bystander exposures and therefore, monitoring data are needed. The results of the MOE analysis are shown in Table 20 below.

Table 20. Estimates of Postapplication Risks to Occupational Handlers of OPP[a] and OPP Salt containing products

Scenarios	Use Site Category	Inhalation MOE (Target MOE =100)	Dermal MOE (Target MOE =100)	Total IT MOE (Target MOE = 100)
Inhalation exposure to vapors as a result of **fogging** with OPP-containing solutions in **agricultural premises**	Indoor Barn	690 (ST) 270 (IT/LT)	NA[d]	NA
Exposures as a result of handling OPP-treated wood via **grading**[b]	Wood preservation	3.7 E05	8,100	7,900
Exposures as a result of handling OPP-treated wood via **trim saw**[b]		1.8 E05	18,000	17,000
Exposures as a result of handling OPP-treated wood via **millwright** responsibilities[b]		1.9 E05	2,000	2,000
Exposures as a result of handling OPP-treated wood via **cleanup crew** responsibilities[b]		18,200	460	450
Exposures as a result of handling OPP-treated wood via **installing construction materials**[b,c]		NA	NA	NA

a: References to OPP containing products can also mean OPP Salt containing products. For simplicity, since these actives are addressed in the same RED, they are generically referred to as OPP containing products.
b: for all of the scenarios listed for wood preservation, refer back to the OPP and OPP Salts ORE chapter for a complete description of the input parameters and assumptions used in the calculations. This specific portion of the assessment was conducted through using MRID 455243-04, "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)*" (Bestari et al., 1999). This is a proprietary task force study (task force # 73154) and it was determined to include the potential ways that the Agency believes an individual can come into contact with preserved wood.
c: Not enough data exists to estimate the amount of exposure associated with construction workers who install treated wood. However, it is believed that the construction worker using a trim saw will have larger dermal and inhalation exposures than the installer, due to the amount of sawdust generated and the greater amount of hand contact that would be necessary to handle the wood when using a saw compared to installing the wood.
d: "NA" indicates the values were not calculated because they were not applicable to the scenario assessed.

i. Fogging

Inhalation exposures were assessed for entry into a building that has gone through a fogging application; it is assumed that dermal post-application exposure is negligible. The inhalation exposure assessment was conducted using the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). Based on the modeled output, both the short-term MOE (690) and the intermediate-term MOE (270) were above the target MOE of 100 but below 1,000.

Therefore, the Agency may request that a confirmatory inhalation toxicity study be submitted since the current inhalation endpoint is based on an oral toxicity study.

ii. Metalworking Fluids: Machinist

There is a potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and a machinist is using/handling this treated end-product.

For dermal exposures, a short-, intermediate-, and long-term exposure estimate were derived using the 2-hand immersion model from ChemSTEER. The dermal MOE value calculated is above the target MOE of 100 for intermediate- and long-term dermal exposures (MOE = 290). However, there is concern with short-term dermal exposure because the calculated MOE of 54 is below the target MOE of 100. It should be noted that the short-term end point is based on the dermal irritation and therefore, a higher film thickness value was used in comparison to the intermediate-term and long-term exposures.

For inhalation exposures, a screening-level intermediate and long term inhalation exposure estimate for treated metalworking fluids has been developed using the OSHA PEL for oil mist. The inhalation MOE values for IT/LT and ST exposures to OPP and OPP salts are all above the target MOE of 100 (IT/LT MOE = 3,600 and ST MOE = 9,300) and are therefore not of concern.

iii. Wood Preservation

OPP and OPP salts are used in products that are intended to preserve wood (non-pressure treated wood). OPP Salt for wood preservation serves to temporarily protect freshly sawn lumber against staining and molding. Products are applied to the freshly sawn lumber by either dipping or spraying.

Calculation of short-, and intermediate term and IT total MOEs for the workers adding the preservative to the wood slurry showed that all of the MOEs were above the target MOE of 100 and therefore do not pose a concern. However, the IT inhalation MOE (840) for the blender/spray operators adding the chemical via closed-liquid pumping is less than 1,000 and therefore a confirmatory inhalation toxicity study may be requested.

For dip tank operators, the exposure assessment was conducted differently than for the other job functions. This was because concentrations of OPP in the diptanks were known. Calculation of dermal and inhalation MOEs as well as total intermediate-term MOEs showed that all were above the target MOE of 100 and are therefore not of concern.

Calculation of short- and intermediate-term dermal and inhalation MOEs for other job functions (chemical operators, trim saw operators, millwrights, cleanup crews, and construction workers) showed all MOEs above the target level of 100. In addition, the total intermediate term MOEs were also above the target level of 100 for the entire list of job functions and are therefore not of concern.

Agricultural Applications:

In the case of Na-OPP/OPP post-harvest commodity applications, workers performing sorting and packing activities are potentially exposed to Na-OPP/OPP following application. Additionally, potential dermal and inhalation exposures exist for storage room re-entry workers following thermo-fogging applications performing post-treatment residue sampling and for workers transporting treated pears from storage to be processed and/or distributed.

Table 21 below summarizes the postapplication risk estimates for citrus and pear facilities. Short-term risk calculations are shown using both the arithmetic mean and maximum reported exposures; intermediate-/long-term risks are calculated using the arithmetic mean only. The short-term dermal risk for pear sorters was reported to be a risk of concern (MOE = 51) when the maximum reported dermal exposure for pear sorters was used. This risk was calculated with the maximum reported single exposure (out of 15 data points) for pear sorters in Washington state. However, it should be noted that it is unlikely that this level of dermal exposure would persist over the entire short-term exposure duration (i.e., up to 30 days), and is a conservative risk estimate. Further, the Agency believes the mean exposure is likely to be more representative of the actual exposure to pear sorters for this duration. Additionally, all dermal risk estimates are calculated with exposures adjusted for the maximum-labeled application rate (2% solution) while the study used was conducted at much lower levels (0.2%). This necessitated the use of linear extrapolation to the higher rate, which may add further conservatism to the assessment. Therefore this risk calculation is very conservative and the MOE is not of concern. The short-term dermal risk using the average of dermal exposure for pear sorters (MOE = 120) may be a more appropriate estimate.

Table 21. Postapplication Risk Estimates for Sorters and Packers in Citrus Fruit and Pear Facilities

Postapplication Activity	Crop (State)	Short-term Risk (Target MOE = 100)				Intermediate-/Long-term Risk (Target MOE = 100*)	
		Dermal MOE		Inhalation MOE		Dermal MOE	Inhalation MOE
		Mean	Max	Mean	Max	Mean	Mean
Pre-sorting	Citrus (FL)	240	150	20000	11000	220	7900
	Citrus (CA)	870	580	5900	2800	790	2300
Sorting	Pears (WA)	120	51	5800	3600	110	2200
	Citrus (FL)	770	550	28000	18000	700	11000
	Citrus (CA)	2200	880	72000	20000	2000	28000
Packing	Pears (WA)	190	130	7300	5700	170	2800

	Citrus (FL)	1300	620	120000	100000	1100	47000
	Citrus (CA)	5500	2400	81000	33000	5000	32000
Note: Dermal risks are calculated with exposures adjusted to the maximum labeled application rate (2% solution).							

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for OPP and salts use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the document "Ecological Hazard and Environmental Risk Assessment: 2-Phenylphenol and Salts", dated April 10, 2006.

1. Environmental Fate and Transport

Orthophenylphenol (and its salts, collectively) is stable and persistent in abiotic aqueous medium at pHs 5, 7 and 9. When exposed to sunlight in neutral aqueous medium, it degrades with a half-life of 14 days. Photolytically, therefore, it is not stable. Exposure to uv light (at 253.7 nm), results in the degradation products: phenyl benzoquinone, phenylhydroquinone, and 2-hydroxy benzofuran. Its half-life in air is 14 hours (measured against the reaction with hydroxyl radical). OPP in its vapor form in the air is unstable and not persistent. It is immobile in soils with a K_{OC} value of 10,000. Ground water contamination does not seem likely. The major degradation route appears to be through biodegradation in aerobic and anaerobic environments. The observed half-life values vary from three hours to three weeks, depending on the exposure site (holding pond to open river etc.) When wood is treated for antisapstain use, NA-OPP leaches up to 58% the first day after application (highest application rate for NA-OPP is 4%). After day 14, 86% of NA-OPP leaches out from the treated wood.

2. Ecological Risk

Most uses of 2-phenylphenol are considered to be indoor uses. The discharge of any effluents which might contain 2-phenylphenol residues is regulated by the NPDES program; facilities discharging any such effluents are required to have an NPDES permit prior to discharging effluents into receiving waters. The EPA Office of Research and Development, National Risk Management Research Laboratory's Treatability Database shows that wastewater treatment technologies have 95% removal efficiency for phenolic compounds. This, coupled with 2-phenylphenol's tendency to degrade under aerobic and anaerobic conditions in the environment, indicates that environmental exposure from the indoor uses of 2-phenylphenol is likely to below.

Based on the results of the antisapstain modeling, runoff from antisapstain treating facilities will exceed acute high risk, restricted use, and endangered species LOCs for freshwater

fish, freshwater invertebrates, and aquatic plants. Chronic risks cannot be assessed at this time due to a lack of chronic toxicity data.

The model used to estimate exposure from antisapstain uses is intended as a Tier I screening model, and, as such, has inherent assumptions and uncertainties that may result in over- or under-estimation of exposure levels. Since the model is only intended as a screening-level model, further refinement of the model is necessary to more accurately assess risks from the antisapstain uses of 2-phenylphenol. Table 22 summarizes the ecotoxicity endpoints used in the risk assessment.

Table 22. Ecotoxicity endpoints used in the Risk Assessment

Guideline	Species	Value	Toxicity category	Status of Guideline
850.2100/71-1 Avian acute oral	Northern bobwhite	LD50 = 1000 mg/kg	Slightly toxic	Fulfilled
850.2200/71-2a	Northern bobwhite	LC50 > 5620 ppm	Practically non-toxic	Fulfilled
850.2200/71-2b	Mallard duck	LC 50 . 5620 ppm	Practically non-toxic	Fulfilled
850.1075/72-1a	Bluegill sunfish	LC50= 4.6 mg/L	Moderately toxic	Fulfilled
850.1075/72-1c	Rainbow trout	LC50 = 4.0 m g/L	Moderately toxic	Fulfilled
850.1010/72-2	Water flea	EC50 = 2.51 mg/L	Moderately toxic	Fulfilled
850.1075/72-3a Marine/estuarine fish acute				Data gap
850.1025/72-3b	Eastern oyster – shell deposition	EC50 = 3.89 mg/L	Moderately toxic	Fulfilled
850.1035/72-3c	Mysid	LC50 = 0.32 mg/L	Highly toxic	Fulfilled
850.1300/72-4a Fish early life-stage				Data gap
850.1400/72-4b Aquatic invertebrate life-cycle				Data gap
850.4225/122-1a Seedling emergence in rice, Tier I	Rice	At 1000 mg/L, percent emergence was decreased 7%, shoot length was decreased by 4% (with 10% mortality), and shoot dry weight was decreased by 2%.	N/A	Fulfilled
850.4225/122-1b Vegetative vigor in rice, Tier I	Rice	At 1000 mg/L, slight decreases in shoot length (5%) early in the study, and a slight decrease in dry weight (2%) by the end of the study.	N/A	Fulfilled

850.4400/123-2 Aquatic vascular plant toxicity	Duckweed	EC50 = 6.2 mg/L	N/A	Not fulfilled (supplemental study)
850.5400/123-2 Algal toxicity on 4 species	Freshwater green alga Freshwater diatom Marine diatom Blue-green alga	EC50 1.39 mg/L EC50 = 1.9 mg/L EC50 = 6.4 mg/L EC50 = 2.3 mg/L	N/A	Fulfilled

3. Listed Species Consideration

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 CFR 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The active ingredient uses of 2-phenylphenol and salts, with the exception of the antisapstain wood preservation use, fall into this category. Using Tier I screening modeling to assess potential exposure from antisapstain wood preservation uses of 2-phenylphenol, risks to Listed Species are indicated. Since the model is only intended as a screening-level model, and, as such, has inherent

uncertainties and limitations which may result in inaccurate exposure estimations, further refinement of the model is necessary before any regulatory action is taken regarding the antisapstain uses of 2-phenylphenol. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors. Due to these circumstances, the Agency defers making a determination for the antisapstain uses of 2-phenylphenol until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the antisapstain use of 2-phenylphenol will be revised, and the risks to Listed Species will be reconsidered.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing OPP and salts as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing OPP and salts.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient OPP and salts. The Agency has determined that OPP containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures where necessary. Appendix A summarizes the uses of OPP that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of OPP and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of OPP and salts, the Agency has determined that OPP products, unless formulated and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of OPP. If all changes outlined in this document are incorporated into the product formulations, then all current risks for OPP and its salts will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for OPP and salts. During the public comment period on the risk assessments, which closed on June 26, 2006, the Agency received comments from the Department of Pesticide Regulation (California), American Mushroom Institute, the Northwest Horticultural Council and Dow Chemical/Lanxess (joint comment) in response to EPA's draft risk assessment (RA) for OPP and salts. The comments submitted by these registrants are related to toxicology, tolerances, and post-harvest application. The Agency's responses to these comments are available in the public docket at www.regulations.gov, docket # EPA-HQ-OPP-2006-0154 and are incorporated into the risk assessment and revised chapters.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with OPP and salts. The Agency has concluded that the tolerance exemption for the use of Na-OPP as an inert ingredient and OPP as a food contact sanitizer, as well as the existing tolerances for OPP and Na-OPP for their post-harvest use, meet the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food and residential exposure. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with OPP and salts. The Agency has determined that the established tolerance exemption for Na-OPP as an inert ingredient and OPP as a food contact sanitizer, as well as the existing tolerance for OPP and Na-OPP for their post-harvest use meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of OPP. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of OPP.

The acute and chronic aggregate risk assessments generally include only dietary (direct, indirect, and inert exposures) and drinking water exposures. As there is no acute dietary endpoint selected for OPP and drinking water exposure is not of concern, an acute aggregate dietary assessment was not performed for OPP. The chronic aggregate assessment included chronic dietary exposures from the direct food, indirect food, and inert uses from OPP. The chronic aggregate risk estimate associated with OPP and salts are well below the Agency's level of concern.

The short- and intermediate-term aggregate assessments were conducted for adults and children that could be exposed to OPP and OPP salt residues from the use of products in non-occupational environments. For short-term aggregate risk to adults, the average dietary exposure was aggregated with short-term oral and inhalation exposures that occur from mopping, wiping, and air deodorizer uses for the short-term incidental oral and inhalation residential exposures and the results were below the Agency's level of concern. The short-term aggregate risk to children is above the target MOE of 100 and is therefore not of concern. Dermal aggregate risk is assessed separately as the effect was different for this route of exposure. Dermal exposure to adults also showed no risk of concern as well as dermal exposure to children. There are no intermediate-term residential scenarios identified for adults while the risk estimate for children was below the Agency's level of concern. The exception to the prior is for adult and child dermal post-application exposures to textile OPP residues (which alone are of concern to the Agency), and which were not included into the aggregate assessment as this alone would make aggregate risk of concern.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerance exemption for Na-OPP as an inert ingredient and OPP as a food contact sanitizer, as well as the existing tolerances for OPP and Na-OPP for their post-harvest use, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of Na-OPP residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from OPP and salts residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for orthophenylphenol and salts based on the available developmental toxicity and reproductive toxicity studies for OPP that are considered acceptable and that show no evidence of increased toxicity to offspring at the same or lower doses as those causing parental/systemic toxicity or evidence of more severe toxicity relative to parental/systemic toxicity.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of OPP and salts. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for OPP and salts. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

e. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the

program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, OPP and salts may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. Tolerance Reassessment Summary

OPP currently has one inert ingredient (Na-OPP) exemption from the requirement of a tolerance for residues as required under the Food Quality Protection Act (FQPA) section 408. Taking into consideration all available information on sodium o-phenylphenate, it has been determined that there is reasonable certainty that no harm to any population subgroup will result from aggregate exposure to sodium o-phenylphenate when used as an inert ingredient in pesticide formulations when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of sodium o-phenylphenate under 40 CFR part 180.920, when used as a preservative at not more than 0.1% of the pesticide formulation and applied before edible portions of plants begin to form, can be considered reassessed as safe under section 408(q) of the FFDCA.

Orthophenylphenol has been used in food-contact surface sanitizing solutions with a tolerance exemption specified in 40 CFR 180.940 (c). Residues for OPP are exempt from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. OPP has a limitation for the ready-to-use end-use concentration not to exceed 400 ppm for food processing equipment and utensils. The Agency will be proposing a change to the 40 CFR 180.940(c) to establish a maximum of 4200 ppm for the end-use concentration of OPP, rather than the current limitation of 400 ppm. The Agency assessed the maximum application rate of 4200 ppm for OPP (as listed on the labels), although the current tolerance exemption has a limitation of 400 ppm. This assessment indicated that risks are not of concern for any subpopulations.

In addition, tolerances (40 CFR Part 180.129) were established for the residues of orthophenylphenol and its sodium salt. The tolerances were established for the fungicidal post-harvest application of these chemicals: Raw agricultural commodities (RAC) including: apple, cantaloupe, carrot, cherry, citrus, citron, cucumber, grapefruit, kiwifruit, kumquat, lemon, lime, nectarine, orange, bell pepper, peach, pear, pineapple, plum, prune, sweet potato, tangerine, tomato. Since the establishment of these tolerances all use sites have been cancelled with the exception of citrus and pear. Therefore, the tolerances remaining are 10 ppm for citrus and 25 ppm for pear while all others are to be revoked.

Also, the Agency believes that the establishment of a tolerance on mushrooms under 40 CFR 180.129 is necessary. The limit would be determined once a petition for establishing the tolerance is received by the Agency and reviewed.

The existing tolerances, exemption from the requirement of a tolerance, and those tolerances to be revoked are summarized in Table 23.

a. Tolerances Currently Listed Under 40 CFR

Table 23. Tolerance Reassessment Summary of OPP

Expression	Commodity	Current Tolerance	Tolerance Reassessment	Use
Listed Under 40 CFR 180.920[1]				
Sodium o-phenylphenate (Na-OPP)	N/A	Exemption: Not more than 0.1% of pesticide formulation	Exemption: Not more than 0.1% of pesticide formulation	Preservative of formulation
Listed Under 40 CFR 180.940(c)				
[1,1'-Biphenyl]-2-ol	N/A	End use concentration not to exceed 400 ppm	End use concentration not to exceed 4200 ppm	food contact sanitizing solutions for food processing equipment and utensils
Listed Under 40 CFR 180.129				
o-Phenylphenol and its sodium salt, sodium o-phenylphenate	Pear	25 ppm	25 ppm	
	Citrus	10 ppm	10 ppm	
	Cherry	5 ppm	Revoke	
	Nectarine	5 ppm	Revoke	
	Citron	10 ppm	Revoke	
	Cucumber	10 ppm	Revoke	
	Grapefruit	10 ppm	Revoke	
	Kumquat	10 ppm	Revoke	
	Lime	10 ppm	Revoke	
	Cantaloupe (edible portion)	10 ppm	Revoke	
	Sweet orange	10 ppm	Revoke	
	Bell pepper	10 ppm	Revoke	
	Pineapple	10 ppm	Revoke	
	Tangerine	10 ppm	Revoke	
	Tomato	10 ppm	Revoke	
	Sweet potato roots	15 ppm	Revoke	
	Carrot roots	20 ppm	Revoke	
	Kiwi	20 ppm	Revoke	
	Peach	20 ppm	Revoke	
	Plum	20 ppm	Revoke	
	Prune	20 ppm	Revoke	
	Apple	25 ppm	Revoke	
	Cantaloupe (non-edible portion).	125 ppm	Revoke	
1.Residues listed in 40 CFR §180.920 are exempted from the requirement of a tolerance when used as inert				

ingredients in pesticide formulations when applied to growing crops only.

b. Codex Harmonization

Currently there are no Codex MRLs established for OPP and salts.

D. Regulatory Rationale

The Agency has determined that 2-phenylphenol and salts is eligible for reregistration provided that additional required data confirm this decision, that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of OPP and salts. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

For all supported uses, the acute and chronic dietary exposure estimates are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to OPP residues in food.

b. Drinking Water Risk Mitigation

2-phenylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. Thus, a drinking water assessment was not conducted. Therefore, no risk mitigation measures are required to address OPP exposure from drinking water.

c. Residential Risk Mitigation

Residential risks from handler and post-application exposure were calculated for short- and intermediate-term dermal, inhalation and incidental oral exposures. All exposure and risk estimates for residential handler scenarios are below the Agency's level of concern. Therefore, no risk mitigation measures are required for these handler scenarios.

Risks of concern have been identified for several post-application exposure scenarios including children's dermal exposure to treated clothing and treated diapers and adult's dermal exposure to treated clothing. The Agency believes that adding clear instructions for washing and rinsing textile items will result in the adequate removal of residues from the treated items and address the Agency's concerns for this scenario.

In summary, to reduce residential exposure, the Agency has determined that the following mitigation and label changes for specific scenarios are appropriate and required for reregistration eligibility:

-Delete all diaper uses
-Delete all use on non-laundered textiles\items including mattresses, helmets, headgear, headphones, face gear, and mouthpieces.
-All labels with laundered textile uses must have directions that indicate that items must be treated prior to washing and rinsing.

d. Occupational Risk Mitigation

i. Handler Exposure

Risks of concern have been identified for several occupational handler scenarios including dermal exposure from: 1. Wiping in commercial/institutional premises, 2. Mopping in medical premises, 3. Liquid pour of the material into textiles (materials preservatives), and 4. Painting through the use of an airless sprayer. Also, dermal and inhalation risks have been identified for fogging applications in agricultural premises.

Although the total MOEs for dermal exposure from mopping without gloves in medical premises and dermal exposure from the gloved liquid pour of the material into textiles is 78 and below the Agency target of 100, the Agency does not believe mitigation measures for these two uses are required at this time. This is because the unit exposure data along with the values for the amount used/handled that were selected for estimating the risks were conservative. For the mopping scenarios, the CMA dermal and inhalation unit exposure values for ungloved mopping were used (71.6 mg/lb a.i. and 2.38 mg/lb a.i., respectively). For the liquid pour scenarios for materials preservatives, the unit exposure is 0.135 mg/lb ai and the inhalation UE is 0.00346 mg/lb ai). As a result, the daily dosages calculated for the scenarios assessed are most likely overestimated. If scenario-specific values were available to the Agency, then the MOEs are expected to be greater than 100 and not of concern to the Agency.

The total calculated MOE (inhalation and dermal) for fogging in agricultural premises for occupational handlers is 98. Although this MOE is below the Agency target of 100, the Agency is not requiring mitigation since it is a conservative assessment with multiple assumptions. In addition, the MOE is very close to the target so that EPA doesn't have risk concerns.

In summary, to reduce occupational handler exposure, the Agency has determined that the following mitigation and label changes for specific scenarios are appropriate and required for reregistration eligibility:

-For products with a wiping use in commercial and institutional premises, the percentage of 2-phenylphenol as an active ingredient must be below 63%. This will result in MOEs that are above the target of 100.
-For products with a paint preservative use (via airless sprayer) the maximum application rate must be less than 0.33 lb ai/gal (% active ingredient by weight of material being treated) to address risks for workers applying paint. This will result in MOEs that are above the target of 100.

ii. Post-Application Risk Mitigation

There is a potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into

the metalworking fluid and a machinist is using/handling this treated end-product and poses a risk of concern. Also, a risk of concern has been identified in the case of Na-OPP/OPP post-harvest commodity applications, whereby workers performing sorting and packing activities are potentially exposed to Na-OPP/OPP following application.

The short-term dermal risk for pear sorters was reported to be a risk of concern (MOE = 51) when the maximum reported dermal exposure for pear sorters was used. This risk was calculated with the maximum reported single exposure (out of 15 data points) for pear sorters in a Washington state study. However, it should be noted that it is unlikely that this level of dermal exposure would persist over the entire short-term exposure duration (i.e., up to 30 days), and is a conservative risk estimate. Further, the Agency believes the mean exposure is likely to be more representative of the actual exposure to pear sorters for this duration. Additionally, all dermal risk estimates are calculated with exposures adjusted for the maximum-labeled application rate (2% solution) while the study used was conducted at much lower levels (0.2%). This necessitated the use of linear extrapolation to the higher rate which may add further conservatism to the assessment. Therefore this risk calculation is very conservative and the MOE is not of concern. The short-term dermal risk using the average of dermal exposure for pear sorters (MOE = 120) may be a more appropriate estimate.

The calculated short-term dermal MOE for the metal working fluid scenario is 54, which is below the Agency's target of 100, and therefore poses a risk of concern. In summary, to reduce occupational handler exposure, the Agency has determined that the following mitigation and label changes for specific scenarios are appropriate and required for reregistration eligibility:

-All products used as a metalworking fluid may not exceed a maximum application rate of 0.81 lb ai/gal (% active ingredient by weight of material being treated). This will result in MOEs that are above the target of 100.

2. Environmental Risk Management

Based on the results of the antisapstain modeling, runoff from antisapstain treating facilities will exceed acute high risk, restricted use, and endangered species LOCs for freshwater fish, freshwater invertebrates and aquatic plants. In order to reduce environmental exposure, those products with an antisapstain use must contain the following language:

> "Treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events."

3. Listed Species Considerations

a. The Endangered Species Program

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 CFR. 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The active ingredient uses of 2-phenylphenol, with the exception of the antisapstain wood preservation use, fall into this category. Using Tier I screening modeling to assess potential exposure from antisapstain wood preservation uses of 2-phenylphenol, risks to Listed Species are indicated. Since the model is only intended as a screening-level model, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations, further refinement of the model is recommended before any regulatory action is taken regarding the antisapstain uses of 2-phenylphenol. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors (see General Risk Mitigation, below). Due to these circumstances, the Agency defers making a determination for the antisapstain uses of 2-phenylphenol until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the antisapstain use of 2-phenylphenol will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

OPP and salts end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing OPP or its salts specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that OPP and salts is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For OPP technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Rebecca M. Miller at (703) 305-0012 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Rebecca Miller
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Rebecca Miller
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

For end use products containing the active ingredient OPP (or Na-OPP/K-OPP), the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. five copies of the draft label incorporating all label amendments outlined in Table 23 of this document;

4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and

5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. the product-specific data responding to the PDCI.

Please contact the product manager, Adam Heyward, at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of OPP and salts has been reviewed and determined to be substantially complete. However, the following additional data requirements outlined in Table 24 have been identified by the Agency as confirmatory data requirements. A generic data call-in will be issued at a later date.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) database. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory. Appropriate air monitoring data in the manufacturing setting may be required dependent on the results of the inhalation toxicity study.

Table 24. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Fish Early Life-Stage Toxicity	850.1300	72-4a
Aquatic Invertebrate Life-Cycle Toxicity	850.1400	72-4b
Marine/Estuarine Fish Acute Toxicity	850.1075	72-3a
Aquatic Vascular Plant Toxicity	850.4400	123-2
Acute inhalation toxicity - Rat	870.1300	81-3
Acute Eye Irritation - Rabbit	870.2400	81-4
Migration Study for Plastics and Polymers	Special Study	Special Study
Indoor Inhalation Exposure and Applicator Exposure Monitoring Data Reporting	875.1400 and 875.1600	234 and 236
Indoor Dermal Exposure and Applicator Exposure Monitoring Data Reporting	875.1200 and 875.1600	233 and 236
Descriptions of Human Activity	875.2800	133-1

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

B. End-Use Products

1. Additional Product-Specific and Efficacy Data Requirements

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

A product-specific data call-in, outlining data requirements, will be sent to registrants at a later date. The PDCI will be based upon current efficacy-related requirements for antimicrobial pesticide products, claims, or patterns of use. A summary of these requirements can be found on the Agency's Antimicrobials Science Policy website at http://www.epa.gov/oppad001/sciencepolicy.htm.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 25.

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 document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in 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.

a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 25. Labeling Changes Summary Table

Summary of Labeling Changes for OPP and its Salts		
Description	Amended Labeling Language	Placement on Label
Delete use on diapers		Use Directions
Delete all use on non-laundered textiles\items including mattresses, helmets, headgear, headphones, facegear, and mouthpieces.		Use Directions
Laundry Use	Clarify language to ensure use requires washing and rinsing prior to wearing clothing	Use Directions
Environmental Hazards Statements Required by the RED	All OPP-containing products with an antisapstain use must contain the following language: "Treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events."	Precautionary Statements
Formulation Restrictions	Use: wiping in the commercial/institutional premises- maximum of 63.0 % active ingredient	Use Directions
Application Restrictions	Use: paint preservative- maximum application rate of 0.33 (% active ingredient by weight of material being treated).	Use Directions
Application Restrictions	Use: metalworking fluids- maximum application rate of 0.81 (% active ingredient by weight of material being treated).	Use Directions

VI. APPENDICES

Appendix A: Table of Use Patterns for OPP and Salts

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Mushroom Farms and Premises	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 1043-26	Sponge, mop, spray	½ oz per gallon of water. 10 minute contact time.	Preclean all surfaces with soap and water. Use between crops and on non-food contact areas
Greenhouse Premises, Tools and Equipment.	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 1043-26	Sponge, mop, spray	Spray, mop, sponge: ½ oz per gallon of water. 10 minute contact time.	Preclean all surfaces with soap and water. Rinse all surfaces with a potable water rinse and allow to air day prior to reuse.
Cattle, Swine and Poultry Farms and Premises and Equipment	Soluble Concentrate 211-25	Sponge, mop, spray or fogger	Spray, mop, sponge: ½-1 oz per gallon of water. 10 minute contact time.	Preclean all surfaces with soap and water. Do not use in food contact areas.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	211-36 303-223 464-70 464-616 3862-179 3862-180 39967-3 49403-21 1043-26 6836-252 6836-253 303-225 1043-91 1043-118 49403-6 49403-23 66171-1 66171-2 70627-6		Fogger: ½ oz per gallon of water. Fog area at 32-64 oz per 1,000 cubic feet.	Fogging: do not remain in treated area. Allow two hours after fogging before re-entry. Remove or protect all food an packaging materials. Treated food contact areas should be scrubbed with a suitable cleaner and rinsed with potable water.
Cattle, Swine and Poultry Farms and Premises and Equipment	Ready to Use 10088-105 70263-1 70263-2 70263-3 11694-99 44446-67 70263-4 70263-5	Spray	Spray until covered with mist. 10 minute contact time.	Preclean all surfaces with soap and water. Do not use in food contact areas.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Hatcheries, Setters, and Chick Processing Facilities	Soluble Concentrate 211-25 211-36 464-70 464-616 3862-179 3862-180 39967-3 49403-21 1043-26 6836-252 6836-253 70627-6	Sponge, mop, spray or fogger	Spray, mop, sponge ½-1 oz per gallon of water. 10 minute contact time. Fogger: ½ oz per gallon of water. Fog area at 32-64 oz per 1,000 cubic feet.	Preclean all surfaces with soap and water. Do not use in food contact areas. Fogging: do not remain in treated area. Allow two hours after fogging before re-entry. Remove or protect all food an packaging materials. Treated food contact areas should be scrubbed with a suitable cleaner and rinsed with potable water.
Egg Washing treatments (Hatching)	Soluble Concentrate 464-70 464-616 39967-3 49403-21 66171-1 66171-2	Immersion, automatic water system, foaming or fogging	½ oz per gallon of water. Use at 78 – 110 degrees F	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Trucks and other Vehicles	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 6836-252 6836-253 303-225 303-223 1043-91 66171-1 66171-2 70627-6	Sponge, mop, spray	Spray, mop, sponge ½-1 oz per gallon of water. 10 minute contact time.	None
	Ready to Use 211-32 10088-105 70263-1 70263-2 70263-4 70263-5	Spray	Spray until covered with mist. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Shoebath sanitizer	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 6836-252 6836-253 66171-1 66171-2 70627-6	Open vessel	½-1 oz per gallon of water.	None
	Ready to Use 706-69 3862-104 70263-5	Spray	Spray until covered with mist. Allow to air dry	Preclean shoes before applying

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Food Handling/storage establishments premises and equipment				
Fruit and Vegetable rinses (Citrus and pears ONLY)	Soluble Concentrate (solid and liquid) 464-70 464-616 49403-21 39967-3 464-78 2792-28 2792-32 **8764-1** 8764-16 8764-24 **33354-2** 39967-20 **43410-9** **43553-20** 57227-7 64864-45	Dip tank, Mechanical spray or foam machine	Citrus: 1 gallon of ingredient per 9-90 gallons of water. A pH of 11-12 should be maintained. Maximum 1 minute contact time. Rinse with Potable water. Wax emulsions: 1 gallon to 40 gallons of emulsion. 1 gallon of emulsion per 10,000 lbs of fruit. Do not rinse. Pears: 1 gallon per 9-80 gallons of water. A pH of 11 should be maintained. Maximum 1 minute contact time. Rinse with Potable water.	**Note:** EPA Reg No. 8764-1, 33354-2, 43410-9 and 43553-20 all have unapproved or cancelled fruits and vegetables on their labels. Orthophenylphenol is no longer approved for use on Apples, Cantaloupes, Carrots, Cherries, Cucumbers, Peaches, Peppers, Pineapples, Plums, Sweet Potatoes and Tomatoes. Tolerance for citrus, 10ppm Tolerance for Pears, 25ppm
Food Processing Plant Non-food Handling Areas	Ready to Use 464-70 464-616 39967-3 49403-21 10088-105 44446-67	Spray	Spray until covered with mist. 10 minute contact time.	Rinse all surfaces with a potable water rinse and allow to air day prior to reuse.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble Concentrate 1043-92 34810-8 70627-6	Sponge, mop, spray	Spray, mop, sponge ½-1 oz per gallon of water. 10 minute contact time.	Rinse all surfaces with a potable water rinse and allow to air day prior to reuse.
Eating Establishment Food Handling Areas (Non-food contact)	Ready to Use 211-32 464-70 464-616 49403-21 39967-3 498-194 706-69 2296-101 10088-105 33176-6 44446-67 69658-3 70627-6	Spray, Sponge	Spray or sponge until damp. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water. Not for use on utensils, glassware and dishes
	Soluble Concentrate 211-25 211-36	Sponge, mop, spray	Spray, mop, sponge ½ oz per gallon of water. 10 minute contact time	Treated food contact areas should be thoroughly cleaned and rinsed with potable water. Not for use on utensils, glassware and dishes

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Commercial, institutional and industrial premises and equipment				
Industrial and Institutional equipment and buildings, non porous, non food	Soluble Concentrate 211-25 211-36	Sponge, mop, spray or fogger	Spray, mop, sponge ½-2 oz per gallon of water. 10 minute contact time.	Preclean all surfaces with soap and water. Do not use in food contact areas.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
contact surfaces	464-70 464-616 675-19 675-43 39967-3 49403-21 1043-26 6836-252 6836-253 303-225 303-223 1043-91 1043-92 1043-115 1043-117 1043-118 3862-179 3862-180 5741-6 34810-8 34810-16 34810-19 34810-28 46851-5 49403-6 49403-23 66171-1 66171-2 70627-6		Fogger: ½ oz per gallon of water. Fog area at 32-64 oz per 1,000 cubic feet.	Fogging: do not remain in treated area. Allow two hours after fogging before re-entry. Remove or protect all food an packaging materials. Treated food contact areas should be scrubbed with a suitable cleaner and rinsed with potable water. Preclean all surfaces with soap and water. Do not use in food contact areas. Fogging: do not remain in treated area. Allow two hours after fogging before re-entry. Remove or protect all food an packaging materials. Treated food contact areas should be scrubbed with a suitable cleaner and rinsed with potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
75	Ready to Use 1270-237 70263-1 70263-2 70263-3 70263-4 70263-5 211-32 7405-51 498-134 498-180 498-154 706-69 1043-19 2296-101 3862-104 5741-22 10807-177 10807-178 11694-98 11694-99 33176-5 33176-6 34810-21 44446-67 55195-3 56392-4 69658-3 70627-14	Spray, Sponge	Spray or sponge until damp. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble Powder 34810-29	Sponge, mop	Mop, sponge ½ oz per gallon of water. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water.
	Impregnated Wipe 46851-10 55195-4	Wipe	Thoroughly wet surface. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water.
Residential and public access premises				
Household/Domestic Dwellings indoor premises	Soluble Concentrate 211-25 211-36 464-70 464-616 49403-21 39967-3 6836-253 777-60 49403-6 49403-23	Sponge, mop, spray	Spray, mop, sponge ½-2 oz per gallon of water. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water. Not for use on utensils, glassware and dishes

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Household/Domestic Dwellings indoor premises	Ready to Use 10088-105 498-134 498-180 498-154 706-69 777-27 777-73 1043-19 5741-22 11694-99 33176-5 33176-6 44446-67 69658-3 70263-4 70627-14	Spray	Spray until covered with mist. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water. Not for use on utensils, glassware and dishes
	Impregnated Wipe 46851-10 55195-4	Wipe	Thoroughly wet surface. 10 minute contact time.	Treated food contact areas should be thoroughly cleaned and rinsed with potable water. Not for use on utensils, glassware and dishes
	Ready to use 4822-479	Spray	For spot use, cracks, crevices and baseboards. Spray until wet and allow to air dry.	Do not spray up in into air. Apply to non-food contact areas only.
Household/Domestic Dwellings outdoor premises and equipment (roofs, decks, fences)	Soluble Concentrate 71240-1	Tank type chemical sprayer	6 oz. per 104 oz. of water AND 18 oz. of bleach. Makes one gallon. Liberally wet	No for interior use.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
			roof, wait five minutes then rinse well.	
Carpets	Soluble Concentrate 464-70 464-616 49403-21 39967-3 70263-5 70263-7	Soak, approved cleaning machine	1-4 oz per gallon of water. Allow carpet to air dry	None
Garbage Cans	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 6836-253 777-60 40510-5 66171-1 66171-2 3862-179 3862-180	Sponge, mop, spray	Spray, mop, sponge ½-2 oz per gallon of water. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Garbage Cans	Ready to Use 10088-105 8284-7 211-32 498-134 498-180 706-69 777-73 3862-104 5741-22 10807-177 10807-178 11694-98 11694-99 33176-5 55195-3 56392-4 69658-3 70263-4 70263-5 70627-14	Spray	Spray until covered with mist. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Animal Kennels and Sleeping Quarters	Soluble Concentrate 211-25 211-36 464-70 464-616 39967-3 49403-21 1043-26 3862-179 6836-252 6836-253 303-225 49403-6 66171-1 66171-2 70627-6	Sponge, mop, spray or fogger	Spray, mop, sponge ½-1 oz per gallon of water. 10 minute contact time. Fogger: ½ oz per gallon of water. Fog area at 32-64 oz per 1,000 cubic feet.	Preclean all surfaces with soap and water. Fogging: do not remain in treated area. Allow two hours after fogging before re-entry. Remove or protect all food an packaging materials. Treated food contact areas should be scrubbed with a suitable cleaner and rinsed with potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Animal Kennels and Sleeping Quarters	Ready to Use 10088-105 70263-1 70263-2 70263-3 70263-5 211-32 498-134 498-180 498-154 33176-5 44446-67 70263-4	Spray	Spray until covered with mist. 10 minute contact time.	None
Laundry Starch	Soluble Concentrate 464-78 464-616 39967-3 49403-21	Open pour	0.025-0.2% by weight of formulation	To preserve liquid during shelf life and use life.
Laundry (household/coin operated)	Soluble Concentrate 464-70 464-616 39967-3 49403-21 777-60	Open Pour	4 oz per load of laundry.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Diaper Pails (empty)	Ready to Use 464-70 464-616 39967-3 49403-21 498-134 498-180 33176-5 70627-14	Spray	Spray until covered with mist. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Bathrooms, Urinals and Chemical toilets	Ready to Use 1207-237 8284-7 211-32 464-70 464-616 39967-3 49403-21 7405-51 498-134 498-180 498-154 706-69 777-27 777-73 2296-101 10807-177 10807-178 33176-5 44446-67 55195-3 56392-1 56392-2 56392-4 69658-3 70263-4 70627-14	Spray, Sponge	Spray or sponge until damp. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Bathrooms, Urinals and Chemical toilets	Soluble Concentrate 211-25 211-36 464-78 3862-179 6836-252 6836-253 777-60 34810-8 34810-16 34810-19 40510-5 49403-6 66171-1 66171-2 70627-6 70263-5	Sponge, mop, spray	Spray, mop, sponge ½-2 oz per gallon of water. 10 minute contact time.	None
	Soluble Powder 34810-29	Sponge, mop	Mop, sponge ½ oz per gallon of water. 10 minute contact time.	None
Air conditioning cooling coils	Soluble Concentrate 464-70 464-616 39967-3 49403-21 5741-6	Spray or approved applicator	2 oz per gallon of water	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Air conditioning Ducts	Ready to Use 464-70 464-616 39967-3 49403-21 70263-5	Spray or approved applicator	Spray areas until thoroughly moist. 10-20 minute contact time.	Follow industry standards for cleanliness and mechanical inspections prior to using this product.
Medical premises and equipment				

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospitals and dental office equipment and premises (noncritical items)	Ready to Use 464-70 464-616 39967-3 49403-21 1207-237 10088-105 211-32 7405-51 498-134 498-180 498-154 706-69 1043-19 5741-22 10807-177 10807-178 11694-98 11694-99 33176-5 33176-6 34810-21 34810-22 44446-67 55195-3 56392-1	Spray	Spray until covered with mist. 10 minute contact time. Wipe off excess.	None
Hospitals and dental office equipment and premises (noncritical items)	Ready to Use 56392-2 56392-4 69658-3 70263-4 70263-5	Spray	Spray until covered with mist. 10 minute contact time. Wipe off excess.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble Concentrate 211-25 211-36 211-62 675-19 675-21 675-43 3862-179 3862-180 6836-252 6836-253 303-225 303-223 1043-87 1043-91 1043-92 1043-115 1043-117 5741-6 34810-8 34810-16 34810-19 34810-28 34810-31 46851-1 46851-5 49403-6 49403-23 66171-1 66171-2 70627-6	Sponge, mop, spray	Spray, mop, sponge ½-4 oz per gallon of water. 10 minute contact time.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble Powder 34810-29	Sponge, mop	Mop, sponge ½ oz per gallon of water. 10 minute contact time.	None
	Impregnated Wipe 46851-10 55195-4	Wipe	Thoroughly wet surface. 10 minute contact time.	None
Laundry	Soluble Concentrate 675-19	Open Pour	Add 1 cup to 17 gallons of water.	See label
	Soluble Concentrate 3862-179	Open pour	Soak in 1 oz per gallong of water for 10 minutes	
Household Sickrooms	Ready to Use 464-70 464-616 49403-21 39967-3 3862-104 70263-5	Spray	Spray until covered with mist. 10 minute contact time. Wipe off excess.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital and Dental Critical Items	Soluble Concentrate 211-25 211-36 464-70 464-616 675-19 675-43 39967-3 49403-21 675-21 1043-114 1043-115 1043-117 2212-17 46851-1	Soak, approved cleaning machine	1/2- 4oz per gallon. 10-20 minute contact time.	May be used in an ultrasonic cleaning system. See individual labels. For interim decontamination prior to terminal cleaning and sterilization. If instruments are to be in contact with solution for more than 20 minutes, add 1g of $NAHC0_3$ per quart of solution, dissolve completely. Also add 2 oz. of Isopropyl alcohol per quart of solution. See individual labels.
	Soluble Powder 34810-29	Soak	½ oz per gallon of water. 10 minute contact time.	For interim decontamination prior to terminal cleaning and sterilization.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Barber Shop and Salon equipment and premises	Soluble Concentrate 211-25 211-36 211-62 303-223 464-70 464-616 3862-179 3862-180 39967-3 49403-21 954-13 10088-105 33176-5 33176-6 62296-1 65596-1 66171-1 66171-2 70627-6	Soak or spray	1-4 oz. per gallon of water. Wet surfaces to be disinfected. 10 minute contact time	None
Barber Shop and Salon equipment and premises	Ready to use 498-194 954-10 211-32	Spray	Wet surfaces to be disinfected. 10 minute contact time	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Veterinary Hospitals and premises	Soluble Concentrate 211-25 211-36 211-62 464-70 464-616 39967-3 49403-21 675-21 1043-26 6836-252 6836-253 303-225 303-223 3862-179 1043-87 1043-91 1043-92 1043-118 46851-1 46851-5 49403-6 49403-23	Sponge, mop, spray or fogger	Spray, mop, sponge ½-4 oz per gallon of water. 10 minute contact time. Fogger: ½ oz per gallon of water. Fog area at 32-64 oz per 1,000 cubic feet.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Veterinary Hospitals and premises	Ready to Use 498-154 70263-1 70263-2 70263-3 70263-4 211-32 7405-51 498-134 498-180 33176-5 44446-67 56392-1 56392-2 56392-4 70627-6 70263-5	Spray	Spray until covered with mist. 10 minute contact time.	None
	Impregnated Wipe 46851-10 55195-4	Wipe	Thoroughly wet surface. 10 minute contact time.	None
Materials preservatives				
Building Materials	Soluble Concentrate 464-126 464-70 464-78 464-616 39967-3 39967-9 39967-11	Open Pour	0.10-2.8% by weight of product to be preserved.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-24 39967-26 49403-21 67869-21			
Water based Conveyor Belt Lubricants	Soluble Concentrate 464-70 464-616 39967-3 49403-21 1677-128 1677-130 1677-157	Spray or approved dispenser	0.27-1.25 oz. per gallon of water	Spray clean conveyors with a suitable detergent to remove soil and slime build up prior to application

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Hides, Leather and Leather products	Soluble Concentrate (solid and liquid), Ready to Use 464-126 464-70 464-78 464-616 49403-21 39967-3 10145-3 10145-4 39967-9 39967-11 39967-23 39967-24 39967-26 67869-24 72136-1	Swab, spray, roller machine or open pour.	Apply thin coat on finished leathers, allow to dry For open pour: Dissolve into retanning or fat-liquoring oils prior to application. Use 1.5-2% active ingredient based upon weight of leather.	None
	Ready to Use 10088-105	Spray	Spray until covered with mist. 10 minute contact time.	None
Paints and Stains	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3	Open Pour, spray	0.1-2.8% by weight of materials treated. Add as a concentrated aqueous solution to the formulation.	Per RED mitigation, for products with a painting use applied via airless sprayer the maximum application rate must be less than 0.33 lb ai/gal (% active ingredient by weight of material being treated).

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	49403-21 464-126 464-656 39967-11 39967-24 67869-21			
Glues and Adhesives	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 39967-9 39967-11 39967-23 39967-26 67869-21	Open Pour	0.1-0.4% by weight of materials treated. Add as a concentrated aqueous solution to organic portion of the ingredients.	None
Concrete Admixtures	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 49403-21 39967-3 464-126 464-656 39967-11	Open Pour	0.01-2.8% by weight of the admixture. Add at a suitable point during the manufacture of the admixture	Conversion to a water dilutable alkaline concentrate using sodium hydroxide is recommended.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-23 39967-24 39967-26 67869-21			
Mineral Pigment Slurries	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 464-656 39967-9 39967-23 39967-26 67869-21	Open Pour	0.025-1.6% by weight of the slurry. Add at a suitable point during the manufacture, loading/filling or shipment of slurry.	If needed add caustic to make a water dilutable alkaline concentrate.
Metal Working Fluids	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 49403-21 39967-3 464-126 464-656 39967-9 39967-11 39967-23	Open Pour	0.05-4.0% by weight of diluted concentrate. Add as a concentrated aqueous solution to the formulation. Add to water-emulsifiable oil concentrate during formulating process.	Per RED mitigation, all products used as a metalworking fluid may not exceed a maximum application rate of 0.81 lb ai/gal (% active ingredient by weight of material being treated).

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-24 39967-26 67869-21			
Inks, Dyes, Tints, Pigments, and Filler Suspensions	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 39967-11 39967-23 39967-24 67869-21	Open Pour	0.018-1.1% by weight of materials treated. Add as a concentrated aqueous solution to the formulation. Add a suitable point during the manufacture, using dispersing agents if necessary.	None
Cleaning solutions, Wax emulsions, polishes	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 464-656 39967-9 39967-11 39967-23 39967-24 39967-26	Open Pour	0.05-2.3% by weight of materials treated. Add as a concentrated aqueous solution to the formulation. Add a suitable point during the manufacture.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	67869-21			
Textiles and auxiliaries	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 39967-9 39967-11 39967-23 39967-24 39967-26 67869-21	Open Pour	Textiles: 0.15-28.3% by weight of materials treated. Add as a solution by dissolving in a suitable solvent. Auxiliaries: 0.05-0.4% by weight of materials treated. Add as a solution by dissolving in a suitable solvent.	Per RED mitigation, all labels with laundered textile uses must have directions that indicate that items must be treated prior to washing and rinsing.
	Ready to Use 10088-105	Spray	Spray until covered with mist. 10 minute contact time.	Per RED mitigation, all labels with laundered textile uses must have directions that indicate that items must be treated prior to washing and rinsing.
Paper Slurries and auxiliaries	Soluble Concentrate (solid and liquid) 464-70	Open Pour	Paper slurries: 0.07%-0.6% by weight of slurry. 3-6 lbs per 10,00 lbs of slurry.	Add as a solution by dissolving in a suitable solvent. Non food contact

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-78 464-616 39967-3 49403-21 464-126 39967-9 39967-11 39967-23 39967-24 39967-26 39967-45 67869-21		Auxiliaries: 0.05-1.7% by weight of materials treated.	
Fire Extinguisher medium	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616 39967-3 49403-21 464-126 39967-9 39967-11 39967-26	Open Pour	0.1-0.4% by weight of solution. Add a suitable point during the manufacture	None
Ceramic Glazes	Soluble Concentrate (solid and liquid) 464-70 464-78 464-616	Open Pour	0.05-2.8% by weight of glaze or slip formation. Add to ingredients of formation as they are charged into a ball mill.	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-3 49403-21 464-126 39967-9 39967-11 39967-26 67869-21			
Photographic solutions	Soluble Concentrate 464-70 464-78 464-616 49403-21 39967-3 464-126 39967-11 67869-21	Open Pour	0.05-0.5% by weight of solution or emulsion.	None
Polymers and Plastic emulsions	Soluble Concentrate 464-70 464-78 464-616 39967-3 49403-21 464-126 39967-11 39967-23 39967-24 67869-21	Open Pour	0.05-1.7% by weight of material to be protected Add a suitable point during the manufacture	Add as a solution by dissolving in a suitable solvent.
Biopolymers	Soluble Concentrate	Open Pour	0.05-1.1% by weight of material to be preserved	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-70 464-78 464-616 39967-3 49403-21 464-126 39967-11 39967-23 67869-21		Add a suitable point during the manufacture.	
Latex Dispersions and Emulsions	Soluble Concentrate 464-70 464-78 464-616 39967-3 49403-21 464-656	Open Pour	0.1-1.0% by weight of dispersion or emulsion	None
Drilling Muds	Soluble Concentrate 464-70 464-78 464-616 39967-3 49403-21 39967-24	Open Pour		None
Wood Preservation				
Green and or Freshly Cut Lumber, Sapstain control	Soluble Concentrate 464-70 464-616	Dip or Spray	1-4 oz. per gallon of water, 15 second dip or uniformly wet all surfaces	Per RED mitigation, the following language must appear on all products with an antisapstain use:

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-3 49403-21 1022-564 39967-11 39967-23 57227-1 43553-20		1.0-4.0% by weight of product to be treated. Use Sodium Hydroxide or another base to make end use product dilutable.	"Treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events." Dip tanks and drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution. DO NOT expose treated lumber to rains immediately after treatment. DO NOT float treated lumber in lakes, rivers, streams, or oceans.
Swimming Pools				
Whirlpool Baths	Soluble Concentrate 211-36 464-70 464-616 49403-21	Open Pour, spray, wipe	1 oz per gallon of water in unit. Start pump and circulate solution for 30-60 seconds. Turn off pump. Drain solution and thoroughly clean the unit	None

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	39967-3		and rinse all cleaned surfaces with water. Other whirlpool components may be sanitized with a 1 oz per gallon solution, 10 minute contact time.	

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

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #3026 (BIT) covered by this RED. It contains generic data requirements that apply to BIT in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1 & 2). 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 Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Guideline Description (Column 3). Identifies the guideline type.

3. Use Pattern (Column 4). This column indicates the standard Antimicrobials Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix A.

(1) Agricultural premises and equipment
(2) Food handling/ storage establishments premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming pools
(12) Aquatic areas

4. Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify 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.

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
		CHEMISTRY		
830.1550	61-1	Product Identity and Composition	All	41609501 41609502 42381901
830.1600 830.1620 830.1650	61-2 A	Starting Materials and Manufacturing Process	All	42097001 42528701 41609502 42381901
830.1670	61-2 B	Formation of Impurities	All	41609501 42381901 41609502
830.1700	62-1	Preliminary Analysis	All	41609501 42381901 41609502

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.1750	62-2	Certification of Limits	All	41609501 42381901 41609502
830.1800	62-3	Analytical Method	All	41609501 42381901 41609502
830.6302	63-2	Color	All	101697 42381901 41609503
830.6303	63-3	Physical State	All	101697 42381901 41609503
830.6304	63-4	Odor	All	101697 42381901 41609503

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7200	63-5	Melting Point	All	101697 42381901 41609503 41609504
830.7220	63-6	Boiling Point	All	101697 42381901 41609503
830.7300	63-7	Density	All	101697 42381901 41609503
830.7840 830.7860	63-8	Solubility	All	42441701 42381901 42500201
830.7950	63-9	Vapor Pressure	All	42441702 42381901 41609505
830.7370	63-10	Dissociation Constant in Water	All	42441703 42381901 42500202 41609503

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	All	42441704 42381901
830.7000	63-12	pH	All	41609503
830.6313	63-13	Stability	All	42457001 42381901 41609503
830.6314	63-14	Oxidizing/Reducing Action	All	42441703
830.6315	63-15	Flammability	All	42441703
830.6316	63-16	Explodability	All	N/A
830.6317	63-17	Storage Stability	All	42441703
830.7100	63-18	Viscosity	All	N/A
830.6319	63-19	Miscibility	All	N/A
830.6320	63-20	Corrosion Characteristics	All	42441703
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test, TGAI - Quail/duck	All	160150 42500204
850.2200	71-2 A	Avian Acute Dietary, TGAI - Quail	10	160149 42500205

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.2200	71-2 B	Avian Acute Dietary, TGAI – Duck	10	160151 42500206
850.1075	72-1 A	Fish Acute Toxicity, TGAI – Warmwater species	All	156044 110232
850.1075	72-1 C	Fish Acute Toxicity, TGAI – Coldwater species	10	156044 110232
850.1010	72-2 A	Acute Aquatic Invertebrate Toxicity, TGAI	All	156044 110222
850.1300	72-4 A	Fish Early Life-Stage Toxicity, TGAI	10	**Required**
850.1400	72-4 B	Aquatic Invertebrate Life-Cycle Toxicity, TGAI	10	**Required**
850.1075	72-3 A	Marine/Estuarine Fish Acute Toxicity, TGAI	10	**Required**
850.1025	72-3 B	Marine/Estuarine Bivalve Acute Toxicity, TGAI	10	46751202
850.1035	72-3 B	Marine/Estuarine Invertebrate Acute Toxicity, TGAI	10	46751203
850.4100	122-1	Seedling Emergence Test Using Rice, TEP or TGAI	10	46751207
850.4150	122-1	Vegetative Vigor Test Using Rice, TEP or TGAI	10	46751204
850.4400	123-2	Aquatic Vascular Plant Toxicity, TGAI	10	**Required**

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.5400	123-2	Algal Toxicity Using Four Species, TGAI	10	45688201 46751205 46751201 46823801
		TOXICOLOGY		
870.1100	81-1	Acute Oral - Rat	All	43334201 43334204
870.1200	81-2	Acute Dermal - Rabbit	All	78779
870.1300	81-3	Acute Inhalation – Rat	All	**Required**
870.2400	81-4	Acute Eye Irritation - Rabbit	All	**Required**
870.2500	81-5	Acute Skin Irritation - Rabbit	All	43334202
870.2600	81-6	Dermal Sensitization	All	43334203 43334205
870.3250	82-2	21-Day Subchronic Dermal	1,2,3,4,5,7, 10, 11	42881901
870.3250	82-3	90 Day Dermal-Rodent	N/A	Reserved
870.3465	82-4*	90-Day Subchronic Inhalation	N/A	Reserved

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3100	82-1 A	90-Day feeding-Rodent	1,2,7,10,11	40760206
870.3150	82-1 B	90-Day feeding-Non-rodent	1,2,7,10,11	41656401
870.4100	83-1 A	Chronic Toxicity-Rodent	10,11	43954301
870.4100	83-1 B	Chronic Toxicity-Non-rodent	10,11	41656401
870.4200	83-2 A	Oncogenicity-Rat	10,11	43954301
870.4200	83-2 B	Oncogenicity-Mouse	10,11	43545501
870.3700	83-3 A	Prenatal Developmental Toxicity - Rat	1,2,3,4,5,7, 10,11	92154037
870.3700	83-3 B	Prenatal Developmental Toxicity – Rabbit	1,2,3,4,5,7, 10,11	41925001 41925002 41925003
870.3800	83-4**	Reproduction and fertility effects - Rat	2,10,11	43928801
870.5100	84-2 A	Bacterial Reverse Mutation Test - Ames	All	92154039 161577
870.5375	84-2 B	In Vitro Mammalian Chromosome Aberration Test	All	161577
	84-4	Other Genotoxic Effects	All	161577 127249 92154038

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.7485	85-1	General Metabolism	10,11	145962 71253 44197601 44197602
870.7600	85-3	Dermal Penetration	10,11	46882301
*For guidelines 82-3 and 82-4, at least one is required to be fulfilled; not both (for both food and non-food uses). **Only required for food use.				
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of Parent and Degradates	All	43994201 43973501
835.2240	161-2	Photodegradation – Water	N/A	Reserved
835.4400	162-3	Anaerobic Aquatic Metabolism	N/A	Reserved
835.4300	162-4	Aerobic Aquatic Metabolism	N/A	Reserved
835.1230	163-1	Leaching and Absorption/desorption	N/A	Reserved
840.1100	164-2	Aquatic Field Dissipation	N/A	Reserved
850.1730	165-4	Bioaccumulation in Fish	N/A	Reserved
850.1950	165-5	Bioaccumulation in Aquatic non-target organisms	N/A	Reserved

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
	168-1 SS	Availability Study/Wood leaching study	10	46601401
OCCUPATIONAL PROTECTION				
875.2100	132-1 A	Foliar Residue Dissipation	N/A	Waived
875.2400	133-3	Dermal Passive Exposure	N/A	Waived 41412201 41742601
875.2500	133-4	Inhalation Passive Exposure	N/A	Waived 41412201 41742601
875.1400	234	Estimation of Inhalation Exposure	All	43432901
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity	All	41609502
860.1200	171-3	Directions for Use	N/A	Reserved
		Migration Study for Plastics		**Required**
	171-5	Reduction of Residues	N/A	Reserved
860.1300	171-4 A	Nature of Residue – Plants	All	43298301 43537101

TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
	171-4 B	Nature of Residue – Livestock	All	44349301
860.1340	171-4 C	Residue Analytical Method – Plant	All	43384101 43742101 44038501 43996401
	171-4 D	Residue Analytical Method – Livestock	N/A	Reserved
860.1380	171-4 E	Storage Stability	All	43992401 44112001 44182601
860.1460	171-4 I	Magnitude of Residue – Food Handling	N/A	Reserved
860.1480	171-4 J	Magnitude of Residue – Meat/Milk/Poultry/Eggs	N/A	**Required**
860.1500	171-4 K	Magnitude of Residue, Crop Field Trials – Citron, Citrus	N/A	Reserved
		Magnitude of Residue, Crop Field Trials – Pear		
860.1520	171-4 L	Magnitude of Residue, Processed food/feed – Citron, Citrus	N/A	Reserved
		Magnitude of Residue, Processed food/feed – Pear		

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket located in Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained preliminary risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov, docket ID # **EPA-HQ-OPP-2006-0154**

These documents include:

1. Ortho-phenylphenol and orthophenylphenol salts: AD Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) Document , 4/17/06
2. Evaluation of the Carcinogenic Potential of Ortho-Phenyelphenol and Sodium Ortho-Phenylphenol, 9/27/05
3. Ortho Phenylphenol, and its Sodium and Potassium Salts. Dietary Exposure Assessments for the Reregistration Eligibility Decision, 2/24/06
4. Ecological Hazard and Envrironmental Risk Assessment, 2-Phenylphenol and Salts, 4/10/06
5. Science Chapter on: Environmental Fate Studies and Environmental Fate Assessment of Orthophenylphenol, 9/20/05
6. Incident Reports Associated with 2 Phenylphenol & Salts, 5/10/05
7. Inert Ingredient Dietary and Non-dietary Risk Assessments for O-Phenylphenol and Salts Reregistration Eligibility Document (RED), 2/22/06
8. 2-Phenylphenol, and salts - Conventional Uses: Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document (Case 2575), 10/6/05
9. Occupational and Residential Exposure Chapter for Ortho-phenylphenol & Ortho-phenylphenol Salts, 4/4/06
10. Product Chemistry Chapter for OPP and Salts, 2/17/06
11. Toxicology Disciplinary Chapter for the Re-Registration Eligibility Decision (RED) Risk Assessment, 4/17/06

Appendix D. Bibliography Citations

MRID STUDIES

Chemistry

MRID 41609501 – Deford, C. (1990) Product Chemistry Data for Dowcide 1 Anti-micro- bial. Unpublished study prepared by Dow Chemicals U.S.A. 74 p.

MRID 41609502 – Deford, C. (1990) Product Chemistry Data for Dowcide A Antimicro- bial. Unpublished study prepared by Dow Chemical U.S.A. 64 p.

MRID 42381901 – Cocciardo, C.; Stroech, K. (1992) Product Chemistry Data Upgrades as Requested in Phase IV Data-Call-In for 2-Phenylphenol (49-155 ortho-Phenylphenol): Lab Project Number: 39967-3. Unpublished study prepared by Bayer Ag. 60 p.

MRID 42097001 – Lickly, L. (1991) O-Phenylphenol: Description of Beginning Materi- als and Manufacturing Process (...): Lab Project Number: Unpub- lished study prepared by The Dow Chemical Co. 6 p.

MRID 42528701 –Lickly, L. (1991) Sodium O-Phenylphenate--Description of Beginning Materials and Manufacturing Process: An amendment. Unpublished study prepared by The Dow Chemical Co. 6 p.

MRID 101697 – Dow Chemical Co. (1969) Dowicide 1 Antimicrobial. Midland, MI: Dow. (Antimicrobial agents, section I-1; also In unpublished submission received Jun 20, 1969 under 464-70; CDL:003397-A)

MRID 41609503 – Deford, C. (1990) Physical and Chemical Characteristics of Dowcide A Antimicrobial. Unpublished study prepared by Dow Chemical U.S.A.. 5 p.

MRID 41609504 – Black, C.; Frurip, D. (1990) Melting Point of Sodium o-Phenyl Phenate (Dehydrated): Lab Project Number: ML-AL 90-020344. Unp- ed study prepared by Dow Chemical U.S.A.. 10 p.

MRID 42441701 – Heimerl, J.; Engel, J. (1992) Solubility of Dowicide 1 Antimicrobial for Registration: Lab Project Number: ML-AL 92-080421. Unpublished study prepared by Dow Chemical USA, Analytical Sciences. 52 p.

MRID 42500201 – Heimeri, J.; Engel, J. (1992) Solubility of Dowicide A Antimicrobial for Registration: Lab Project Number: ML-AL 92-080543. Unpublished study prepared by Dow Chemical, USA, Analytical Sciences. 45 p.

MRID 42441702 – Srivastava, R.; Chakrabarti, A.; Griffin, K. (1992) Vapor Pressure of Ortho-Phenylphenol Measured by the Knudsen-Effusion/Weight Loss Method: Lab Project Number: ML-AL 91-020408. Unpublished study prepared by Dow Chemical USA. 15 p.

MRID 41609505 – Chakrabarti, A. (1990) Vapor Pressure of the Sodium Ortho-phenyl- phenate Measured by the Knudsen-Effusion/Weight Loss Method: Lab Project Number: ML-AL 90-020313. Unpublished study prepared by Dow Chemical U.S.A.. 10 p.

MRID 42441703 – Reim, R. (1992) Dissociation of Dowicide 1 Antimicrobial: Lab Project Number: ML-AL 92-080459. Unpublished study prepared by The Dow Chemical Co. 15 p.

MRID 42500202 – Reim, R. (1992) Dissociation of Dowicide A Antimicrobial: Lab Project Number: ML-AL 92-041093. Unpublished study prepared by Dow Chemical, USA, Analytical Sciences. 15 p.

MRID 42441704 –Heimerl, J. (1992) Octanol/Water Partition Coefficient Determination of Dowicide 1 Antimicrobial for Registration: Lab Project Number: ML-AL 92-080459. Unpublished study prepared by The Dow Chemical Co. 43 p.

MRID 42457001 –Engel, J.; Heimerl, J. (1992) Stability of Dowicide 1 Antimicrobial for Registration: Lab Project Number: ML-AL 92-080398. Unpublished study prepared by Dow Chemical USA. 45 p.

EcoTox
ACC232113. Batchelder, T.L., and W. M. McCarty. 1977. Toxicity of Dowicide A to Daphnids. Unpublished data. Conducted by Environmental Sciences Research, Dow Chemical Co., and submitted by Dow Chemical Co.

MRID 42500204 – Campbell, S.M. and M. Jaber. 1992. Sodium o-phenylphenalte (DOWICIDE A): An Acute Oral Toxicity Study with the Northern Bobwhite. Unpublished data. Conducted by Wildlife International for the Dow Chemical Co.

MRID 42500205 – Campbell, S.M., and S.P. Lynn. 1992. Sodium o-phenylphenate (DOWICIDE A): A Dietary LC50 Study with the Northern Bobwhite. Unpublished data. Conducted by Wildlife International for the Dow Chemical Co.

MRID 42500206 – Campbell, S.M., and M Jaber. 1992. Sodium o-phenylphenate (DOWICIDE A): A Dietary LC50 Study with the Mallard. Unpublished data. Conducted by Wildlife International for the Dow Chemical Co.

MRID 45688201 – Hicks, S. 2002. Ortho-phenyl Phenol: Growth Inhibition Test with Green Alga, *Selenastrum capricornutum*. Unpublished data. Conducted by ABC Laboratories for The Dow Chemical Co.

MRID 160150 – Grimes, J. (1986) Ortho-phenylphenol Technical: An Acute Oral Toxi- city Study with the Mallard: Final Report: Project No. 103-248. Unpublished study prepared by Wildlife International Ltd. 18 p.

MRID 160149 – Grimes, J. (1986) Ortho-phenylphenol Technical: A Dietary LC50 Study with the Bobwhite: Final Report: Project No. 103-246. Un- published study prepared by Wildlife International Ltd. 17 p.

MRID 160151 – Grimes, J. (1986) Ortho-phenylphenol Technical: A Dietary LC50 Study with the Mallard: Final Report: Project No. 103-247. Un- published study prepared by Wildlife International Ltd. 18 p.

MRID 156044 – Dill, D.; Milazzo, D.; Bartlett, E.; et al. (1985) Evaluation of the Toxicity of Dowicide 1 Antimicrobial, Technical O-Phenyl- phenol, to Representative Aquatic Organisms: ES-811. Unpub- lished study prepared by Dow Chemical U S A. 17 p.

MRID 110232 – Bentley, R. (1975) Acute Toxicity of Dowicide CO to Bluegill ... and Rainbow Trout ...: GH-RC 62. (Unpublished study re- ceived Aug 25, 1976 under 464-126; prepared by Bionomics, EG & G Environmental Consultants, submitted by Dow Chemical U.S.A., Midland, MI; CDL:233706-A)

MRID 110222 – Batchelder, T.; McCarty, W. (1977) Toxicity of Dowicide A to Daph- nids: ES-154. (Unpublished study received Oct 28, 1977 under 464-78; submitted by Dow Chemical U.S.A., Midland, MI; CDL: 232113-A)

MRID 46751202 – Cafarella, M. (2006) OPP/SOPP - Acute Toxicity to Eastern Oyster (Crassostrea virginica) Under Flow-Through Conditions. Project Number: 12550/6382, 050368. Unpublished study prepared by Springborn Bionomics. 60 p.

MRID 46751203 – Hoberg, J. (2006) OPP/SOPP - Acute Toxicity to Mysids (Americamysis bahia) Under Flow - Through Conditions. Project Number: 12550/6383, 050369. Unpublished study prepared by Springborn Bionomics. 61 p.

MRID 46751207 –Teixeira, D. (2006) OPP/SOPP - Determination of Effects on Seedling Emergence of Rice (Oryza sativa). Project Number: 12550/6384, 050370. Unpublished study prepared by Springborn Smithers Laboratories. 60 p.

MRID46751204 – Teixeira, D. (2006) OPP/SOPP - Determination of Effects on Vegetative Vigor of Rice (Oryza sativa). Project Number: 12550/6385, 050371. Unpublished study prepared by Springborn Bionomics. 61 p.

MRID 46751205 – Hoberg, J. (2006) OPP/SOPP - Acute Toxicity to the Freshwater Diatom (Navicula pelliculosa). Project Number: 12550/6388, 050374. Unpublished study prepared by Springborn Bionomics. 63 p.

MRID 46751201 – Hoberg, J. (2006) OPP/SOPP - Acute Toxicity to the Marine Diatom, Skeletonema costatum, Under Static Conditions. Project Number: 12550/6389, 050375. Unpublished study prepared by Springborn Bionomics. 68 p.

MRID 46823801 – Hoberg, J. (2006) OPP/SOPP - Growth Inhibition Test with Freshwater Blue-Green Alga (Anabaena flos-aquae). Project Number: 12550/6387, 050373. Unpublished study prepared by Springborn Smithers Laboratories. 66 p.

Environmental Fate

MRID 43994201 – The Hydrolysis of o-Phenylphenol in Buffered Solution: SJ Gonsior, 1996, Study ID#: ES 3034, Performing Lab: The Environmental Chemistry Research Laboratory, The Dow Chemical company, Midland, Michigan 48674

MRID 43973501 – Dullau (1990) Preventol O Extra Hydrolysis Study: (Ortho-phenylphenol): Lab Project Number: G 89/0056/02 LEV: ZF-DZA/OAL: K2011-0058701-95E. Unpublished study prepared by Bayer AG. 162 p.

MRID 46601401 – Davis, J.; Gonsior, S. (2005) Ortho-Phenylphenol, Sodium Salt: Determination of the Leaching Rate from Wood Following a Simulated Sapstain Treatment. Project Number: 051089. Unpublished study prepared by The Dow Chemical Co. 31 p.

Toxicology

MRID 43334201 – Gilbert, K.; Crissman, J. (1994): Dowicide 1 Antimicrobial: Acute Oral Toxicity study in Fischer 344 Rats: Lab Project Number: K/001024/057A: K/001024/057A2: K/001024/057A3. Unpublished study prepared by Dow Chemical Co. 53 p.

MRID 43334202 – Gilbert, K. (1994): Dowicide 1 Antimicrobial: Primary Dermal Irritation study in New Zealand White Rabbits: Lab Project Number: K/001024/057B. Unpublished study prepared by Dow Chemical Co. 18 p.

MRID 43334203 – Gilbert, K. (1994): Dowicide 1 Antimicrobial: Dermal Sensitization Potential in the Hartley Albino Guinea Pig: Lab Project Number: K/001024/057E. Unpublished study prepared by Dow Chemical Co. 16 p.

MRID 43334204 – Gilbert, K.; Stebbins, K. (1994): Dowicide A Antimicrobial: Acute Oral Toxicity study in Fischer 344 Rats: Lab Project Number: K/001024/014A: K/001024/014A2. Unpublished study prepared by Dow Chemical Co. 78 p.

MRID 43334205 – Gilbert, K. (1994): Dowicide A Antimicrobial: Dermal Sensitization Potential in the Hartley Albino Guinea Pig: Lab Project Number: K/001025/014E. Unpublished study prepared by Dow Chemical Co. 16 p.

MRID 40760206 – Iguchi, S.; Takahashi, H.; Fujii, T.; et al. (1984): Subchronic Toxicity of o-Phenolphenol (OPP) by Food Administration to Rats. Unpublished translation of Ann. Rept. Tokyo Res. Lab. 35: 407- 415. 29 p.

MRID 41925001 – Zablotny, C.L., et al. (1991): Ortho-phenylphenol (OPP): 13-Day Range Finding Oral Gavage Study in New Zealand White Rabbits. The Toxicology Research Laboratory, Midland, MI. Study ID K-001-24-043.

MRID 41925002 – Zablotny, C.L., et al. (1991): Ortho-phenylphenol (OPP): Gavage Teratology Probe Study in New Zealand White Rabbits. The Toxicology Research Laboratory, Midland, MI. Study ID K-001-24-044.

MRID 41925003 – Zablotny, C.L., et al. (1991): Ortho-phenylphenol (OPP): Gavage Teratology Study in New Zealand White Rabbits. The Toxicology Research Laboratory, Midland, MI. Study ID K-001-24-045.

MRID 43928801 – Eigenberg, D.; Lake, S. (1995): A Two-Generation Dietary Reproduction Study in Sprague-Dawley Rats Using Technical Grade ortho-Phenylphenol: Lab Project Number: 93-672-VX: 7788. Unpublished study prepared by Bayer Corp. 1213 p.

MRID 42881901 – Zempel, J.A. and J.R. Szabo (1993): Ortho-Phenylphenol: 21-Day Repeated Dermal Dose Study of Systemic Toxicity in Fischer 344 Rats. Health and Environmental Sciences- Texas, Freeport, Texas. Study ID K-001024-056.

MRID 43954301 – Wahle, B.S. and W.R. Christenson (1996): Technical Grade ortho-PHENYLPHENOL: A Combined Chronic Toxicity/ Oncogenicity Study in the Rat. Bayer Corporation, Stillwell, KS. Study ID 92-272-SC.

MRID 44832201 – Wahle, B.S. and W.R. Christenson (1996): Supplemental Submission to Bayer Toxicology Report No. 7908 (EPA MRID 43954301). Bayer Corporation, Stillwell, KS. Study ID 92-272-SC.

MRID 44852701 – Wahle, B.S. and W.R. Christenson (1996): Supplemental Submission to Bayer Toxicology Report No. 7908 (EPA MRID 43954301). Bayer Corporation, Stillwell, KS. Study ID 92-272-SC.

MRID 43545501 – Quast, J.F. and McGuirk, R.J. (1995): Ortho-phenylphenol: Two Year Dietary Chronic Toxicity/Carcinogenicity Study in B6C3F1 mice. Study conducted by Dow Chemical Company, Midland, Michigan and Freeport Texas for Dow Chemical Company, Midland, Michigan and Miles Inc., Stillwell, KS.

MRID 46882301 – Timchalk, C. (1996) ^{14}C-Orthophenylphenol: Pharmacokinetics following dermal application in male human volunteers. Unpublished report No. HET-K-001024-064 from Dow Chemical Co., Midland, Michigan, USA. Submitted to WHO by Leng Associates, Midland, Michigan, USA.

MRID 92154037 – John, J.S. et al. (1978, reformatted 1990): Phase 3 Reformat of MRID 00067616/ 164362: The Effect(s) of Orally Administered Orthophenylphenol on Rat Embryonal and Fetal Development. Toxicology Research Laboratory, Midland, MI. Study ID HET K-0001024-33 (R).

MRID 78779 – Carreon, R.E.; New, M.A. (1981) Dowicide(TM) 1: Acute Percutaneous Absorption Potential: HET K-1024-(37). (Unpublished study received Jun 18, 1981 under 464-70; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:245514-A)

MRID 41656401 – Cosse, P.; Stebbins, K.; Stott, W.; et al. (1990) Ortho-phenylphen- ol: Palatability/Probe, Four-week and One-year Oral Toxicity Studies in Beagle Dogs: Lab Project

Number: K-001024-038: K-001024-038A: K-001024-039. Unpublished study prepared by Dow Chemical Co., Health and Environmental Sciences. 321 p.

MRID 92154039 – Brusick, D. (1990) Dow Chemical U S A Phase 3 Reformat of MRID 00073282 and Related MRIDs 00079551. Mutagenicity of Ortho-Phenylphenol: LBI Project No. 2547. Prepared by Litton Bionetics, Inc. 11 p.

MRID 161577 – US Public Health Service, National Institutes of Health (1986) NTP Technical Report on the Toxicology and Carcinogenesis Studies of Ortho-phenylphenol (CAS No. 90-43-7) Alone and with 7,12-Di- methylbenz(a)anthracene (CAS No. 57-97-6) in Swiss CD-1 Mice: (Dermal Studies). NIH Publication No. 86-2557. 144 p.

MRID 127249 – Reitz, R.; Fox, T.; Quast, J.; et al. (1983) Follow-up Studies of the Effects of Orthophenylphenol ... and Sodium Orthophenyl- phenol ... on the Urinary Tract of F344 Rats: HET K-1025-(11). (Unpublished study received Mar 28, 1983 under 464-70; sub- mitted by Dow Chemical U.S.A., Midland, MI; CDL:249835-A)

MRID 92154038 – Deford, C. (1990) Dow Chemical U S A Phase 3 Summary of MRID 00127249. Biochemical Factors Involved in the Effects of Orthophenylphenol (OPP) and Sodium Orthophenylphenol (SOPP) on the Urinary Tract of Male F344 Rats. Prepared by Dow Chemical Company. 6 p.

MRID 145962 – Reitz, R.; Fox, T.; Quast, J.; et al. (1983) Molecular mechanisms involved in the toxicity of orthophenylphenol and its sodium salt. Chem.-Biol. Interactions 43:99-119.

MRID 71253 – Savides, M.C.; Oehme, F.W. (1980) Urinary metabolism of orally administered~ortho~-phenyl phenol in dogs and cats. Toxicology 17:355-363. (Also~In~unpublished submission received Feb 12, 1981 under 464-70; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:244358-A)

MRID 44197601 – Christenson, W.; Wahle, B.; Cohen, S. (1996) Technical Grade ortho-Phenylphenol: A Special Subchronic Dietary Study to Examine the Mechanism of Urinary Bladder Carcinogenesis in the Male Rat: Lab Project Number: 92-972-MS: 8042. Unpublished study prepared by Bayer Corp. and University of Nebraska Medical Center. 47 p.

MRID 44197602 – Christenson, W.; Wahle, B.; Cohen, S. (1996) Technical Grade ortho-Phenylphenol: A Special Subchronic Dietary Study to Examine the Mechanism of Urinary Bladder Carcinogenesis in the Male Rat: Supplement: Lab Project Number: 92-972-MS: 8042-1. Unpublished study prepared by Bayer Corp. and University of Nebraska Medical Center. 11 p.

Residue Chemistry

MRID 41609502 – Deford, C. (1990) Product Chemistry Data for Dowcide A Antimicro- bial. Unpublished study prepared by Dow Chemical U.S.A. 64 p.

MRID 43298301 – Wu, D. (1994) Metabolism of (carbon 14) Sodium Ortho-Phenylphenate (SOPP) in Stored Oranges: Nature of the Residue in Plants: Lab Project Number: XBL/93011: RPT00165. Unpublished study prepared by XenoBiotic Lab., Inc. 150 p.

MRID 43537101 – Wu, D. (1995) Metabolism of (carbon 14)Sodium Ortho-Phenylphenate (SOPP) in Stored Pears: Nature of the Residue in Plants: Lab Project Number: 93013: RPT00211. Unpublished study prepared by XenoBiotic Labs., Inc. 209 p.

MRID 44349301 – Thalacker, F. (1997) Nature of the Residue of (carbon-14)-Orthophenylphenol in Lactating Goats: Final Report: Lab Project Number: CHW 6578-105: AM-066: MILKG2S2.XLS. Unpublished study prepared by Corning Hazleton Inc. 160 p.

MRID 43384101 –Harsy, S. (1994) Validation of Method for Determination of o-Phenylphenol Residues in Pears: Lab Project Number: HWI 6524-106. Unpublished study prepared by Hazleton Wisconsin, Inc. 36 p.

MRID 43742101 – Harsy, S. (1995) Validation of Method for Determination of o-Phenylphenol Residues in Pears: Addendum No. 1 to the Final Report: Lab Project Number: HWI 6524-106. Unpublished study prepared by Hazleton Wisconsin, Inc. 13 p.

MRID 44038501 – Harsy, S. (1996) Validation of Methods for Determination of o-Phenylphenol Residues and Phenylhydroquinone Residues in Citrus: Addendum No.1 to the Final Report: Lab Project Number: HWI 6524-107. Unpublished study prepared by Hazleton Wisconsin, Inc. 14 p.

MRID 43996401 – Harsy, S. (1996) Validation of Methods for Determination of o-Phenylphenol Residues and Phenylhydroquinone Residues in Citrus: Final Report: Lab Project Number: HWI 6524-107. Unpublished study prepared by Hazleton Wisconsin, Inc. 89 p.

MRID 43992401 – Johnson, G.; Strickland, M. (1996) Storage Stability of Orthophenylphenol and Phenylhydroquinone Residues in/on Raw Orange, Grapefruit, Lemon Fruit and Processed Orange Products: Final Report: Lab Project Number: CCQC 94-06: 101-009: HWI 6578-104. Unpublished study prepared by Western EcoSystems Technology (WEST, Inc.); Research for Hire; and Wm. J. Englar & Associates, Inc. 178 p.

MRID 44112001 – Johnson, G.; Strickland, M. (1996) Storage Stability of Orthophenylphenol and Phenylhydroquinone Residues in/on Raw Orange, Grapefruit, Lemon Fruit, and Processed Orange Products: Addendum 1 to the Final Report: Lab Project Number: 101-009: R289505: CCQC 94-06. Unpublished study prepared by Western EcoSystems Technology (WEST, Inc.); Research for Hire; and Corning Hazleton. 42 p.

MRID 44182601 – Johnson, G.; Strickland, M. (1996) Storage Stability of Orthophenylphenol and Phenylhydroquinone Residues in/on Raw Orange, Grapefruit, Lemon Fruit and Processed Orange Products Addendum 2 to the Final Report (MRID 43992401): Lab Project Number: 101-009: R289505: CCQC 94-06. Unpublished study prepared by Western EcoSystems Technology. 33 p.

Human Exposure

MRID 45524304 – Bestari et al., 1999 Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III). (Task force #73154).

MRID 41412201 – Popendorf, W.; Selim, M.; Kross, B. (1990) Chemical Manufacturers Association Antimicrobial Exposure Assessment Study: Lab Project ID: Q626. Unpublished study prepared by Univ. of Iowa, Insti- tute of Agricultural Medicine and Occupational Health. 209 p. Has different statistics when compared to 41742601 and 41761201.

MRID 41742601 – Popendorf, W.; Selim, M.; Kross, B. (1990) Chemical Manufacturers Association Antimicrobial Exposure Assessment: Lab Project Number: Q626. Unpublished study prepared by The Univ. of Iowa. 209 p.

MRID 43432901 – Maxey, S.; Murphy, P. (1994) Evaluation of Post-Application Exposures to Sodium o-Phenylphenate Tetrahydrate/ o-Phenylphenol to Workers During Post-Harvest Activities at Pear and Citrus Fruit Packaging Facilities: Lab Project Number: HEH2.1-1-174(39). Unpublished study prepared by Dow Chemical Co. 180 p.

OPEN LITERATURE

EcoTox

Bentley, R.E. 1975. Acute Toxicity of Dowicide Co to the Bluegill and Rainbow Trout. Unpublished data. Conducted by Bionomics EG&G Environmental Consultants for The Dow Chemical Co.

Blair, R.M., H. Fang, W.S. Branham, B.S. Hass, S.L. Dial, C.L. Moland, W. Tong, L. Shi, R. Perkins, and D. M. Sheehan. 2000. The Estrogenic Receptor Relative Binding Affinities of 188 Natural and Xenochemicals: Structural Diversity of Ligands. Toxicol Sci 54; 138-53.

Broderius, S. J., M.D. Kahl, and M.D. Hoglund. 1995. Use of Joint Toxic Response to Define the Primary Mode of Toxic Action for Diverse Industrial Organic Chemicals. Environ Toxicol Chem 14(9): 1591-1605.

Davis, H. C. 1961. Effects of Some Pesticides on Eggs and Larvae of Oysters (*Crassostrea virginica*) and Clams (*Venus mercenaria*). Commer Fish Rev 23(12): 18-23.

Davoren, M., and A. M. Fogarty. 2005. Ecotoxicological Evaluation of the Biocidal Agents Sodium o-Phenylphenol, sodium o-Benzyl-p-Chlorophenol, and sodium p-Tertiary Amylphenol. Ecotox and Environ Safety 60: 203-212.

Hu, J., and T. Aizawa. 2003. Quantitative Structure-Activity Relationships for Estrogen Receptor Binding Affinitiy of Phenolic Chemicals. Water Res 37: 1213-22.

Kuhn, R., M. Pattard, K. Pernak, and A. Winter. 1989. Results of the Harmful Effects of Selected Water Pollutants (Anilines, Phenols, Aliphatic Compounds) to *Daphnia magna*. Water Res 23(4): 495-499.

McCann, J. 1973. Fish Toxicity Laboratory Report on Dowicide A, Test No. 640. Unpublished data. Conducted by the Animal Biology Laboratory, EPA-PR, ARC, Beltsville, MD.

Miller, D., B. B. Wheals, N. Beresford, and J. P. Sumpter. 2001. Estrogenic Activity of Phenolic Additives Determined by an *In Vitro* Yeast Bioassay. Environ Health Perspec 109(2); 133-38.

Routledge, E. J., and J. P. Sumpter. 1997. Structural Features of Alkylphenolic Chemicals Associated with Estrogenic Activity. J Biol Chem 272(6): 3280-88.

Schmeider, P.K., M.A. Tapper, J.S. Denny, R.C. Kolanzyk, B.R. Sheedy, T.R. Henry, and G. D. Veith. 2004. Use of Trout Liver Slices to Enhance Mechanistic Interpretation of Estrogen Receptor Binding for Cost-Effective Prioritization of Chemicals within Large Inventories. Environ. Sci. Technol. 38: 6333-6342.

Schmeider, P., M. Tapper, A. Linnum, J. Denny, R. Kolanzyk, and R. Johnson. 2000. Optimization of a Precision-Cut Trout Liver Tissue Slice Assay as a Screen for Vitellogenin Induction: Comparison of Slice Incubation Techniques. Aquat. Toxicol. 49: 251-268.

Toxicology

Brunsman, L. 2005. Orthophenylphenol: Qualitative Risk Assessment Based on CDF(F-344)/BR Rat and B6C3F1 Albino Mouse Dietary Studies. May 19, 2005, TXR No. 0053394.

Bartels, M.J., McNett, D.A., Timchalk, C., Mendrala, A.L., Christenson, W.R., Sangha, G.K., Brzak, K.A., Shabrang, S.N. (1998): Comparative metabolism of ortho-phenylphenol in mouse, rat, and man. Xenobiotica 28(6): 579-594.

Kolachana, P. et al. (1991): Metabolism of phenylhydroquinone by prostaglandin (H) synthase: possible implications in o-phenylphenol carcinogenesis. Carcinogenesis 12(1): 145-149.

Niho, N et al. (2002): Dose- and time-response studies of sodium o-phenylphenate urinary bladder carcinogenicity in rats. Food and Chemical Toxicology 40: 715-722.

Ozawa, S. et al. (2000): Metabolic activation of o-phenylphenol to a major cytotoxic metabolite, phenylhydroquinone: role of human CYP1A2 and rat CYP2C11/CYP2E1. Xenobiotica 30(10): 1005-1017

Reitz, R.H. et al. (1983): Molecular mechanisms involved in the Toxicity of Orthophenylphenol and its Sodium salt. Chem.-Biol. Interactions 43: 99-119.

Department for Environment, Food, and Rural Affairs, Pesticide Safety Directorate (1993): Evaluation of Fully Approved or Provisionally Approved Products: Evaluation on 2-Phenyl Phenol.

Environmental Fate

Hazard Substances Databank (HSDB), A Database of the National Library of Medicine's TOXNET System.

K. Verschwren, 1996; Handbook of Environmental Data on Organic Chemicals, 3rd. Edition, Van Nostrand, NY, pp 536

RC Gore et al. J. Assoc. Official Analytical Chemists, 1971, Volume 54, pp 1042-82

J. Suzuki et al.; Bull Environ Contam. Toxicol, 1990, Volume 45, pp 512 and M.

Sarakha et al.; Chemophere, 1989, volume 18, pp 1391)

L. Krumenacker, 1995; Kirk-Othmer Encyclopedia of Chem. And Technol., 4th Edition, John Wiley, NY, Volume 13, pp 1004

W.M Meylan, and PH Howard, 1993; Chemosphere, Volume 26, pp 2293.

AW Garrison, 1969 Analytical Studies of Textile Wastes, Presented to Division of Drinking Water/ Air/ Waste Chem. American Chemical Society)

TR Tallin, 1975; Polytech. Inst., Volume 390, pp 107

SJ Gonsior, J. Agri. Food Chem, 1984, Volume 34, pp 593

Human Exposure
Cinalli, Christina, et al. A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands. Exposure Evaluation Division. September 1992.

National Institute for Occupational Safety and Health (NIOSH): Criteria for a Recommended Standard-Occupational Exposure to Metalworking Fluids. Department of Health and Human Services (DHHS) NIOSH Publication #98-102 (1998).

WEBSITES

Dietary

FDA, 2003a. "Guidance For Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations. Final Guidance." April, 2003. http://www.cfsan.fda.gov/~dms/opa2pmnc.html. Last accessed June 9, 2003.

FDA, 2003b. "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions." January, 1993. http://www.cfsan.fda.gov/~dms/opa-cg3a.html. Last accessed June 9, 2003

EcoTox

Addinsoft, 2004. XLSTAT v7.5. http://www.xlstat.com.

Toxicology

IPCS, 1999: Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment: 2-phenylphenol and its sodium salt. Available at: www.inchem.org/documents/jmpr/jmpmono/v99pr08.htm

Human Exposure

SIMetric, 2005. Mass, Weight, Density, or Specific Gravity of Bulk Materials. http://www.simetric.co.uk/si_materials.htm , last accessed June 2005.

Whatman, 2005. Whatman Absorbent Sinks. http://www.whatman.com/products/?pageID=7.32.42 , Accessed March 2005.

INTERNAL DOCUMENTS

Dietary

EPA, 1997. "Exposure Factors Handbook, Volume III: Activity Factors." EPA/600/P-95/002Fc August 1997.

EPA, 1999. "Available Information on Assessing Exposure from Pesticides, A User's Guide." http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf. Last accessed June 9, 2003.

Human Exposure

USEPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. EPA Office of Pesticide Programs–Human Health Effects Division (HED). Dated December 18, 1997.

USEPA. 1997a. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

USEPA 1997b. Risk Analysis for Microban Additive "B" (Triclosan or Irgason DP300) Treated Toys for Infants. Memorandum from Winston Dang, USEPA to Frank Sanders and William Jordan, USEPA. Dated February 27, 1997.

USEPA. 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. Washington, DC: U.S. Environmental Protection Agency.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax,

USEPA. Dated November 4, 1999. DP Barcode D247642. (HED's Science Advisory council for Exposure Policy #009. Agricultural Default Daily Acres Treated. April 1, 1999).

USEPA. 2000. Residential SOPs. EPA Office of Pesticide Programs–Human Health Effects Division. Dated April 5, 2000.

USEPA. 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.

Environmental Fate

USEPA, A. Najm Shamim, and Kathryn Montague, 2005 (memorandum); Review on the Determination of the Leaching Rate of NA-OPP From Wood Following A Simulated Sapstain Treatment (DP Bar Code: 319656)

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. ANTIMICROBIAL DIVISION'S BATCHING OF PRODUCTS CONTAINING *Phenylphenol and Salts* AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing any of the active ingredients in the Reregistration Case *Phenylphenol and Salts*, 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), and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar," since they may not have similar use patterns.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. 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 partial list of 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. The Agency must approve any new or canceled formulations (that were presented to the Agency after the completion of the RED) before data derived from them can be used to cover other products in a batch. 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.

If a registrant would like to have the batching status of a product reconsidered, he/she needs to submit detailed information on the product, including a detailed rationale for the inclusion of the product into a batch. An MSDS for each "inert" ingredient should be included where possible. However, registrants and manufacturers should realize that the more unusual their formulation is, the less likely it is to be able to batch that product.

119 products were found which contain o-phenylphenol or one of its salts as an active ingredient. These products have been placed into 22 batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Any product in a batch may cite new or previously submitted acute toxicity data (if it meets current Agency standards) from any other product in the same batch, except as specified below:

- In Batch 1, Reg. No^{s}. 39967-20 and 40510-5 each must cite its own eye irritation study.
- In Batch 2, each product must cite its own data or data conducted on Reg. No. 464-78, 464-616, or 39967-24.
- In Batch 3, each product must cite its own data or data conducted on Reg. No. 464-656 or 57227-7.
- In Batch 4, each product must cite its own eye irritation and skin irritation studies.
- In Batch 5, each product must cite its own data or data conducted on Reg. No. 64864-54.
- In Batch 9, each product must cite its own data or data conducted on Reg. No. 3862-178.
- In Batch 10, each product must cite its own data or data conducted on Reg. No. 303-225.
- In Batch 11, each product must cite its own data or data conducted on Reg. No. 66171-1.
- In Batch 12, each product must cite its own data or data conducted on Reg. No. 211-25.
- In Batch 13, each product must cite its own data or data conducted on Reg. No. 3862-179.
- In Batch 14, for eye irritation data, each product must cite its own study or a study conducted on Reg. No. 70263-7.
- In Batch 15, each product must cite its own eye irritation study.
- In Batch 19, each product must cite its own eye irritation study.

- In Batch 20, each product must cite its own eye irritation study.
- In Batch 21, each product must cite its own data or data conducted on Reg. No. 70263-2.
- In Batch 22, each product must cite its own data or data conducted on Reg. No. 70263-1.

In the No Batch category, each product must cite its own data. I.e., registrants of these products may only cite data obtained from the specific product itself to support the acute toxicity data requirements for that product.

If a product can be assumed corrosive to the skin or has pH less than 2 or greater than 11.5, then if the registrant requests a data waiver for eye or skin irritation (or both), the study can be waived. Acute Toxicity Category I will then be assigned for eye or skin irritation (or both), and the applicable precautionary wording (including the signal word DANGER) will be required on the product label.

Batch 1	EPA Reg. No.	% Active Ingredient
	464-70	o-Phenylphenol 99.5
	464-126	o-Phenylphenol 99.5
	39967-3	o-Phenylphenol 99.9
	39967-11	o-Phenylphenol 99.9
	39967-20*	Sodium o-phenylphenate 99
	40510-5*	Sodium o-phenylphenate 97
	49403-21	o-Phenylphenol 99.5

*Reg. No^{s}. 39967-20 and 40510-5 each must cite its own eye irritation study.

Batch 2	EPA Reg. No.	% Active Ingredient
Each Batch 2 product must cite its own data or data conducted on Reg. No. 464-78, 464-616, or 39967-24.	464-78	Sodium o-phenylphenate 71.7
	464-616	o-Phenylphenol 63
	39967-24	Sodium o-phenylphenate 71.7
	39967-45	Potassium o-phenylphenate 55.6

Batch 3	EPA Reg. No.	% Active Ingredient
Each Batch 3 product must cite its own data or data conducted on Reg. No. 464-656 or 57227-7.	464-656	Sodium o-phenylphenate 25.3
	1022-564	Sodium o-phenylphenate 23
	39967-23	Sodium o-phenylphenate 20
	57227-1	Sodium o-phenylphenate 23
	57227-7	Sodium o-phenylphenate 22.6
	67869-24	Sodium o-phenylphenate 20

Batch 4	EPA Reg. No.	% Active Ingredient
Each Batch 4 product must cite its own eye and skin irritation studies.	2792-28	Sodium o-phenylphenate 14.5
	2792-32	Sodium o-phenylphenate 14.5

Batch 5	EPA Reg. No.	% Active Ingredient
Each Batch 5 product must cite its own data or data conducted on Reg. No. 64864-54.	33354-2	Sodium o-phenylphenate 14.15
	64864-45	Sodium o-phenylphenate 13
	64864-54	Sodium o-phenylphenate 14.52

Batch 6	EPA Reg. No.	% Active Ingredient
	6836-252	o-Phenylphenol 9.5 o-Benzyl-p-chlorophenol 9.5
	70627-6	o-Phenylphenol 10.5 o-Benzyl-p-chlorophenol 10.5

Batch 7	EPA Reg. No.	% Active Ingredient
	1043-87	p-tert-Amylphenol 7.66 o-Phenylphenol 9.09
	1043-114*	p-tert-Amylphenol 7.66 o-Phenylphenol 9.09
	1043-115	p-tert-Amylphenol 7.66 o-Phenylphenol 9.09
	1043-117	p-tert-Amylphenol 7.66 o-Phenylphenol 9.09

*Not including "Enzyme Presoak" component.

Batch 8	EPA Reg. No.	% Active Ingredient
	1043-91	o-Phenylphenol 7.7 p-tert-Amylphenol 7.6
	1043-92	o-Phenylphenol 7.7 p-tert-Amylphenol 7.6

Batch 9	EPA Reg. No.	% Active Ingredient
Each Batch 9 product must cite its own data or data conducted on Reg. No. 3862-178.	3862-178	o-Benzyl-p-chlorophenol 6.5 p-tert-Amylphenol 10 o-Phenylphenol 6
	3862-180	o-Benzyl-p-chlorophenol 5.06 p-tert-Amylphenol 7.78 o-Phenylphenol 4.67

Batch 10	EPA Reg. No.	% Active Ingredient
Each Batch 10 product must cite its own data or data conducted on Reg. No. 303-225.	303-223	o-Benzyl-p-chlorophenol 5.32 p-tert-Amylphenol 1.81 o-Phenylphenol 3.55
	303-225	o-Benzyl-p-chlorophenol 10.6 p-tert-Amylphenol 3.62 o-Phenylphenol 7.06

Batch 11	EPA Reg. No.	% Active Ingredient
Each Batch 11 product must cite its own data or data conducted on Reg. No. 66171-1.	66171-1	o-Benzyl-p-chlorophenol 6 p-tert-Amylphenol 4 o-Phenylphenol 11
	66171-2	o-Benzyl-p-chlorophenol 3 p-tert-Amylphenol 2 o-Phenylphenol 5.5

Batch 12	EPA Reg. No.	% Active Ingredient
Each Batch 12 product must cite its own data or data conducted on Reg. No. 211-25.	211-25	Potassium o-benzyl-p-chlorophenate 8.03 Potassium p-tert-Amylphenate 4.3 Potassium o-Phenylphenate 6.28
	211-36	Sodium o-benzyl-p-chlorophenate 4.4 Sodium p-tert-Amylphenate 2.49 Sodium o-Phenylphenate 2.82

Batch 13	EPA Reg. No.	% Active Ingredient
Each Batch 13 product must cite its own data or data conducted on Reg. No. 3862-179.	2212-17	o-Benzyl-p-chlorophenol 3.8 p-tert-Amylphenol 3.74 o-Phenylphenol 2.35
	3862-179	o-Benzyl-p-chlorophenol 3 p-tert-Amylphenol 5.25 o-Phenylphenol 3

Batch 14	EPA Reg. No.	% Active Ingredient
For eye irritation data, each Batch 14 product must cite its own study or a study conducted on Reg. No. 70263-7.	49403-6	o-Benzyl-p-chlorophenol 5 p-tert-Amylphenol 1.25 o-Phenylphenol 4.25
	70263-7	o-Benzyl-p-chlorophenol 4.9 p-tert-Amylphenol 1.2 o-Phenylphenol 4.02

Batch 15	EPA Reg. No.	% Active Ingredient
Each Batch 15 product must cite its own eye irritation study.	706-69	Ethanol 49.95 p-tert-Amylphenol .045 o-Phenylphenol .176
	1270-237	Ethanol 66.825 p-tert-Amylphenol .054 o-Phenylphenol .216
	3862-104	p-tert-Amylphenol .02 o-Phenylphenol .08
	7405-51	Ethanol 53.72 p-tert-Amylphenol .03 o-Phenylphenol .1
	10088-104	Ethanol 53.46 p-tert-Amylphenol .044 o-Phenylphenol .176
	10088-105	Ethanol 69 p-tert-Amylphenol .058 o-Phenylphenol .249
	10807-177	Ethanol 61.348 p-tert-Amylphenol .045 o-Phenylphenol .177
	10807-178	Ethanol 67 p-tert-Amylphenol .045 o-Phenylphenol .177
	44446-67	Ethanol 53 p-tert-Amylphenol .046 o-Phenylphenol .199

Batch 16	EPA Reg. No.	% Active Ingredient
	55195-3	Glutaraldehyde .275 p-tert-Amylphenol .0027 o-Phenylphenol .0137
	55195-4	Glutaraldehyde .275 p-tert-Amylphenol .0028 o-Phenylphenol .0138

Batch 17	EPA Reg. No.	% Active Ingredient
	46851-5	o-Phenylphenol .28 o-Benzyl-p-chlorophenol .03
	46851-10	o-Phenylphenol .28 o-Benzyl-p-chlorophenol .03

Batch 18	EPA Reg. No.	% Active Ingredient
	211-32	o-Phenylphenol .21 Ethanol 69.623
	56392-2	o-Phenylphenol .12 Ethanol 66.6
	56392-4	o-Phenylphenol .12 Ethanol 69.1

Batch 19	EPA Reg. No.	% Active Ingredient
Each Batch 19 product must cite its own eye irritation study.	11694-98	o-Phenylphenol .19 Ethanol 68
	11694-99	o-Phenylphenol .19 Ethanol 68

Batch 20	EPA Reg. No.	% Active Ingredient
Each Batch 20 product must cite its own eye irritation study.	498-134	o-Phenylphenol .1 Ethanol 63.2
	498-194	o-Phenylphenol .1 Ethanol 63.2

Batch 21	EPA Reg. No.	% Active Ingredient
Each Batch 21 product must cite its own data or data conducted on Reg. No. 70263-2.	70263-2	o-Phenylphenol .22 Diisobutylphenoxyethoxy ethyl dimethyl benzyl ammonium chloride monohydrate .7 N-Octyl bicycloheptene dicarboximide .33 Piperonyl butoxide .2 Pyrethrins .1 Bromine .04
	70263-3	o-Phenylphenol .22 Diisobutylphenoxyethoxy ethyl dimethyl benzyl ammonium chloride monohydrate .7 N-Octyl bicycloheptene dicarboximide .33 Piperonyl butoxide .2 Pyrethrins .1

Batch 22	EPA Reg. No.	% Active Ingredient
Each Batch 22 product must cite its own data or data conducted on Reg. No. 70263-1.	70263-1	o-Phenylphenol .22 Diisobutylphenoxyethoxy ethyl dimethyl benzyl ammonium chloride monohydrate .7 Bromine .04
	70263-5	o-Phenylphenol .22 Diisobutylphenoxyethoxy ethyl dimethyl benzyl ammonium chloride monohydrate .7

No Batch	EPA Reg. No.	% Active Ingredient
Each "No Batch" product must cite its own data.	211-62	o-Phenylphenol 8.085 o-Benzyl-p-chlorophenol 6.65
	498-180	o-Phenylphenol .1 Isopropanol 55
	675-19	o-Phenylphenol 2.8 o-Benzyl-p-chlorophenol 2.7
	675-21	o-Phenylphenol 15 p-tert-Amylphenol 6.3
	675-43	o-Phenylphenol 10.63 o-Benzyl-p-chlorophenol 5.11
	777-27	o-Phenylphenol .42
	777-60	o-Phenylphenol .78 Pine oil 15
	777-73	o-Phenylphenol .07
	954-10	o-Phenylphenol .41 Isopropanol 45.63
	954-13	o-Phenylphenol 1.65 o-Benzyl-p-chlorophenol 5
	1043-19	o-Phenylphenol .041 o-Benzyl-p-chlorophenol .077 p-tert-Amylphenol .074 Ethanol 53.096 Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) .042 Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C12, 30%C14, 17%C16, 3%C18) .042
	1043-26	o-Phenylphenol 10 o-Benzyl-p-chlorophenol 8.5 p-tert-Amylphenol 2
	1043-118	o-Phenylphenol .5 o-Benzyl-p-chlorophenol 6.4 p-tert-Amylphenol 3
	1677-128	o-Phenylphenol 1.5 o-Benzyl-p-chlorophenol 1.4
	1677-130	o-Phenylphenol 7.5 o-Benzyl-p-chlorophenol 7.4
	1677-157	o-Phenylphenol 3 o-Benzyl-p-chlorophenol 2.85
	2296-101	o-Phenylphenol .05

	3862-177	o-Phenylphenol 12 o-Benzyl-p-chlorophenol 10 p-tert-Amylphenol 4
	4822-479	o-Phenylphenol .1 Piperonyl butoxide .25 Pyrethrins .1 Permethrin .2
	5741-6	o-Phenylphenol 6.13
	5741-22	o-Phenylphenol .051 o-Benzyl-p-chlorophenol .071 Ethanol 64
	6836-253*	o-Phenylphenol 4.75 o-Benzyl-p-chlorophenol 4.75
	8284-7	Sodium o-phenylphenate .31
	8764-1	Sodium o-phenylphenate 25
	8764-16	Sodium o-phenylphenate 24
	8764-24	Sodium o-phenylphenate 1
	10145-3	o-Phenylphenol 10.95
	10145-4	o-Phenylphenol 3.92
	33176-5	o-Phenylphenol .25 Ethanol 44.25 Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16) .33
	33176-6	o-Phenylphenol .1 o-Benzyl-p-chlorophenol .08
	34810-8	o-Phenylphenol 6.73 o-Benzyl-p-chlorophenol 5.76
	34810-16	Sodium o-phenylphenate 8.45 Sodium o-benzyl-p-chlorophenate 7.15
	34810-19	o-Phenylphenol 7 Thymol 7
	34810-21	o-Phenylphenol .026 o-Benzyl-p-chlorophenol .023
	34810-22	o-Phenylphenol .027 Thymol .027
	34810-28	o-Phenylphenol 10.1 o-Benzyl-p-chlorophenol 2.64
	34810-29	o-Phenylphenol 7.33 o-Benzyl-p-chlorophenol 6.09
	34810-31	o-Phenylphenol 3.4 o-Benzyl-p-chlorophenol 3.03

	39967-9	o-Phenylphenol 12.5 p-Chloro-m-cresol 29.6
	39967-26	Sodium o-phenylphenate 13.1 Sodium p-chloro-m-cresolate 31.9 Sodium pyrithione 1.2
	43410-9	o-Phenylphenol 2.5
	43553-20	Sodium o-phenylphenate 31
	46851-1	o-Phenylphenol 9 o-Benzyl-p-chlorophenol 1
	49403-23	o-Phenylphenol 4.9 o-Benzyl-p-chlorophenol 10.1 p-tert-Amylphenol 2.5
	56392-1	o-Phenylphenol .37
	62296-1	o-Phenylphenol .99 o-Benzyl-p-chlorophenol 5.25
	65596-1	o-Phenylphenol 1
	69658-3	o-Phenylphenol .4 Phenol .6 Ethanol 98
	70263-4	o-Phenylphenol .22 Allethrins .1 N-Octyl bicycloheptene dicarboximide .33 Piperonyl butoxide .2 Diisobutylphenoxyethoxy ethyl dimethyl benzyl ammonium chloride monohydrate .7
	70627-14	Potassium o-phenylphenate .159
	71240-1	Sodium o-phenylphenate .25
	71654-17	o-Phenylphenol 7.92 o-Benzyl-p-chlorophenol 9.97 p-tert-Amylphenol 1.95
	72136-1	o-Phenylphenol .248

*Reg. No. 6836-253 optionally may cite studies conducted on Reg. No. 6836-252, as previously permitted.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the Data Call-In will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

a. Registration Division Personnel Contact List

b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This

service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition. To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.