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United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-08-010
March 2009

Reregistration Eligibility Decision for Phenol & Salts

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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 phenol and salts. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for phenol and salts on September 30, 2004. 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 phenol and salts 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 the phenol and salts are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2004-0301 at: http://www.regulations.gov.

The phenol and salts RED was developed through EPA's public participation process, published in the Federal Register on September 17, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and 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 phenol and salts 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 phenol and salts alone. This document also contains both generic and product-specific data that the Agency intends to require in 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 phenol and salts 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 phenol and salts. 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, K. Avivah Jakob, at (703)-305-1328. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Joan Harrigan Farrelly

Joan Harrigan-Farrelly, Director
Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Phenol & Salts
List D
CASE 4074

Approved By:

Joan Harrigan-Farrelly
Director, Antimicrobials Division
March 30, 2009

Attachment

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Phenol and salts Reregistration Team

Health Effects Risk Assessment
Jonathan Chen
Timothy McMahon
Timothy Leighton
Timothy Dole
Najm Shamim

Ecological Risk Assessment
Kathryn Montague

Environmental Fate Risk Assessment
Najm Shamim

Risk Management
K. Avivah Jakob
Diane Isbell

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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	Protection 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

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ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for phenol and salts and is issuing its risk management decision. 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 phenol and salts that pose risks of concern. As a result of this review, EPA has determined that products containing phenol and salts are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

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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.

The Agency made its reregistration eligibility determination for phenol and salts based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered phenol and salts products are eligible for reregistration provided that the risk mitigation and label amendments identified in this reregistration eligibility decision (RED) document are implemented.

In 2004, the EPA issued the "Phenol/Sodium Phenate Reregistration Decision" memo, dated September 30, 2004. The decision memo addresses the risks of concern identified in the phenol and salts risk assessment ("Phenols RED Document," July 7, 2004) and the Agency's risk management decisions to address these risks of concern. However, the use of fogging clean rooms use and the use of phenol and salts to treat HVAC ductwork were, inadvertently, not addressed in either of these documents. The purpose of this reregistration eligibility decision document is to not only summarize the findings and mitigation decisions outlined in the "Phenols RED Document" and the "Phenol/Sodium Phenate Reregistration Decision" memorandum but to present the findings of the Occupational and Residential Exposure (ORE) assessments that have been recently conducted for the fogging clean room and HVAC ductwork treatment uses. In addition, the Agency's risk management decisions to support the continuation of these uses are also provided in this document. For further information refer to the "Phenols RED Document," dated July 7, 2004, the "Occupational and Residential Exposure and Risk Assessment for the Existing Fogging Clean-room Use of Phenol (Sporicidin)," dated December 18, 2008 and the "Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)," dated December 18, 2008. These documents are located in the Public Docket at http://www.regulations.gov in docket number EPA-HQ-OPP-2004-0301.

This document consists of six sections: Section I contains the regulatory framework for reregistration reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and Data Call-In (DCI) information. The final risk assessment documents, related

addenda, and public comments are not included in this document and are available in the Public Docket at http://www.regulations.gov in docket number EPA-HQ-OPP-2004-0301.

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II. Chemical Overview

A. Regulatory History

Phenol and salts is regulated by both the U.S. EPA and the U.S. Food and Drug Administration (FDA). The EPA regulates the antimicrobial uses of phenol and salts when used as a materials preservative, disinfectant and deodorizer. Phenol and salts (PC Codes 064001 & 064002) were first registered as active ingredients by the United Sates Department of Agriculture (USDA) on June 11, 1969. In 1970, the Environmental Protection Agency (EPA) was established and was charged with protecting human health and the environment, and assumed all pesticide registration from USDA. Currently there are six products that contain phenol and salts as active ingredients. Phenol and salts are active ingredients in disinfectant, deodorizer and cleaning formulations. Phenol and salts are also used as materials preservatives for polishes and cleansers, and protectants. These formulations have bactericidal, virucidal, fungicidal and tuberculocidal properties, kill mold and mildew, and eliminate odor. Prior to April 12, 2005 phenol and salts were used as a materials preservative in paints. However, this use was voluntarily cancelled as a result of the risks identified in the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004.

Use site categories for these formulations include material preservatives, commercial, institutional and industrial premises and equipment, medical premises and equipment, food handling establishments and residential and public access premises. A review of product labels indicate that most of these formulations are intended for use in hospitals, clinics, medical and veterinary offices, nursing homes, laboratories, industrial clean rooms, ambulances, hotels, restaurants, schools, transportation facilities, health spas and toilets. The FDA-regulated uses of phenol and salts can be found in over-the-counter drugs, which are used for the treatment of various conditions including insect bites, poison ivy, diaper rash, antiseptics and acne (21 CFR § 310.531 and §310.545).

B. Chemical Identification

Technical Phenol

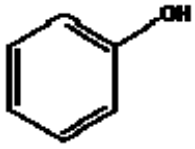

Figure #1. Molecular Structure of Phenol

Common name: Phenol

Chemical name: Phenol

Chemical family: Phenols

Empirical formula: C_6H_6O

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CAS Registry No.: 108-95-2

Case number: 4074

OPP Chemical Code: 064001

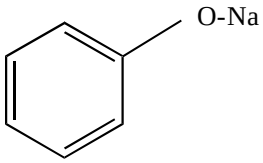
Molecular weight: 94.11 g/mol

Other names: Carbolic acid; Hyroxybenzene

Registrants: Contec, Inc. and World Pharmaceuticals Corporation

Chemical properties: Phenol is colorless to light pink. Its physical state is crystalline solid and it is mildly acidic. Phenol is stable at normal conditions and its melting point is at 43.0°C and 40.9°C (ultra pure material). Its boiling point is 181.8°C at 760 mm Hg and its water solubility is 67 g/L in water at 16°C. Phenols Log K_{OW} is 1.46 at 25° C. Its vapor pressure is 0.341 mm Hg at 25°C, 2.48 mm Hg at 50°C and 41.3 mm Hg at 100°C. Phenol's relative vapor density is 3.24 and its saturation concentration in air is 0.77 g/m^3 at 20°C.

Technical Phenol Salts



Sodium Phenoate

Figure #2. Molecular Structure of Phenol Salts

Common name: Phenol salts (salts)

Chemical name: Sodium phenate

Chemical family: Phenoxy

Empirical formula: C_6H_6ONa

CAS Registry No.: 139-02-6

Case number: 4074

OPP Chemical Code: 064002

Molecular weight: 116.10 g/mol

Other names: Sodium phenolate; Phenol, sodium salt; Salts

Basic manufacturer: Contec, Inc.

Chemical properties: The color of phenol salts is white to reddish in color and its physical state is crystalline needles or rods. Its pH is alkaline in aqueous solutions, and it is stable at normal conditions and is highly soluble in water.

C. Use Profile

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

Type of Pesticide: Sanitizer, Bacteriostat, Fungicide/Fungistat, Tuberculocide, Disinfectant, Virucide

Summary of Use:

Agricultural Premises & Equipment
Phenol and salts are used as disinfectants, deodorizers and cleaners for the following hard, non-porous surfaces: farm equipment, animal and poultry housing, barns, kennels, breeding pens, hatcheries, trucks and other vehicles.

Commercial, Institutional and Industrial Premises & Equipment
Phenol and salts are used as disinfectants, deodorizers and cleaners for the following hard, non-porous surfaces: telephones, keyboards, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, bathrooms, kennels and animal areas, schools, restaurants, hotels, boats, planes, buses, industrial clean rooms (fogging), and air ducts (HVAC). Phenol and salts are also used to clean, deodorize and remove debris from carpets and fabrics.

Food Handling/Storage Establishments Premises & Equipment
Phenol and salts are used as disinfectants, deodorizers and cleaners for the following hard, non-porous surfaces: food processing plants, food handling areas, poultry and meat packaging facilities and slaughter houses, sinks, drain boards, cabinets, garbage cans, under sinks, faucets.

Medical Premises and Equipment
Phenol and salts are used as disinfectants, deodorizers and cleaners for the following hard, non-porous surfaces: health/hospital treatment and patient rooms, operating rooms, ambulances, medical and dental equipment, beds, surgical carts, countertops, mannequins, hemodialysis and dialysis machines, bathrooms, wheelchairs, walkers, animal areas, trash containers, medical devises.

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Residential and Public Premises
Phenol and salts are used as disinfectants, deodorizers and cleaners for the following hard, non-porous surfaces: telephones, keyboards, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, bathrooms, kennels and animal areas, schools, restaurants, hotels, boats, planes, trains, buses, health spas, nursing homes, walls, countertops, floors, and air ducts (HVAC). Phenol and salts are also used to clean, deodorize and remove debris from carpets and fabrics.

Materials Preservative
Phenol and salts are used as an industrial additive for polishes, cleansers and protectants. Prior to April 12, 2005 phenol and salts were used as a materials preservative in paints. This use was voluntarily cancelled as a result of the risks identified in the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004. However, the findings of the risk assessment conducted for the paint use are outlined in this document.

Target Pests: Animal Pathogenic Bacteria (G- and G+ Vegetative); Animal Pathogenic Fungi; Aspergillus Niger; Avian Influenza Virus A; Canine Parvovirus; Coronavirus; Cytomegalovirus; Herpes Simplex Virus I; Herpes Simplex Virus II; HIV-I (Human Immunodeficiency Virus); Hydrophilic Virus; Influenza A2 (Hong Kong); Influenza Virus A2 (Japan 305/57 Asian Strain); Lipophilic Viruses; Mold/Mildew; Mycrobacterium SPP (Tubercle Bacilli); Parvovirus; Poliovirus Type 1; Pseudomonas SPP; Streptococcus Pyogenes; Vaccinia Virus

Formulation Types: Ready-to-Use, Pressurized Liquid, Impregnated Materials

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III. Summary of 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 phenol and salts. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2004-0301, and may also be accessed from www.regulations.gov. Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South 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 Agency's use of human studies in the phenol 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. Human Health Risk Assessment

1. Toxicity of Phenol and Salts

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 1. Further details on the toxicity of phenol and salts can be found in the "Phenol/Sodium Phenate: Toxicology Chapter for the AD Preliminary Risk Assessment Document. PC Code: 064001, 064002," dated July 6, 2004 and the "Phenol-Report of the Antimicrobials Division Toxicology Endpoint Selection Committee," dated July 7, 2004. These documents are available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID EPA-HQ-OPP-2004-0301).

The Agency has reviewed all toxicity studies submitted for phenol and salts and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. Table 1 is a summary of the acute toxicity data and Table 2 summarizes the toxicological endpoints selected for the exposure scenarios.

a. Acute Toxicity

The acute toxicity database for phenol and salts is considered complete. For oral and dermal routes of exposure the acute toxicity of phenol and salts is moderate (Toxicity Category II or III) and produces severe and marked irritation to the eyes and skin (Toxicity Category I or II). Phenol concentration used in acute inhalation studies failed to induce mortality in the study animals and, therefore, toxicity endpoints and a toxicity category could not be established.

The following table summarizes the acute toxicity of phenol and salts.

Table 1. Summary of Acute Toxicity Data for Phenol and Salts

Guideline No.	Study Type/ Test Substance (% AI)	MRID #(s)/ Citation	Results	Toxicity Category
Acute Toxicity				
870.1100 (§81-1)	Acute Oral- Rat Phenol purity > 99%	Berman, et al., 1994	LD_{50} = 400 (297-539) mg/kg/day	II
870.1100 (§81-1)	Acute Oral- Rat Phenol purity 100%	OTS# 0515567 86-870001405	LD_{50} = 1,030 (940-1120) mg/kg/day	III
870.1100 (§81-1)	Acute Oral- Rat Phenol purity not reported	Flickinger, 1976	LD_{50} = 650 (490-860) mg/kg/day	III
870.1200 (§81-2)	Acute Dermal Toxicity- Rat Phenol Purity not reported	Brown, et al., 1975	LD_{50} (non-occluded) = 0.68 (0.57-0.78) mL/kg LD_{50} (occluded) = 0.50 mL/kg	II
870.1200 (§81-2)	Acute Dermal- Rabbit Sodium Phenate purity 57%	OTS # 0515564 86-870001402	LD_{50} = 2,350 (1,880-2,940) mg/kg/day	III
870.1200 (§81-2)	Acute Dermal- Rabbit Phenol purity 100%	OTS # 0515567 86-870001405	LD_{50} = 0.63 (0.56-0.70) mL/kg	II
870.1200 (§81-2)	Acute Dermal- Rat Phenol purity laboratory reagent grade	Conning et al., 1970	LD_{50} = 669.4 mg/kg/day	II
870.1200 (§81-2)	Acute Dermal- Rabbit Phenol purity not reported	Flickinger, 1976	LD_{50} = 850 (600-1,200) mg/kg/day	II
870.1300 (§81-3)	Acute Inhalation- Rat Phenol purity 100%	OTS # 0515567 86-870001405	No deaths occurred at 2.5 L/min for 8 hours	Not established
870.1300 (§81-3)	Acute Inhalation- Rat Phenol purity not reported	Flickinger, 1976	No deaths occurred at 900 mg/m^3 for 8 hours Irritation and time-related CNS effects	Not established
870.2400 (§81-4)	Acute Eye Irritation- Rabbit Sodium Phenate purity 57%	OTS #0515564 86-870001402	15% solution caused corneal necrosis and conjunctiva lesions	II
870.2400 (§81-4)	Acute Eye Irritation- Rabbit Phenol purity 100%	OTS # 0515567 86-870001405	Severe damage to the cornea at 15% and lesser damage in 5%	Not established
870.2400 (§81-4)	Acute Eye Irritation- Rabbit Phenol purity not reported	Flickinger, 1976	Dose not provided. Severe conjunctiva, iritis, corneal opacities and ulcerations with no improvement after 14 day observation period.	I

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Guideline No.	Study Type/ Test Substance (% AI)	MRID #(s)/ Citation	Results	Toxicity Category
870.2500 (§81-5)	Acute Dermal Irritation-Rabbit Sodium Phenate purity 57%	OTS # 0515564 86-870001402	Mild to marked erythema and marked capillary injection were observed in 50% of animals tested	II
870.2500 (§81-5)	Acute Dermal Irritation-Rabbit Phenol purity 100%	OTS # 0515567 86-870001405	10% solution caused moderate to marked erythema	Not established
870.2500 (§81-5)	Acute Dermal Irritation-Rabbit Phenol purity not reported	Flickinger, 1976	Corrosive	I

b. Carcinogenicity

The two carcinogenicity studies preformed by the National Cancer Institute produced no incidences of neoplasms in male and female mice or rats following administration of phenol, with the exception of a statistically significant increase in the occurrence of leukemia, lymphoma, or interstitial-cell tumors in low-dose male rats. Due to the lack of significant tumors in high-dose males, females and mice, phenol was found to be non-carcinogenic in the 2-year drinking water studies. Although phenol-treated rats and mice experienced a decrease in mean body weight and body weight gain, reduction was not significantly different from the respective controls and there was no chronic toxicity at concentration up to 5,000 ppm. A 20-week dermal toxicity study exhibited effects of chronic irritation and hair growth inhibition with administration of 3 mg phenol (in 200 uL acetone). A single papilloma was found 7 weeks into the study but there was no evidence that it was significantly increased or treatment-related. In a special mechanistic study there was no evidence of tumor initiation or hepatocyte GSH depletion following administration of 100 mg/kg/day phenol.

c. Toxicological Endpoints

The phenol and salts toxicity endpoints used in the current risk assessment are summarized below in Table 2.

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Table 2. Toxicological Endpoints for Phenol and salts

Exposure Scenario	Dose Used in Risk Assessment, UF	Target MOE, Uncertainty Factory (UF) for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (gen population)	This risk assessment is not needed because there are no use patterns that result in acute dietary exposure.		
Acute Dietary (females 13-49)	This risk assessment is not not needed because there are no use patterns that result in acute dietary exposure.		
Chronic Dietary (all populations)	NOAEL= 60 mg/kg/day UF = 100 Chronic RfD = 0.6 mg/kg/day Chronic PAD = 0.6 mg/kg/day	FQPA SF = 1x	Developmental toxicity study in rats (Argus, 1997) NOAEL based on decreases in maternal body weight gain at 120 mg/kg/day (LOAEL).
Non-Dietary Risk Assessments			
Incidental Oral (short-term) Residential Only	NOAEL= 60 mg/kg/day	MOE = 100	Developmental toxicity study in rats (Argus, 1997) NOAEL based on decreases in maternal body weight gain at 120 mg/kg/day (LOAEL).
Incidental Oral (intermediate-term) Residential Only	NOAEL= 60 mg/kg/day	MOE = 100	Developmental toxicity study in rats (Argus, 1997) NOAEL based on decreases in maternal body weight gain at 120 mg/kg/day (LOAEL).
Dermal[1] (short- and intermediate-term	NOAEL = 60 mg/kg/day	MOE = 100	Developmental toxicity study in rats (Argus, 1997) NOAEL based on decreases in maternal body weight gain at 120 mg/kg/day (LOAEL).
Inhalation (All durations)	LOAEL = 0.1 mg/L (26 mg/kg/day)	MOE = 300 (ST, IT) MOE = 1,000 (LT)	Dalin and Kristofferson: Physiological Effects of a Sub-lethal Concentration of Inhaled Phenol on the Rat. Ann. Zool. Fennici 11: 193-199, 1974 LOAEL of 0.1 mg/L, based on alterations in sliding angle from tilting plane test, and significant increases in liver enzymes.
Cancer	Data inadequate for assessment of human carcinogenic potential (USEPA, 2002a)		

[1]A dermal absorption factor of 50% is used since an oral endpoint was selected. Dermal absorption data were available from the IRIS Toxicological profile for phenol. From the available data, dermal absorption percentages of 20-50% have been observed from in-vivo and in-vitro studies. The Agency selected the 50% dermal absorption value for phenol for use in risk assessments as a conservative value. This value also takes into account the irritant properties of phenol which may increase its dermal absorption.

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2. Endocrine Disruptor Potential

The EPA is required under the FFDCA, as amended by the Food Quality Protection Act (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 endocrine effects as the Administrator may designate." Following 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 EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use its authorities under FIFRA and/or the FFDCA to require any necessary data on endocrine-related effects. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

3. 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 Agency has concluded that the FQPA Safety Factor should be removed (i.e., reduced to 1X) for phenol and salts based on: (1) a complete toxicology data base with respect to assessing the increased susceptibility to infants and children as required by FQPA; (2) a lack of evidence that phenol and salts will induce neurotoxic effects; (3) no evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies; (4) no evidence of increased susceptibility to the offspring when adults are exposed in the two-generation reproductive study; and (5) the risk assessment does not underestimate the potential exposure for infants and children. 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 post-natal toxicity.

4. Dietary Exposure and Risk

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. The Agency has conducted a dietary exposure and risk assessment for the use of phenol and salts as a had-surface disinfectant for counter tops (e.g., kitchen countertops). Currently, phenol and salts products are registered to disinfect countertops in kitchens, among other areas. A dietary risk assessment was conducted to address the possibility of indirect food contact resulting from the use of phenol and salts as a disinfectant on countertops, which may come in to contact with food after treatment. For further information on the dietary exposure assessment for phenol and salts, please refer to the "Phenol Dietary Exposure Assessment for the Reregistration Eligibility Decision," document, dated May 18, 2004.

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a. Dietary Exposure Assumptions

There are two exemptions from the requirement of a tolerance for phenol as an inert ingredient under 40 CFR 180.920 and 180.930; however, there are no active registrations for these uses. Therefore, as outlined in the "Phenol/Sodium Phenate Reregistration Decision" document memo, the Agency recommends that these exemptions from the requirement of a tolerance be revoked. The revocation of these exemptions from tolerances will be revoked in the future.

The dietary risk assessment considered potential food exposures from the use of phenol and salts as a disinfectant for hard surface, non-porous countertops (e.g., kitchen countertops). There are two phenol and salts products, which are currently registered to disinfect countertops in kitchens, among other areas. One product is a ready-to-use solution, while the other is a wettable disposable cloth that is impregnated with phenol and salts. A countertop that has been treated with either of these products may come into contact with food prepared on the treated countertop, which in turn may be ingested. Although neither product label states that it should be used on food preparation equipment, it is possible that food could be prepared or placed on treated kitchen countertops before being eaten and, therefore, a dietary exposure assessment was needed.

In the absence of residue data, the Agency estimated residue levels that may occur in food that contacts countertop surfaces treated with disinfectants from the maximum application rates on phenol and salts product labels. When assessing the dietary risks, the Agency used the Food and Drug Administration's (FDA) Center for Food Safety & Applied Nutrition's (CFSAN) screening-level approach as presented in the "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations," dated April 2002. Using the maximum application rates and U.S. FDA's default assumptions, "worst-case" dietary concentration values were calculated by the Agency. This model was used to determine the estimated daily intake (EDI). The Agency also used this methodology to assess possible indirect food contact exposure and risk from disinfectants. Additional information regarding the dietary exposure assessment can be found in the "Phenol Dietary Exposure Assessments for the Reregistration Eligibility Decision," dated May 18, 2004, the "Phenol RED Document," dated July 7, 2004 and the "Phenol/Sodium Phenate Reregistration Decision" document memo, dated September 30, 2004.

5. Dietary Risk Assessment

a. Acute PAD

Acute dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose modified by the FQPA Safety Factor. An acute dietary assessment was not conducted for phenol and salts because no endpoints appropriate for a dietary risk assessment were identified in the toxicity database, which is largely complete. This conclusion was based on examination of the available toxicity hazard data. Also, the body weight effects observed in the available data were not felt to be the result of a single exposure and there were no other adverse effects from the data that were considered reflective of

a single exposure. Therefore, an acute RfD/PAD value was not selected. Phenol and salts do not pose as an acute dietary risk and an acute dietary risk assessment was not conducted.

b. Chronic PAD

Chronic dietary risk for phenol and salts 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 (0.6 mg/kg/day) modified by the FQPA Safety Factor (1x). The cPAD was derived from a developmental toxicity study in rats in which the NOAEL (60 mg/kg/day) was determined. For the disinfectant solutions use, the cPAD is 7.5% for adult males, 9.0% for adult females and 36% for children. Because the risk estimate is less than 100% of the chronic PAD, there are no chronic dietary risks of concern from the use of phenol and salts as a disinfectant. The disinfectant solutions use was assessed for indirect food contact and 10% transfer efficiency was assumed. The Agency determined that there are no chronic dietary concerns as a result of this use.

Table #3. Disinfectant Solutions Indirect Dietary Exposure and Risk

Population Subgroup	EDI (mg/person/day)	Chronic Dietary	
		Dietary Exposure (mg/kg/day) [a]	% cPAD [b]
Disinfectant Solutions			
Adult male	3.2400	4.50e-02	7.50
Adult female	3.2400	5.40e-02	9.0
Child	3.2400	2.16e-01	36.0

a- For adult males, chronic exposure analysis is based on a body weight of 70 kg. For adult females, chronic exposure analysis is based on a body weight of 60 kg. For children, exposure is based on a body weight of 15 kg.
b- %cPAD = dietary exposure (mg/kg/day) * 100 / cPAD, where cPAD for adults and children = 0.6 mg/kg/day.

c. Dietary Risk from Drinking Water

Phenol and salts are not used for water treatment and the active ingredients are not expected to contact fresh water environments. Despite phenol's high water solubility and poor sorption to soil, biodegradation of phenol is sufficiently rapid. Therefore, the probability of groundwater contamination is low. Because phenol absorbs lightly (in the region of 290-330 nm) it might photodegrade directly in surface water and it is not expected to absorb to sediment in the water column. Also, based on its use patterns, the potential for phenol and salts to impact drinking water sources is negligible. Therefore, a drinking water assessment was not conducted.

6. Residential Exposure and Risk Assessments

a. Residential Handler Exposure and Risk

The residential exposure scenarios assessed for phenol and salts represent worst case exposure scenarios. The EPA selected high-end representative use scenarios based on maximum

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application rates as stated on the product labels. The Agency considered the following use scenarios for residential handlers of phenol and salts:

Residential Handler Use Scenarios

- Application of treated paint- brush/roller
- Application of treated paint- airless sprayer
- Hard surface disinfection- aerosol spray
- Hard surface disinfection- towelettes
- Painting- vapor exposure
- General purpose cleaning solution- vapor exposure

Dermal and inhalation exposures were assessed for these scenarios using the Pesticide Handler Exposure Database (PHED, Version 1.1) and values were found in the EPA's *Standard Operating Procedures (SOP) for Residential Exposure Assessments* (U.S. EPA, 1997a, 2001). The dermal and inhalation exposures from these techniques have been normalized by the amount of active ingredient handled and are reported as unit exposures (UE), which are expressed as mg/lb of active ingredient handled. Dermal and inhalation exposures were also assessed by using surrogate data from the Chemical Manufacturers Association (CMA, 1992), the Exposure and Fate Assessment Screening Tool Model (EFAST, v1.0), Wall Paint Exposure Assessment Model (WPEM) and several studies that relate to the use patterns of phenol and salts.

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation risk assessments for residential handler exposure. An MOE greater than or equal to 100 is considered adequately protective for the dermal route of exposure. Also, a dermal absorption factor of 50% is used since an oral endpoint was selected. For inhalation exposure the target MOE for identifying risks of concern for short- and intermediate-term exposure durations is 300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a LOAEL). For long-term inhalation exposures the target MOE is 1,000 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a LOAEL and 3x for lack of a long-term study). However, no long-term uses for phenol and salts have been identified. For the residential handler risk assessment the following use scenarios indicate risks of concern:

Residential Handler Risks of Concern
(Target Inhalation MOE = 300/ Target Dermal MOE = 100)

- Painting: Airless Sprayer[1]
  (ST Dermal MOE = 12)
  (ST/IT Inhalation MOE = 290)

- Painting: Paintbrush/Roller[1]
  (ST Dermal MOE = 12)

- Painting: Vapor Exposure[1]
  (ST Inhalation MOE = 27)

However, it should be noted that all phenol and salts paint uses were voluntarily cancelled on April 12, 2005 to mitigate the residential and occupational risks of concern that

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were identified within the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004. Therefore, there are no longer any residential or occupational applicator risks of concern associated with the use of phenol and salts as a paint preservative because this use has been cancelled.

For further information regarding the residential handler exposure and risk estimates refer to the "Phenols Occupation & Residential Exposure Assessment," dated September 9, 2004, the "Phenol RED Document," dated July 7, 2004 and the "Phenol/Sodium Phenate Reregistration Decision" memo, dated September 30, 2004.

b. Post-Application Residential Exposure and Risk

Residential post-application exposures result when adults and children come in contact with phenol and salts in areas where pesticide end-use products have recently been applied (e.g., treated carpets, HVAC ductwork), or when children incidentally ingest the pesticide residues through mouthing the treated end-products/treated articles (i.e., hand-to-mouth or object-to-mouth contact). The residential post-application exposure scenarios assessed for phenol and salts represent worst case exposure scenarios. The EPA selected high-end representative use scenarios based on maximum application rates as stated on the product labels. The Agency considered the following use scenarios for post-application residential exposure to phenol and salts:

Post-Application Residential Exposure Scenarios

- Treated Carpets (machine cleaned/shampooed)
  (ST Dermal & Oral- children)
  (ST Inhalation exposure from vapors- adults & children)
- Paint Vapors (resulting from painting indoors)
  (ST Inhalation)
- Re-entering residential and/or occupational sites with treated HVAC Ductwork
  (ST/IT Inhalation- occurs as the phenol evaporates from the duct surface and mixes with air flowing through the duct)

At this time, the Agency does not have residue dissipation data or reliable use pattern data, including the frequency and duration of use of antimicrobial products in the residential setting. Therefore, to assess residential handler and post-application risks, the Agency used surrogate unit exposure data from the following proprietary resources: Chemical Manufacturers Association (CMA) antimicrobial exposure study; the Pesticide Handlers Exposure Database (PHED); Exposure and Fate Assessment Screening Tool Model (EFAST, v1.0), and the Wall Paint Exposure Assessment Model (WPEM). Additionally, the EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments*, was used when estimating post-application/ bystander exposures.

The Agency assessed potential post-application inhalation exposure to residents resulting from re-entry into residential and occupational buildings, which previously had HVAC duct-work treatment. Post-application inhalation exposures resulting from re-entry into buildings with treated HVAC duct-work were assessed using the Indoor Air Quality and Inhalation Exposure

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(IAQX Model 21, Version 1.0), a chamber emissions study and the Antimicrobial Version of the EPA Risk Model (Antimicrobial Screening Model Version 1.9, Les Sparks, US EPA ORD, 10/1/2004). Given that there are many uncertainties with the HVAC assessment, the Agency used several models to assess possible exposure resulting from the phenol and salts HVAC use. Uncertainties with this risk assessment include extremely limited label instructions (e.g., no application rates on registered label), lack of model validation for this specific use pattern, and limitations regarding the submitted chamber emission study. When estimating possible post-application residential risks of concern resulting from the HVAC use, the Agency used the model that yielded the most conservative risk estimates to account for these uncertainties.

Based on the registered phenol and salts HVAC use label there are no risks of concern, if re-entry is delayed for 24 hours after application to residential buildings (e.g., homes) and 3 hours after application to occupational/commercial buildings (e.g., offices/commercial sites). However, if there is no re-entry delay after application to residential buildings, post-application inhalation risks of concern were identified (MOE = 47 w/ no waiting time before re-entry into a residential building, using IAQX Model). Post-application inhalation risks of concern were also identified if there is no re-entry delay after application to an occupational building (MOE = 26 w/ no waiting time before re-entry into occupational building, using Anti-Microbial Risk Model).

The registrant has voluntarily requested to lower the application rate for the HVAC use to 4 ounces per 2,000 square feet (sf) of building area to reduce the REI at which exposures do not result in risks of concern, from 24 hours to 3 hours (for residential sites) and from 3 hours to none (for occupational sites). Using the lower application rate, the estimated MOEs (for residential treated sites) are greater than the target MOE of 300 if re-entry into treated residential buildings is delayed by 3 hours after application (using the AntiMicrobial Risk Model). For the occupational/commercial treated sites the MOEs are at or above 300 immediately after application and no re-entry delay is needed for the commercial building scenarios using the lower application rate of 4 ounces per 2,000 square ft.

Also, confirmatory data are needed to support the Agency's post-application HVAC exposure assessment due to uncertainties with this assessment. Uncertainties with this risk assessment include extremely limited label instructions (e.g., no application rates on registered label), lack of model validation for this specific use pattern and limitations regarding the submitted chamber emission study. Additional data are needed to quantify phenol emissions and exposures. This data must include chamber data to determine the emission rate of phenol under the conditions of use and whole building data to determine how these conditions affect real world phenol exposures.

The MOEs for all of the other post-application residential exposure scenarios assessed are above their respective target MOEs and, therefore, there are no residential post-application exposure risks of concern from phenol and salts for these use scenarios. However, as previously mentioned, in order to lower the REI at which exposures do not result in risks of concern, from 24 hours to 3 hours for treated residential sites and to eliminate the need for an REI for treated occupational sites, all HVAC use labels must be updated with the new application rate of 4 ounces per 2,000 square feet.

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For further information regarding the residential post-application exposures and risk estimates please refer to the "Phenols Occupation & Residential Exposure Assessment," dated September 9, 2004, the "Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)," dated December 18, 2008 and the "Phenol RED Document," dated, July 7, 2004.

7. Aggregate Risk Assessment

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 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 is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

When selecting the exposure scenarios for the aggregate assessments, the use patterns of phenol and salts and the probability of co-occurrence were considered. Dietary and residential exposure scenarios for phenol and salts were aggregated for adults and children (dietary & residential exposure from cleaning solutions for adults; dietary & dermal and incidental oral exposure from treated carpets for children). The aggregate exposure MOEs were all above the target MOEs of 100 and, therefore, there are no aggregate risks of concern for phenol and salts. Inhalation exposures were not aggregated because the Agency believes that inhalation exposures are not likely to co-occur (e.g., the use of phenol and salts as a paint preservative was cancelled and the likelihood for inhalation co-exposure resulting from the use of phenol and salts to treat HVAC systems and fogging clean rooms is very unlikely). For further information regarding the aggregate assessment please refer to the "Phenol RED Document," dated July 7, 2004.

Table 4. ST/IT Aggregate Oral/Dermal Exposure and Risk Assessment

Population	**Exposure Scenarios (ST/IT)**					
	NOAEL mg/kg/day	Target MOE[1]	Max Exposure[2] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]
Adult Male	60	100	0.6	0.045	0.46	119
Adult Female	60	100	0.6	0.054	0.46	117
Toddlers	60	100	0.6	0.216	0.0035	273

[1] 10x intra-species, 10x inter-species uncertainty factors applied.
[2] Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential Exposure = Dermal exposure from cleaning (adults); dermal + incidental oral exposure from carpets (toddlers)
[4] Aggregate MOE = [NOAEL ÷ (Avg. Food Exposure + Residential Exposure)] Target MOE of 100.

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8. Occupational Handler Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, applying a pesticide, or re-entering treated sites. Phenol and salts are used as disinfectants and as materials preservatives. Potential occupational handler exposure can occur in various use sites during the application and use of disinfectant solutions, disinfectant/deodorizing sprays, and disinfectant towelettes; and the preservation of materials. The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (paint, etc.) through either liquid pour or liquid pump methods. The representative uses that were assessed are as follows:

Occupational Exposure Scenarios

- Materials Preservation of Paints- liquid pour
- Application of Treated Paint- airless sprayer
- Application of Treated Paint- paintbrush/roller
- Hemodialysis Machine- liquid pour of disinfectant
- Hard Surface Disinfection- aerosol spray
- Hard Surface Disinfection- towelette
- Loading fogger (for fogging clean rooms)- liquid pour
- Application of disinfectant to HVAC ductwork- fogging
- Paint vapor exposure (WEPM)
- General purpose cleaning solution vapor exposure

Dermal and inhalation exposures were assessed for these scenarios using application rates from currently registered product labels, EPA estimates of daily amount handled, the Pesticide Handler Exposure Database (PHED, Version 1.1), surrogate data from the Chemical Manufacturers Association (CMA, 1992), the Exposure and Fate Assessment Screening Tool Model (EFAST, v1.0), the Wall Paint Exposure Assessment Model (WPEM), and by using the Multi-Chamber Concentration and Exposure Model (MCCEM, v1.2).

An MOE greater than or equal to 100 is considered adequately protective for the dermal route of exposure. A dermal absorption factor of 50% was used because an oral endpoint was selected. For inhalation exposure the target MOE for identifying risks of concern for short-term and intermediate-term exposure durations is 300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a LOAEL). For long-term inhalation exposures the target MOE is 1,000 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a LOAEL and 3x for lack of a long-term study). However, no long-term uses for phenol and salts have been identified. For the occupational handler risk assessment the following use scenarios indicate risks of concern.

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Occupational Handler Risks of Concern

(Target Inhalation MOE = 300/ Target Dermal MOE = 100)

- Hard Surface Disinfection: Towelette
  (ST Dermal (with gloves) MOE = 70)

- Painting: Airless Sprayer[1]
  (ST Dermal MOE = 21)
  (ST/IT Inhalation MOE = 88)

- Painting: Vapor Exposure [1]
  (ST/IT Inhalation MOE = 72)

It should be noted that all phenol and salts paint uses were voluntarily cancelled on April 12, 2005 to mitigate the residential and occupational risks of concern that were identified within the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004. Therefore, there are no longer any residential or occupational risks of concern associated with the use of phenol and salts as a paint preservative because this use has been cancelled.

Short-term dermal risks of concern were identified for occupational handlers who use impregnated towelettes to disinfect hard surfaces (MOE = 70 with gloves). Although the MOE is below the target of 100, the Agency does not believe that there is a real risk issue of concern resulting from this use. Therefore, the Agency is requiring indoor dermal exposure data (OPPTS GL 875.1200) to confirm this assumption. The Agency used conservative methods in the absence of chemical specific data to assess this use. For example, the Agency used surrogate data from the Chemical Manufacturers Association (CMA, 1992) and the Pesticide Handlers Exposure Database; and in the absence of more specific use information, it was assumed that 1 liter (equivalent to two 16oz cans) of the solution (used to wet the towelette) is used by the exposed individual per day. Therefore, confirmatory indoor dermal exposure data are required because the Agency believes that this data will confirm that these risk estimates are conservative and that there are in fact no dermal risks of concern resulting from the treated towelette use. Also, all phenol and salts product labels must be amended to require the use of gloves (PPE) by occupational handlers for all uses.

For the application of phenol and salts to ductwork via fogging, there are no risks of concern if Personal Protective Equipment (PPE) is used during application. Product labels must be amended to include appropriate PPE as identified in Section IV of this document. If applications are made using probes inserted into the ductwork, such as might occur during residential and smaller scale commercial jobs, exposures will be limited to dermal contact with the probe and can be mitigated with the use of protective gloves. If the applications are made by an operator in the duct or plenum, such as might occur during large scale commercial jobs, both significant dermal and inhalation exposures could occur.

[1] The use of phenol and salts as a materials preservative in paints was voluntarily cancelled on April 12, 2005 to mitigate the residential and occupational risks of concern identified in the memo "Phenol/Sodium Phenate Reregistration Decision," dated September 30, 2004. Therefore, there are no longer any risks of concern associated with the use of phenol and salts as a paint preservative because this use has been cancelled.

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For further information regarding the occupational handler exposure and risk estimates refer to the "Phenols Occupation & Residential Exposure Assessment," dated February 14, 2005, the "Phenol RED Document," dated July 7, 2004, the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004, the "Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)," dated December 18, 2008 and the "Occupational and Residential Exposure and Risk Assessment for the Existing Fogging Cleanroom Use of Phenol (Sporicidin)," dated December 18, 2008.

9. Post-Application Occupational Exposure and Risk

Occupational handlers may have post-application inhalation exposure to phenol and salts by remaining in areas of treatment (e.g., medical personnel, janitors, etc.) and by re-entering treated sites (e.g., fogging clean rooms). The representative post-application occupational uses that were assessed are as follows:

Post-Application Occupational Exposure Scenarios

- General solution cleaning vapor exposure (medical personnel, janitors, etc.) (ST/IT Inhalation)
- Re-entering a treated fogging clean room site (ST/IT Inhalation)

Inhalation exposures for these post-application occupational scenarios were assessed using application rates from labels, EPA estimates of daily amount handled, the Exposure and Fate Assessment Screening Tool Model (EFAST, v1.0) and the Multi-Chamber Concentration and Exposure Model (MCCEM, v1.2).

The MOEs for all of the post-application occupational exposure scenarios assessed are above their respective target MOEs and, therefore, there are no occupational post-application exposure risks of concern from phenol and salts for these use scenarios.

For further information regarding the post-application occupational handler exposure and risk estimates refer to the "Phenols Occupation & Residential Exposure Assessment," dated February 14, 2005, the "Phenol RED Document," dated July 7, 2004, the "Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)," dated December 18, 2008 and the "Occupational and Residential Exposure and Risk Assessment for the Existing Fogging Cleanroom Use of Phenol (Sporicidin)," dated December 18, 2008.

10. Phenol and salts Human Incident Data

The Agency reviewed the following information for human poisoning incidents related to phenol and salts use and discovered that a large number of incidences associated with the exposure to phenol and salts end-use products have been reported: (1) OPP Incident Data System (IDS)- The Office of Pesticides Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) California Department of Pesticide Regulation (1982-2004)- The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of

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illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Telecommunications Network (NPTN)- NPTN is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991; and (4) National Poison Control Centers (PCC) (1993-2002)- The Agency has received PCC data covering the years 1993-2002 for all pesticides. Most of the national PCCs participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings involving drugs, household products, pesticides, etc.

After review of the available incidence data it was determined that the primary routes of exposure are dermal, ocular and inhalation pathways. For dermal exposure, most of the incidents are related to irritation and/or allergic type reaction. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash, itching, skin discoloration/redness and blistering. Also, allergic type reactions have been reported. For ocular exposure incidents eye pain, burning of eyes, conjunctivitis, blurring vision and acute inflammation have been reported. The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms and headache. Other systemic effects associated with phenol exposure can also occur through oral, dermal and inhalation routes of exposure. Neurologic effects, cardiac effects, nephrology and death have also been reported.

For additional information refer to the "Incident Reports Associated with Phenol," dated July 27, 2004 and the "Phenols RED Document," dated July 24, 2004.

B. Environmental Risk Assessment

Phenol and salts are registered for indoor use only (e.g., disinfectants and sanitizers for non-porous hard-surfaces, materials preservatives). These indoor uses are considered to have minimal to no environmental exposure potential following use. It is unlikely that any appreciable exposure to terrestrial or aquatic organisms will occur when phenol and salts are used according to labeled directions. Also, the rapid degradation through multiple pathways in environmental media, as well as low toxicity to fish, invertebrates and aquatic plants indicate a low potential for risk in the unlikely event of environmental exposure from the registered uses. The toxicity of phenol and salts to birds could not be assessed due to a lack of available data; however, the low exposure potential makes risk to birds unlikely from the registered indoor uses of phenol and salts. Therefore, as a result of the extremely low probability for environmental exposure, an environmental exposure risk assessment was not needed or conducted for phenol and salts.

For a detailed discussion of all aspects of the environmental hazard assessment refer to the "Ecological Hazard and Environmental Risk Assessment: Phenol and Salts," July 28, 2004, the "Science Chapter on Environmental Fate Studies and Environmental Fate Assessment of Phenol," dated January 29, 2003 and the "Phenols RED Document," July 7, 2004.

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1. Environmental Fate and Transport

Phenol degrades rapidly in soil, air and water and has a half life of less than one to five days. Its low Kow indicates little potential for bioaccumulation in fish and although it is readily taken up by plants, the high respiratory decomposition rate of phenol to CO_2 indicates little potential for bioaccumulation in plant tissues. It is not expected to sorb to sediment. Due to multi-media degradation pathways, phenol and salts are not expected to be of environmental concern.

2. Risks to Listed Species

Section 7 of the Endangered Species Act (ESA), 16 U.S.C. Section 1536(a)(2), requires that federal agencies consult with the National Marine Fisheries Service (NMFS) for marine and andronomus listed species, or with the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if 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 is to "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 comply with subsection (a)(2) of the ESA, EPA's Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce 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). If any of the Listed Species LOC Criteria are exceeded for either direct or indirect effects in the Agency's screening-level risk assessment, the Agency identifies any listed or candidate species that may occur spatially and temporally in the footprint of the proposed use. Further biological assessment is undertaken to refine the risk. The extent to which any species may be at risk determines the need to develop a more comprehensive consultation package as required by the ESA.

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. Phenol and salts are registered for indoor use only (e.g., disinfectants and sanitizers for non-porous hard-surfaces, materials preservatives) and these uses typically fall into this category. This preliminary analysis does not indicate whether there is a potential for such phenol and salts uses to overlap with listed species and whether a more refined assessment is warranted, to include direct, indirect and habitat effects. The more refined assessment should involve clear delineation of the action area associated with proposed use of phenol and salts and the best available information on the temporal and spatial co-location of listed species with respect to the

action area. This analysis has not been conducted for this assessment. Therefore, an endangered species effect determination will not be made at this time.

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IV. Reregistration Eligibility and Risk Management Decisions

A. Determination of Reregistration Eligibility Decision

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

The Agency has completed its assessment of the residential, occupational and ecological risks associated with the use of pesticide products containing the active ingredients phenol and salts. The Agency has determined that all uses of phenol and salts presented in Appendix A will not pose unreasonable risks to humans or the environment provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data needs are addressed; and 3) label amendments are made as described in Section V. Appendix A summarizes the uses of phenol and salts that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination for reregistration eligibility of phenol and salts 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.

The Agency has concluded that continued use of phenol and salts products would not meet the "no unreasonable adverse effects" criteria of FIFRA unless the mitigation measures and associated label changes presented in this document are implemented and confirmatory data are submitted. Accordingly, should a registrant fail to implement the risk mitigation measures, submit confirmatory data and make the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of phenol and salts. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of phenol and salts for the purpose of this determination.

1. Public Comments and Response

Through EPA's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for phenol and salts. During the public comment period ending on September 29, 2004, the Agency received comments on the risk assessments from several respondents: California Regional Water Quality Control Board San Francisco Bay Region, Sanitation Districts of LA County, and the Natural Resource Defense Council (NRDC). All comments are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2004-0301.

2. Regulatory Rationale

The Agency has determined that phenol and salts are eligible for reregistration provided that the registrants implement the conditions, requirements and risk mitigation measures outlined within this RED including amended labeling and submission of additional data. The Agency

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believes that the uses presented in Appendix A will not present risks inconsistent with FIFRA as long as the required label amendments and risk mitigation measures, which are described in detail below, are implemented. A summary of the EPA's rationale for reregistering and managing risks associated with continued use of phenol and salts products is presented below.

In 2004, the EPA issued the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004. The decision memorandum addresses the risks of concern identified in the 2004 phenol and salts risk assessment ("Phenols RED Document," dated July 7, 2004) and the Agency's risk management decisions to address these risks of concern. However, the fogging clean rooms use and the use of phenol and salts to treat HVAC ductwork were, inadvertently, not addressed in either of these documents. The purpose of this reregistration eligibility decision document is to not only summarize the findings and mitigation decisions outlined in the "Phenols RED Document" and the "Phenol/Sodium Phenate Reregistration Decision" memorandum but to present the findings of the Occupational and Residential Exposure (ORE) assessments that have been recently conducted for the fogging clean room and HVAC ductwork treatment uses. In addition, this document presents the Agency's risk management decisions to support the continuation of these uses. For further information regarding these two assessments please refer to the "Occupational and Residential Exposure and Risk Assessment for the Existing Fogging Clean-room Use of Phenol (Sporicidin)," dated December 18, 2008 and the "Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)," dated December 18, 2008. Also, for further information regarding the risk management decisions discussed below please refer to the "Phenol/Sodium Phenate Reregistration Decision" memorandum, dated September 30, 2004. This document is located at http://www.regulations.gov in docket number EPA-HQ-OPP-2004-0301.

a. Risk Management

The following is a summary of the Agency's risk management measures developed to mitigate identified risks of concern associated with the use of phenol and salts products.

Residential Handler Exposure Risk Mitigation

Short-term dermal risks of concern were identified for residential paint application via airless sprayer and via paintbrush/roller. Risks of concern were also identified for short-/intermediate-term inhalation exposure resulting from painting via airless sprayer. The use of phenol and salts as a paint preservative was voluntarily cancelled on April 12, 2005 to mitigate residential and occupational handler exposure risks of concern. Therefore, there are no longer any residential handler risks of concern associated with the use of phenol and salts as a paint preservative, because this use has been cancelled. All phenol and salts labels have been amended to delete the paint preservative use in April of 2005.

Residential Post-Application Exposure Risks

Residential post-application inhalation exposures are anticipated following the application of phenol and salts to HVAC ductwork, as phenol evaporates from the duct surface

and mixes with air flowing through the duct. For residential buildings (e.g., houses) with treated HVAC systems there are no post-application risks of concern if re-entry into the residential building is delayed for 24 hours after application. However, if there is no waiting time before re-entry into a residential treated site, post-application inhalation risks of concern are identified (MOE = 47 if no time before re-entry; MOE = 300 if re-entry delayed by 24 hrs). For occupational buildings (e.g., offices/commercial settings) with treated HVAC systems there are no post-application risks of concern if re-entry into the occupational building is delayed for 3 hours after application. However, if there is no waiting time before re-entry into an occupational treated site, post-application inhalation risks of concern are identified (MOE = 26 if no time before re-entry; MOE = 500 if re-entry delayed by 3 hrs). Therefore, to mitigate possible post-application inhalation risks of concern all product labels with the HVAC use must be amended to indicate a 24 hour Restricted Entry Interval (REI) for re-entry into a residential treated site and a 3 hour REI for re-entry into an occupational treated site.

In order to reduce the REI from 24 hours to 3 hours (for residential sites) and from 3 hours to none (for occupational sites), the registrant has voluntarily requested to lower the application rate for the HVAC use to 4 ounces per 2,000 square feet (sf) of building area. Using the lower application rate, the estimated MOEs (for residential treated sites) are greater than the target MOE of 300 if re-entry into treated residential buildings is delayed by 3 hours after application. For the occupational/commercial treated sites the MOE is above 300 immediately after application and no re-entry delay is needed for the commercial building scenarios using the lower application rate of 4 ounces per 2,000 square ft. Therefore, to reduce the REI from 24 hours to 3 hours for re-entry into treated residential sites and to eliminate the need for an REI for treated occupational sites all labels with the HVAC duct-work treatment use must be amended to indicate the new application rate of 4 ounces per 2,000 sf. Also, to mitigate possible post-application inhalation risks of concern resulting from re-entry into residential sites (MOE = 145 with no waiting time before re-entry into residential settings with the lower application rate of 4 ounces per 2,000 sf), all HVAC duct-work treatment use labels must be amended to include an REI of 3 hours for re-entry into treated residential sites. However, if the HVAC use labels are not amended to include the new application rate of 4 ounces per 2,000 square feet, an REI of 24 hours for re-entry into treated residential sites and an REI of 3 hours for re-entry into treated occupational sites will be required on all HVAC labels to mitigate potential post-application inhalation risks of concern.

Also, confirmatory data are needed to support the Agency's current HVAC use assessment due to many uncertainties with this assessment. Uncertainties with this risk assessment include extremely limited label instructions (e.g., no application rates on registered label), lack of model validation for this specific use pattern and limitations regarding the submitted chamber emission study. The current chamber study that was used for the risk assessment has serious limitations, which include the fact that the chamber was maintained at an elevated temperature of 38^{o} C (i.e. 100 F) and the first samples were not collected until four hours after application. Given these conditions, it is likely that a substantial amount of phenol was emitted before the first sample was collected. Therefore, new data (OPPTS GL 875.1200) are needed to determine the emission rate of phenol under the conditions of use. Also, whole building data (OPPTS GL 875.1200) are needed to determine how these conditions affect real

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work phenol exposures. The current label must also be amended to specify the application rate (4 ounces per 2,000 square feet) and methods of duct treatment.

Occupational Handler Exposure Risks

Short-term dermal and short-/intermediate-term inhalation risks of concern were identified for occupational paint application via an airless sprayer. The use of phenol and salts as a paint preservative was voluntarily cancelled on April 12, 2005 to mitigate residential and occupational handler exposure risks of concern. Therefore, there are no longer any occupational handler risks of concern associated with the use of phenol and salts as a paint preservative, because this use has been cancelled. All phenol and salts labels were amended to delete the paint preservative use in April of 2005.

There are no occupational handler risks of concern resulting from the application of phenol and salts to HVAC ductwork if appropriate personal protective equipment (PPE) are used during application. Applicators treating the inside of an air duct system must wear chemical resistant coveralls, chemical resistant gloves and chemical resistant goggles. If the level of contamination cannot be determined in the space being treated, a maximum respiratory protection (SCBA or airline with an escape bottle) must be used. If needed, the full face respirator should also be equipped with a spray mist pre-filter in addition to the charcoal filters. All HVAC use labels must be amended to require the use of appropriate PPE. Also, all HVAC labels must be amended to include an application rate of 4 ounces per 2,000 sf. For a detailed explanation of the required PPE and application rate label language, please refer to Table 6 in this document.

Short-term dermal risks of concern were identified for occupational handlers who use impregnated towelettes to disinfect hard surfaces (MOE = 70 with gloves). Although the MOE is below the target of 100, the Agency does not believe that there is a real risk issue of concern resulting from this use. Therefore, the Agency is requiring indoor dermal exposure data (OPPTS GL 875.1200) to confirm this assumption. The Agency used conservative methods in the absence of chemical specific data to assess this use. For example, the Agency used surrogate data from the Chemical Manufacturers Association (CMA, 1992) and the Pesticide Handlers Exposure Database; and in the absence of more specific use information, it was assumed that 1 liter (equivalent to two 16oz cans) of the solution (used to wet the towelette) is used by the exposed individual per day. Therefore, confirmatory indoor dermal exposure data are required because the Agency believes that this data will confirm that these risk estimates are conservative and that there are in fact no dermal risks of concern resulting from the treated towelette use. Also, all phenol and salts product labels must be amended to require the use of gloves (PPE) by occupational handlers for all uses.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing phenol and salts. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document

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V. What Registrants Need to Do

The Agency has determined that products containing phenol and salts are eligible for reregistration provided that the conditions and requirements for reregistration identified in this RED are implemented (see Section IV). The registrants will also need to amend product labeling.

The database supporting the reregistration of phenol and salts has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, additional confirmatory data are required to support continued registration.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic databases supporting the reregistration of phenol and salts for currently registered products has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements and are included in the generic data-call-in (DCI) for this RED. The confirmatory data presented in Table 5 are required.

Occupational Hander Confirmatory Data Needs

Dermal risks of concern were identified for occupational handlers using impregnated towelettes to disinfect hard surfaces (MOE = 70 with gloves). Although the MOE is below the target of 100, the Agency does not believe that there is a real risk issue of concern resulting from this use. Therefore, the Agency is requiring indoor dermal exposure data (OPPTS GL 875.1200) to confirm this assumption. The Agency used conservative methods in the absence of chemical specific data to assess this use. For example, the Agency used surrogate data from the Chemical Manufacturers Association (CMA, 1992) and the Pesticide Handlers Exposure Database; and in the absence of more specific use information it was assumed that 1 liter (equivalent to two 16oz cans) of the solution used to wet the towelette, is used by the exposed individual per day. Therefore, the Agency believes the required dermal exposure data will confirm that these risk estimates are conservative and that there are in fact no dermal risks of concern resulting from this use.

Residential & Occupational Post-Application Confirmatory Date Needs

Due to uncertainties with the HVAC ductwork treatment assessment a chamber study and whole building study are needed to support the Agency's current assessment. Uncertainties with this risk assessment include extremely limited label instructions (e.g., no application rates on label), lack of model validation and limitations regarding the submitted chamber emission study. These data are needed to quantify phenol emissions and exposures.

The chamber study must be based on OPPTS Guideline 875.1200- Indoor Inhalation Exposure and ASTM D5116-06-Standard Guide for Small-Scale Environmental Chamber Determinations of Organic Emissions from Indoor Materials/Products. The specific conditions of the chamber study such as ventilation rate, air temperature, application method and

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application rate must match the conditions of the labeled use. It is recommended that a study protocol be submitted for review by the Agency prior to the initiation of the actual study.

The whole building study must be based on OPPTS Guideline 875.1200- Indoor Inhalation Exposure. This study must be conducted at a representative application site during an actual application or at a simulated application site that is configured to match the characteristics of a representative application. The specific conditions such as ventilation rate, air temperature, application method and application rate must match the conditions of the labeled use. It is recommended that a study protocol be submitted for review by the Agency prior to the initiation of the actual study.

Ecological Data Requirements

As previously noted, an environmental exposure risk assessment was not conducted because the indoor uses of phenol and salts are considered to have minimal to no environmental exposure potential following use. However, in the event of accidental environmental exposure to phenol and salts (e.g., a spill resulting from a transportation accident), data are needed to determine the toxicity effects to non-target organisms.

The following ecological studies are needed so that the Agency can determine whether a precautionary label statement concerning toxicity or potential adverse effects to non-target organisms is necessary: OPPTS GL 850.2100- avian acute oral; OPPTS GL 850.1075- acute freshwater fish; and OPPTS GL 850.1010- acute freshwater invertebrates. These acute studies measure toxicity in representative species of the non-target species most likely to be adversely affected and allow the EPA to develop precautionary labeling. Such labeling includes statements such as, “This product is extremely toxic to birds,” or “This product is toxic to fish.” These statements provide needed information in case of unintended or coincident exposure to phenol and salts, such as a transportation accident.

Generally, registrants will have 90 days from receipt of a generic data call-in (GDCI) to complete and submit response forms or request time extensions and/or waivers with a full written justification. Timeframes for submitting generic data will be presented in the GDCI.

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Table 5. Generic Data Required to Support Phenol and Salts Registrations

EPA Guideline Number	Requirement Name
875.1200	Dermal Indoor Exposure
875.1200	Dermal Indoor Exposure[1]
875.1200	Dermal Indoor Exposure[2]
850.2100	Avian Acute Oral Toxicity
850.1075	Fish Acute Toxicity- freshwater & marine
850.1010	Aquatic Invertebrate Acute Toxicity- freshwater daphnids

1- A chamber study is needed as confirmatory data for the HVAC ductwork treatment use. This chamber study must be based on *OPPTS Guideline 875.1200 Indoor Inhalation Exposur*e and *ASTM D5116-06 Standard Guide for Small-Scale Environmental Chamber Determinations of Organic Emissions from Indoor Materials/Products.* The specific conditions of the chamber study such as ventilation rate, air temperature, application method and application rate must match the conditions of the labeled use. It is recommended that a study protocol be submitted for review by the Agency prior to the initiation of the actual study.
2- A whole building study is needed as confirmatory data for the HVAC ductwork treatment use. The whole building study must be based on OPPTS Guideline 875.1200 Indoor Inhalation Exposure. This study must be conducted at a representative application site during an actual application or at a simulated application site that is configured to match the characteristics of a representative application. The specific conditions such as ventilation rate, air temperature, application method and application rate must match the conditions of the labeled use. It is recommended that a study protocol be submitted for review by the Agency prior to the initiation of the actual study.

For phenol and salts 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 K. Avivah Jakob at (703) 305-1328 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
K. Avivah Jakob
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
K. Avivah Jakob
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

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B. End-Use Products

1. Product Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant 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. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

Generally, registrants will have 90 days from receipt of a PDCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. Registrants will have eight months to submit product-specific data.

For end-use products containing the active ingredients phenol and salts, the registrants need 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 10 of this document;

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

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.

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Please contact K. Avivah Jakob at (703) 305-1328 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
K. Avivah Jakob
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
K. Avivah Jakob
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 10. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

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.

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Table 6. Required Label Changes for Manufacturing and End-Use Products Containing Phenol and Salts

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End-Use Products		
Fogging Clean-Room End-Use Products	Sporicidin product label 8383-3 and Bulletin 301 must be amended to include an application rate of "1 gallon per 30,000 sq/ft" for the fogging clean-room use.	Directions for Use
PPE Requirements-Must be on all end-use product labels with occupational uses	"All handlers must wear chemical resistant gloves."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements-Must be on all HVAC end-use product labels	"**Special Instructions For Applicators:** Applicators treating the inside of an air duct system with this product must wear chemical resistant coveralls, chemical resistant gloves and chemical resistant goggles. In addition, the ductwork must be ventilated with an airflow of approximately 50 CFM per sq. foot of duct cross sections. If this is not possible, Occupational Safety and Health Administration (OSHA) confined space regulations must be followed and the requirements for a permit required space apply. These requirements include testing the atmosphere and use of adequate respirator protection. If the level of contamination cannot be determined, then maximum respiratory protection (SCBA or airline with an escape bottle) must be used. If needed, the full face respirator should also be equipped with a spray mist pre-filter in addition to the charcoal filters." "**Engineering Controls:** During ULV application the duct interior must be maintained under slight negative pressure (0.015 to 0.025 In WG) with an outdoor exhaust. Avoid higher pressure differentials that would be likely to disrupt the coverage pattern."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

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Directions for Use- Air Duct Treatment End-Use Products		
HVAC Use Application Rate- Must be on all HVAC/Air Duct end-use labels	"Apply up to 4 fluid ounces of product per 2,000 square feet of building space by ULV application only."	Directions for Use
Restricted Entry Interval (REI)- Must be on all HVAC/Air Duct end-use labels	"Affected areas of the building are not to be occupied during treatment. Do not enter treated residence until 3 hours after treatment."	Directions for Use
HVAC/Air Duct Use Directions- Must be on all HVAC/Air Duct end-use labels	**PERSONAL PROTECTIVE EQUIPMENT REQUIRMENTS FOR HANDLERS:** All handlers must wear protective eyewear, long pants, long sleeved shirts and chemical resistant gloves. **SPECIAL INSTURCTIONS FOR APPLICTORS:** Applicators treating an air duct system with this product must wear chemical resistant coveralls, chemical resistant gloves, and chemical resistant goggles. In addition, the ductwork must be ventilated with an airflow of approximately 50 CFM per square foot of duct cross section. If this is not possible, OSHA confined space regulations must be followed and the requirements for a permit-required space apply. These requirements include testing the atmosphere and use of adequate respirator protection. If the level of contamination cannot be determined, then maximum respiratory protection (SCBA or airline with an escape bottle) must be used. If needed, the full face respirator should also be equipped with a spray mist pre-filter in addition to the charcoal filters. **ENGINERRING CONTROLS:** During ULV application, the duct system interior must be maintained under slight negative pressure (0.015 to 0.025 in WG) with an outdoor exhaust or using a negative air machine equipped with HEPA filter. Avoid higher pressure differentials that would be likely to disrupt the overage pattern. **FOR USE ONLY BY HVAC INSTALLERS AND REPARIERS** When using this product for HVAC (fungistatic) (bacteriostatic), all Personal Protective Equipments (PPE) must be used. Please read all instructions before using this product. All applicable use directions must be followed precisely. If you do not understand the use of this product for HVAC (fungistatic) (bacteriostatic), please contact (company name) for more information at (company number). **HVAC DIRECTIONS FOR USE** For use on hard non-porous air duct surfaces only. ULV application only. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.	Directions for Use

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THE PERSON APPLYING THIS PRODUCT IS RESPONSIBLE FOR FOLLOWING THESE DIRECTIONS UNDER BOTH STATE AND FEDERAL LAWS.

For use on Unlined Ductwork only.

1.0 General

This product is designed to be used as one component of a comprehensive HVAC and duct maintenance program. The purpose of such a program is to assure that the HVAC system and ducts function in the manner they were designed to, remain free from mold and other microbial growth and other contamination, and continue in that condition. This product should only be used in only those cases where visible microbial growth has been detected in the system and then only after removing that growth and identifying and correcting the conditions that led to that growth. If you need help in understanding any part of these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PRODUCT until you have received the answers for all of your questions.

2.0 Inspection

Prior to inspecting, cleaning, treating, repairing or otherwise working on the HVAC or duct section, the HVAC system should be turned off or the section under repair physically isolated from sections in active use.

Prior to any application of this product the system must be inspected for cleanliness and mechanical condition. When initiating any measures to repair, clean or treat HVAC system components or air ducts, industry standards from the American Society of Heating and Refrigeration Engineers (ASHRAE), National Air Duct Cleaners Association (NADCA), Indoor Air Quality Association (IAQA) and other organizations must be followed.

HVAC systems should be routinely inspected for cleanliness by visual means. The NADCA Standard, Assessment, Cleaning and Restoration of HVAC Systems (ACR 2002or the latest revision), provides minimum recommended inspection frequency schedules for ducts and other system components. More information on NADCA standards can be obtained from the NADCA web site at www.nadca.com.

2.1 Cleanliness Inspection

According to NADCA Standards, HVAC system cleaning must be performed when any of the following conditions are found in the cleanliness inspection. If any of these deficiencies are found during inspection, cleaning in accordance with industry standards must be performed prior to the application of this product.

2.1.1 Contamination

- HVAC systems should be operated in a clean condition. If significant accumulations of

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	contaminants or debris are visually observed within the HVAC system, then cleaning is necessary. Likewise, if evidence of microbial growth is visually observed or confirmed by analytical methods, then cleaning is required. • If the HVAC system discharges visible particulate into the occupied space, or a significant contribution of airborne particles from the HVAC system into the indoor ambient air is confirmed, then cleaning is necessary. • Heat exchange coils, cooling coils, air flow control devices, filtration devices, and air-handling equipment determined to have restrictions, blockages, or contamination deposits that may cause system performance inefficiencies, air flow degradation, or that may significantly affect the design intent of the HVAC system, require cleaning. • Drain pans must be free from slime and sludge or other contamination. Badly rusted or corroded drain pans must either be repaired or replaced. • Fans and fan housings must be free from accumulations of microbial growth and particulate matter. If you need help in understanding existing industry standards, consult a professional or consult the information at www.epa.gov (search on "HVAC Systems" or "air ducts"). In addition, the following association and society internet sites should be consulted for information on standards and guidelines they have developed: ACCA - www.acca.org ASHRAE - www.ashrae.org NADCA - www.nadca.com NAIMA - www.naima.org SMACNA - www.smacna.org **2.2 Mechanical Inspection** This product must be used only on HVAC air ducts in sound mechanical condition as defined in 2.2.1 and 2.2.2 (below). The HVAC system components must be designed and installed in conformance with industry standards and guidelines. Prior to using the product, inspect the HVAC system and ducts and assure that they are in sound mechanical condition. The following general guidelines, supplemented by industry standards from SMACNA, NAIMA, ASHRAE, ACCA and other organizations, must be followed: **2.2.1 Air Leaks and Mechanical Defects** The ducts must be free from air leaks and other mechanical defects. Air leaks will promote condensation of water that causes microbial growth and will lead to failure of this product to protect the system adequately.	

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2.2.2 Design and Installation

ASHRAE, SMACNA, NAIMA and other industry organizations have established guidelines and standards for the design and installation of HVAC and duct systems. You should determine that the duct system you wish to treat conform to industry practice. If you are not knowledgeable of industry guidelines and standards, consult a qualified professional for assistance.

In some situations, the inspection may reveal that a component of the HVAC or duct system is badly damaged or in such poor operating condition that it cannot be corrected through cleaning and/or minor repair. In these situations, the system should be replaced or rebuilt in conformity to the applicable industry standards prior to using this product. Some (but not all) of the conditions that would indicate the need for major repairs or replacement of the system include:

- Improper size of ducts- The ducts must be sized to achieve correct airflow. When air-handling equipment is changed or new inlets or outlets added, the size of all components in the system should be recalculated and replacements made as needed.
- Physical damage - Crushed or physically damaged equipment may leak or fail to perform as designed. Deformed air ducts will restrict airflow and may leak (especially at joint areas). Damaged equipment must be repaired or replaced or if there is extensive damage, the entire system should be replaced.
- Badly corroded metal components including duct sections, housings and cabinets, coil assemblies, drain pans, fans and their housings and heat exchange surfaces.
- Loose, damaged, friable or missing insulation - Insulation is important in preventing moisture condensation and subsequent growth of mold and other organisms. If insulation (either interior or exterior) is damaged, missing or not properly fastened it must be repaired or replaced or the associated duct sections replaced. Air handler, mixing, and VAV box housings are also normally insulated and this insulation should be checked for damage in a like manner.

Removed components that are contaminated with mold and other microbial growth may spread contamination while being removed from the building. To prevent this, smaller items should be placed in plastic bags that should then be sealed before being removed. Larger items that cannot be safely packaged should be treated before being moved through occupied spaces. An appropriately labeled disinfectant can be used during treatment. Care must be used during treatment to assure that fumes from the agent being used are not released into occupied spaces. Products used should be used according to their label directions.

AIR DUCTS

For use on hard non-porous air duct surfaces only. ULV application only. Affected areas of the building are not to be occupied during treatment. Do not enter treated residence until 3 hours after treatment.

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	3.0 General Directions for (This Product) Usage This product effectively controls by inhibiting growth of odor causing bacteria, fungi, and other odor, stain or damage causing organisms in air ducts in residential, commercial, institutional, and industrial buildings. This product also eliminates odors associated with bacteria, mold, mildew, animals, cooking, spoilage, musty and other odors and removes odor-causing organisms when used as part of such a comprehensive preventative maintenance program in air ducts. This product is a bacteriostat, fungistat (mold and mildew), mildewstat and deodorizer for use in residential, commercial and industrial settings. Apply up to 4 fluid ounces of product per 2,000 square feet of building space by ULV application only. Follow the directions below for the specific type of duct being treated. It is vital that the following directions be carefully read and understood prior to using the product. **3.1 Application Instructions** For use on hard non-porous air duct surfaces only. Apply up to 4 fluid ounces of product per 2,000 square feet of building space by ULV application only. **3.2 Application Equipment and Devices** ULV application only. Refer to the precautionary statements for the Personal Protective Clothing and other special instructions that must be followed. **3.2.1 ULV** ULV application only. Equipment capable of generating particles in the 15 to 60 micron range is most satisfactory. Avoid use of thermal type fog generators. Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so adequate penetrations must be cut in the ducts to assure complete coverage without wetting. SMACNA, NADCA and NAIMA have established standards and guidelines for making and sealing openings in ducts. Operators should be trained on proper application techniques as well as correct duct penetration and sealing procedures using these standards and guidelines. Operators should also carefully read and follow directions for the brand of equipment used. Duct penetrations should be properly closed following application, in accordance with industry standards. **3.3 Application Techniques** This product must be applied evenly throughout the duct system and over other surfaces that are being treated. Even and uniform application is essential for satisfactory results. The procedures, equipment and techniques described below have been tested and provide the desired results. Other procedures, equipment and techniques may also achieve satisfactory results but should not be used without discussing the specific situation and equipment with a qualified professional for assistance.	

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	3.3.1 Application from the Exterior of the HVAC System This product may be sprayed into openings at intervals throughout the duct system or on components that are accessible through removable panels or access doors. Spray into openings every 8 feet at a minimum. Existing supply openings can be used where they will provide a clear view of the surfaces being sprayed so that uniform application can be achieved. However, additional penetrations will have to be made as needed so that enough openings will be available to achieve total and uniform coverage. Spray application is not an acceptable technique where openings are greater than 8 feet apart, additional openings cannot be made and properly sealed and/or the duct geometry does not allow for uniform coverage. In such cases, application from within the HVAC system is necessary (see 3.3.2 below). **3.3.2 Application from Within the HVAC System** When this product cannot be sprayed into openings at intervals throughout the ducts system, you must gain entry into the system and spray the product onto interior duct and other surfaces until they are thoroughly and uniformly covered using hand or power spray equipment. This is the most frequently used technique and is the technique of choice for air-handlers, other components with access panels or doors and large diameter (generally 20" X 20" minimum) ducts where direct access can be gained to surfaces being treated. **3.4 Rate of Application** Users of this product must carefully follow the rate of application instructions provided below. Apply up to 4 fluid ounces of product per 2,000 square feet of building space by ULV application only. **3.4.1 Bare Metal and Flexible Ducts** Apply until surface is evenly wet. Apply up to 4 fluid ounces of product per 2,000 square feet of building space by ULV only. If the above application rate results in surface runoff or liquid pooling on the bottom of the duct, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling. **AIR DUCTS** This product is formulated for use on hard non-porous air duct surfaces only. ULV application only. Affected areas of the building are not to be occupied during treatment. Do not enter treated residence until 3 hours after treatment. It is vital that the directions for use are carefully read and understood prior to using this product. **3.5 Frequency of Application** Normally, infrequent application (registrant must provide a time frame) will provide effective control. (The registrant must provide product specific details on the frequency of application of this product here.) Prior to reapplication, the interior of the ducts and other surfaces must be inspected and found to be free of	

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	accumulated soil. If soil or growth is found, the cause should be determined and corrected and then the ducts cleaned in accordance with accepted industry practice. If microbial growth persists following application re-inspect for duct leaks carryover of water from cooling coils or humidifiers and other sources of moisture promoting growth. Eliminate such sources of moisture before re-treating. **3.6 Returning the System to Operation Following Application** Fans and blowers in the section of duct being treated must be turned off during application of this product. If the system cannot be shut down, the section of duct being treated must be isolated until treatment is complete. This will prevent the spray of fog from being blown away from the surface that is being treated. Do not attempt to use the system fan or blower to carry this product to the surfaces in the air duct system. Such a practice will not result in uniform application of the product to the surfaces being treated and will lead to ineffective control. This should never be attempted. The system can be returned to full operation as soon as treatment is complete anytime following completion of treatment. This product will dry on surfaces within (provide time frame) following application. Extended drying time does not have an impact on effectiveness of treatment. Affected areas of the building are not to be occupied during treatment. Do not enter treated residence until 3 hours after treatment.	
Use Cancellation		
All product labels	The use of phenol and salts as a paint preservative must be deleted from all product labels. This use was voluntarily cancelled by the registrant on April 12, 2005.	

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Appendix A: Table of Use Patterns for Phenol & Salts

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural Premises and Equipment				
Hard Non-Porous Surfaces: Farm Equipment, Animal and Poultry Housing, Barns, Kennels, Breeding Pens, Hatcheries, Trucks and Other Vehicles	Ready to Use 8383-3	Spray, Immerse or Soak	Remove poultry, animal feed, water, trucks, coops, and crates from the premises. Remove liter droppings from floors, walls, and surfaces of facilities occupied or transversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply product and allow it to remain wet for 10 minutes. Allow to air dry.	Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment absorbed, set dried. For Avian Influenza A- the use is only for surfaces which are conducive to treatment by immersion or excess liquid. Do not dilute or mix with other chemicals.
Commercial, Institutional and Industrial Premises and Equipment				
Carpets and Fabrics Hard Non-Porous Surfaces: Telephones, Keyboards, Furniture, Wheelchairs, Walkers, Sinks, Floors, Walls, Light Switches, Linen Hampers, Bathrooms, Kennels and Animal Areas, Schools, Restaurants, Hotels, Boats, Planes, Buses, Air Ducts (HVAC)	Ready to Use 8383-3	Spray, Immerse or Soak	**Pre-clean**: Clean surfaces using product to remove soil or filth. Wipe dry with a paper towel, cloth or sponge. **Disinfect and Deodorize**: Thoroughly wet pre-cleaned surface with product and allow to remain wet for 10 minutes at room temperature to kill listed organisms. Use spray for surfaces that cannot be immersed or soaked.	All surfaces and materials that come into contact with food must be washed with soap or detergent and rinsed with potable water prior to use. Do not dilute or mix with other chemicals.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Carpets and Fabrics Hard Non-Porous Surfaces: Telephones, Keyboards, Furniture, Wheelchairs, Walkers, Sinks, Floors, Walls, Light Switches, Linen Hampers, Bathrooms, Kennels and Animal Areas, Schools, Restaurants, Hotels, Boats, Planes, Buses.	Impregnated Materials 8383-7	Wipe	**Pre-clean**: Clean surfaces with product's solution to remove soil and filth. Wipe dry with a paper towel, cloth or sponge. **To Disinfect and Deodorize**: Items which cannot be immersed such as electrical panels: Thoroughly wet pre-cleaned surface with disinfectant towelettes and allow surface to remain wet for 10 minutes. Use as many towelettes as necessary for the treated area to remain wet for 10 minutes at room temperature 28 Degrees Celsius/68 Degrees Fahrenheit to kill listed organisms. **To Spot Clean, Deodorize and remove Debris from Carpets and Fabrics:** Blot or scrub area to be treated with disinfectant towelette to remove soiling. Wipe dry with a clean cloth or towel.	Do not dilute or mix with other chemicals.
Hard Non-Porous Surfaces: Industrial Clean Rooms	Pressurized Liquid 8383-4	Spray	**Pre-clean**: Clean surfaces using product to remove soil or filth. Wipe dry with a paper towel, cloth or sponge. **Disinfect and Deodorize**: Thoroughly wet pre-cleaned surface with product and allow to remain wet for 10 minutes at room temperature to kill listed organisms. Use spray for surfaces that cannot be immersed of soaked.	Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperature above 130 degrees may cause bursting.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Fogging Clean-Rooms	Ready To Use 8383-3, Sporicidin Bulletin No. 301	Fogging	1 gallon per 30,000 sq/ft For fogging articles and surfaces in sealed rooms and cubicles as an adjunct to manual cleaning and disinfecting procedures. Unscrew pump bottle and change the fogging device with the required volume of solution. Seal all windows and doors. Set time for treatment cycle as recommended by device manufacturer. Turn on device, leave room and reseal door. Do not allow anyone to re-enter room or cubicle for at least 2 hours after fogging cycle has been completed. Upon re-entering room or cubicle, following regular cleaning and disinfecting procedures.	Avoid eye contact. Do not allow anyone to re-enter room or cubicle for at least 2 hours after fogging cycle has been completed.
Food Handling /Storage Establishments Premises and Equipment				
Hard Non-Porous Surfaces: Food Processing Plants, Food Handling Areas, Poultry and Meat Packaging Facilities, and Slaughter Houses	Ready to Use 8383-3	Spray, Immerse or Soak	**Pre-clean**: Clean surfaces using product to remove soil or filth. Wipe dry with a paper towel, cloth or sponge. **Disinfect and Deodorize**: Thoroughly wet pre-cleaned surface with product and allow to remain wet for 10 minutes at room temperature to kill listed organisms. Use spray for surfaces that cannot be immersed of soaked.	All surfaces and materials that come into contact with food must be washed with soap or detergent and rinsed with potable water prior to use. Do not dilute or mix with other chemicals

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hard Non-Porous Surfaces: Food Processing Plants, Food Handling Areas, Poultry and Meat Packaging Facilities, and Slaughter Houses	Ready to Use 8383-7 Impregnated Materials	Wipe	**Pre-clean**: Clean surfaces with product's solution to remove soil and filth, wipe dry with a paper towel, cloth or sponge. **To Disinfect and Deodorize**: Items which cannot be immersed such as electrical panels: Thoroughly wet pre-cleaned surface with disinfectant towelettes and allow surface to remain wet for 10 minutes. Use as many towelettes as necessary for the treated area to remain wet for 10 minutes at room temperature 28 Degrees Celsius/68 Degrees Fahrenheit to kill listed organisms.	Do not dilute or mix with other chemicals
Hard Non-Porous Surfaces: Sinks, Drain Boards, Cabinets, Garbage Cans, Under Sinks, Faucets	Ready to Use 69658-3	Spray	Use as a start day/end day antimicrobial treatment on pre-cleaned surfaces. Allow product to fully dry. **To Sanitize Non-Food Contact Surfaces**: Before treatment clean surface of loose dirt. Hold spray bottle upright 4-6 inches from surfaces. Spray surfaces 2-4 seconds until covered with mist. Allow to air dry and remain undisturbed for 15 minutes.	This product must not result in the direct or indirect contamination of food products.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Medical Premises and Equipment				
Hard Non-Porous Surfaces: Health/Hospital Treatment and Patient Rooms, Operating Rooms, Ambulances, Medical and Dental Equipment, Beds, Surgical Carts, Countertops, Mannequins, Hemodyalysis and Dialysis Machines, Bathrooms, Wheelchairs, Walkers, Animal Areas, Trash Containers, Air Ducts (air duct use is only on 8383-3 and 8383-4 only)	Ready to Use 8383-3 8383-6 Pressurized Liquid 8383-4	Spray, Immerse, or Soak	**Pre-clean**: Clean surfaces using product to remove soil or filth. Wipe dry with a paper towel, cloth or sponge. **Disinfect and Deodorize**: Thoroughly wet pre-cleaned surface with product and allow to remain wet for 10 minutes at room temperature to kill listed organisms. Use spray for surfaces that cannot be immersed or soaked **Dialysis Machine**: Place 150cc into the hemodialysate system. Allow machine to run until all of the product is down into the concentrate line. This will allow for automatic proportioning of solution with water. **Multipatient Delivery System**: Place 1.0 liter into the hemodialysate system. Allow machine to run until all of the product is down into the concentrate line. This will allow for automatic proportioning of solution with water. Fill machine for a minimum of 10 minutes. Drain product from system and thoroughly rinse with water. Test final rinse water for residual using product's residual test kit to assure complete rinsing.	**Dialysis Machine**: It is recommended that disinfection procedures be accompanied preceding use of hemodialysate system. **Pressurized Liquid**: Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperature above 130 degrees may cause bursting. This product is not to be used as a terminal sterilant/ high level disinfectant on any instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Do not dilute or mix with other chemicals.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hard Non Porous Surfaces: Health/Hospital Treatment and Patient Rooms, Operating Rooms, Ambulances, Medical and Dental Equipment, Beds, Surgical Carts, Countertops, Mannequins, Hemodyalysis and Dialysis Machines, Bathrooms, Wheelchairs, Walkers, Animal Areas, and Trash Containers	Impregnated Materials 8383-7	Wipe	**Pre-clean**: Clean surfaces with product's solution to remove soil and filth, wipe dry with a paper towel, cloth or sponge. **To Disinfect and Deodorize**: Items which cannot be immersed such as electrical panels: Thoroughly wet pre-cleaned surface with disinfectant towelettes and allow surface to remain wet for 10 minutes. Use as many towelettes as necessary for the treated area to remain wet for 10 minutes at room temperature 28 Degrees Celsius/68 Degrees Fahrenheit to kill listed organisms. **To Spot Clean, Deordorize Carpets and Fabric:** Blot or scrub area to be treated with disinfectant towelette to remove soiling. Wipe dry with a clean cloth or towel. **Dialysis Machine**: Place 150cc into the hemodialysate system. Allow machine to run until all of the product is down into the concentrate line. This will allow for automatic proportioning of solution with water.	This product is not to be used as a terminal sterilant/high level disinfectant on any instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Do not dilute or mix with other chemicals.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Medical Devices	Ready to Use 69658-3	Spray	This product may be used to pre-clean or decontaminate critical or semi critical medical devices prior to sterilization or high level disinfection. **To Sanitize Non-Food Contact Surfaces**: Before treatment clean surface of loose dirt. Hold spray bottle upright 4-6 inches from surfaces. Spray surfaces 2-4 seconds until covered with mist. Allow to air dry and remain undisturbed for 15 minutes.	This product must not result in the direct or indirect contamination of food products.
Residential and Public Premises				
Carpets and Fabrics <u>Hard Non-Porous Surfaces</u>: Telephones, Keyboards, Furniture, Wheelchairs, Walkers, Sinks, Floors, Walls, Light Switches, Linen Hampers, Bathrooms, Kennels and Animal Areas, Schools, Restaurants, Hotels, Boats, Planes, Trains, Buses, Health Spas, Nursing Homes, and Air Ducts.	Ready to Use 8383-3 Pressurized Liquid 8383-4	Spray, Immerse or Soak	**Pre-clean**: Clean surfaces using product to remove soil or filth. Wipe dry with a paper towel, cloth or sponge. **Disinfect and Deodorize**: Thoroughly wet pre-cleaned surface with product and allow to remain wet for 10 minutes at room temperature to kill listed organisms. Use spray for surfaces that cannot be immersed of soaked. **Carpets and Fabrics**: For manual cleaning spray product onto carpet and wipe clean with a cloth or sponge. Allow to air dry. For machine cleaning apply product in accordance with machine manufacturer's guidelines.	Do not dilute or mix with other chemicals. **Pressurized Liquid**: Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperature above 130 degrees may cause bursting.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Carpets and Fabrics Hard Non-Porous Surfaces: Telephones, Keyboards, Furniture, Wheelchairs, Walkers, Sinks, Floors, Walls, Light Switches, Linen Hampers, Bathrooms, Kennels and Animal Areas, Schools, Restaurants, Hotels, Boats, Planes, and Buses.	Impregnated Materials 8383-7	Wipe	**Preclean:** Clean surfaces with product's solution to remove soil and filth, wipe dry with a paper towel, cloth or sponge. **To Disinfect and Deodorize:** Items which cannot be immersed such as electrical panels: Thoroughly wet pre-cleaned surface with disinfectant towelettes and allow surface to remain wet for 10 minutes. Use as many towelettes as necessary for the treated area to remain wet for 10 minutes at room temperature 28 Degrees Celsius/68 Degrees Fahrenheit to kill listed organisms. **Carpets and Fabrics**: To Spot Clean, Deodorize and remove Debris from Carpets and Fabrics. Blot or scrub area to be treated with disinfectant towelette to remove soiling. Wipe dry with a clean cloth or towel. (Continued)	This product is not to be used as a terminal sterilant/high level disinfectant on any instrument introduced directly into the human body or either introduced in contact with the bloodstream or normally sterile areas of the body. Do not dilute or mix with other chemicals
Hard Non-Porous Surfaces: Walls, Counter Tops, Floors	Ready to Use 69658-3	Spray	**To Sanitize Non-Food Contact Surfaces:** Before treatment clean surface of loose dirt. Hold spray bottle upright 4-6 inches from surfaces. Spray surfaces 2-4 seconds until covered with mist. Allow to air dry and remain undisturbed for 15 minutes.	This product must not result in the direct or indirect contamination of food products.

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials Preservatives				
Industrial Additive for Polishes, Cleansers and Protectants	Ready to Use 8383-1	Add	Add 2.5% weight of active ingredient according to directions of the manufacturer.	Rinse empty container thoroughly with water and discard it.

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APPENDIX B: Phenols and Salts (Case 4074)

Guide to Appendix B

Appendix B lists the **generic** (not product specific) data requirements which support the reregistration of phenol and salts. These requirements apply to phenol and salts in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

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

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

(1) Agricultural premises and equipment
(2) Food handling/ storage establishment 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
Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(7) (10) Wood preservatives
(11) Swimming pools
Aquatic areas

3. (12) **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		41605001, 42381901, 41609502
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		41605001, 41609501, 42381901, 41609502, 42097001, 42528701
830.1670	61-3	Formation of Impurities		41605001, 41609501, 41609502
830.1700	62-1	Preliminary Analysis		41605001, 41609501, 41609502
830.1750	62-2	Certification of Limits		41605001, 41609501, 41609502
830.1800	62-3	Analytical Method		41609501, 41609502
	63-0	Reports of Multiple phys/chem Characteristics		42381901, 101697, 41609503
830.7200	63-5	Melting Point		41609504
830.7840 830.7860	63-8	Solubility		42441701, 42500201
830.7950	63-9	Vapor Pressure		42441702, 41609505
830.7370	63-10	Dissociation Constant		42441703, 42500202
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		42441704
830.7000	63-12	pH		41914901
830.6313	63-13	Stability		42457001
830.6317	63-17	Storage Stability		41605001
ECOLOGICAL EFFECTS				
850.1010	72-2	Aquatic Invertebrate Acute Toxcitiy- freshwater daphnids		DATA GAP
850.1025	72-3	Acute Toxicity to Estuarine/Marine Organisms		46751203

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.1075	72-1 and 72-3	Fish acute toxicity test, freshwater and marine		DATA GAP
850.1025	72-3	Oyster acute toxicity test (shell deposition)		46751202
850.1035	72-3	Mysid acute toxicity test		46751203
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		DATA GAP
850.2200	71-2	Avian Dietary Toxicity		42500205, 42500206, 160149, 160151
850.4100	122-1	Terrestrial plant toxicity, Tier 1 (seeding emergence)		46751207
850.4150	122-1	Terrestrial plant toxicity, Tier 1 (vegetative vigor)		46751204
840.5400	123-2	Aquatic plant growth		45688201
850.4225	123-1	Seedling emergence dose-response in rice		46751207
850.4250	123-1	Vegetative vigor dose-response in rice		46751204
850.5400	123-2	Acute algal dose-response toxicity - 4 species		46751205, 46751201, 46823801
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat		43334201, 433342402, 43334204
870.1200	81-2	Acute Dermal - Rabbit		00078779
870.1200	81-2	Acute Dermal - Rat		00078779
870.2500	81-5	Primary Dermal Irritation - Rabbit		43334202
870.2600	81-6	Dermal Sensitization – Guinea pigs		43334203, 43334205
870.3100	82-1	Subchronic Oral Toxicity: 90-Day Study		40760206, 145962
870.3200	82-2	21/28-Day Dermal Toxicity - Rat		42881901
870.4100	83-1	Chronic Toxicity		43954301, 44852701, 44832201, 43545501, 41656401, 41656401, 161577
870.4200	83-2	Oncogenicity		43954301, 44852701, 44832201, 43545501

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.3700	83-3	Teratogenicity -- 2 Species		00067616, 92154037, 41925003, 41925001, 41925002, 92154037 43735402, 43735401, 000164362
870.3700a	83-3a	Teratogenicity - rat		43735402
870.3800	83-4	2-generation repro.-rat		43928801
870.3800	83-4	Reproduction - Rat		Ryan et al., 2001 (Intl. J. of Tox. Vol. 20)
870.4200a	83-2	Carcinogenicity - rat		NIH PB# 80-1759 Non-guideline
870.4200b	83-2	Carcinogenicity - mouse		NIH PB# 80-1759 Non-guideline
870.5100	84-2	Bacterial reverse mutation test		Florin, et al. 1980 (Toxicology Vol. 15) Non-guideline, Haworth et al., 1983 (Env. Mutagenesis Suppl. Vol.1) Non-guideline, Pool and Lin, 1982 (Food Chem. Tox. Vol. 20) Non-guideline, Gocke et al., 1981 (Mutat. Res. Vol. 90) Non-guideline
Non-Guideline	Non-Guideline	Excretory System Effects		44197601, 44197602, 127249
Non-Guideline	Non-Guideline	Sub-acute Oral Toxicity		44197601, 44197602
870.5275	82-4	Sex-linked recessive lethal test in *Drosophila melanogaster*		Gocke et al., 1981 (Mutat. Res. Vol. 90) Non-guideline, Woodruff et al., 1985 (Env. Mutagenesis Vol. 7) Non-guideline
	84-2	Intreraction with Gonadal DNA		92154039, 92154038, 145962

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
	84-2	Intreraction with Gonadal DNA: Structural Chromosome Aberration/ Mammalian Cells/ Tissues in Culture		145962
	84-2	Intreraction with Gonadal DNA: Structural Chromosome Aberration/ Laboratory Mammals (Rat)		145962
870.5300	84-2	In Vitro mammalian call gene mutation test		Pashin and Bahitova,. 1982 (Mutation Res. Vol. 104) Non-guideline
870.5375	84-2	In Vitro mammalian chromosome aberration test		Kolachana et al., 1993 (Cancer Res. Vol. 53) Non-guideline
870.5380	84-2	Mammalian spermatogonial chromosomal aberration test - Rat		Bulsiewicz, 1977 (Folia Morphology Vol. 36) Non-guideline
870.5385	84-2	Mammalian bone marrow chromosome aberration test - Mouse		Kolachana et al., 1993 (Cancer Res. Vol. 53) Non-guideline
870.5395	84-2	Mammalian erythrocyte - Mouse		Barale et al., 1990 Acceptable - Non-guideline Chen and Eastmond, 1995 (Carcinogenesis Vol. 16) Acceptable - Non-guideline, Gocke et al., 1981 (Mutation Res. Vol. 90)
870.7485	85-1	Metabolism and pharmacokinetics - Rat		Capel et al., 1972 (Xenobiotica Vol. 2) Non-guideline, Hughes and Hall, 1995 Non-guideline
870.7485	85-1	Metabolism and pharmacokinetics - Mouse		Capel et al., 1972 (Xenobiotica Vol. 2) Non-guideline
870.7485	85-1	General metabolism/Biotransformation		71253
870.7485	85-1	General metabolism/ Excretion & Secretion		71253
870.7485	85-1	General metabolism: Pesticide Fate in Animals/ Laboratory Mammals (Rat)		145962

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.7600	85-3	Dermal Penetration		Behl and Linn, 1983 (J Pharm. Sci. Vol. 72) Non-guideline
875.1200	233	Dermal Indoor Exposure		DATA GAP
875.2400 875.2900	133-3	Dermal passive dosimetry expo		43432901, 45524304, 41412201, 43432901
875.2500 875.2900	133-4	Inhalation passive dosimetry expo		43432901, 45524304, 41412201, 43432901
None-Guideline	None-Guideline	Excretory System Effects		127249
Non-Guideline	Non-Guideline	Kidney		127249
Non-Guideline	Non-Guideline	Bladder/Duct		12749
Non-Guideline	Non-Guideline	Exposure of Humans -- General Population		41742601
Environmental Fate				
835.2120	161-1	Hydrolysis of Parent and Degradates		43994201, 43973501
870.7600	85-3	Dermal Penetration/Absorption		46882301
Non-Guideline	Non-Guideline	Physiological/Anatomical Effects of Pesticides		46882301
835-6200	164-2	Dissipation in Water (Field Studies)		46601401
860.1300 835.2120	171-4A2	Nature of the Residue in Plants		43298301, 43537101
860.1300	171-4A3	Nature of the Residue in Livestock		44349301
860.1340	171-4B	Residue Analytical Methods		43384101, 43742101, 44038501, 43996401
860.1400	171-4C	Magnitude of the Residue [by commodity]: Orange		43992401, 44112001, 44182601
860.1400	171-4C	Magnitude of the Residue [by commodity]: Grapefruit		43992401, 44182601
860.1400	171-4C	Magnitude of the Residue [by commodity]: Lemon		43992401, 44182601

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
860.1520	171-4C	Magnitude of the Residue [by commodity]: PROCESSED FOOD		43992401, 44112001, 44182601

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Appendix C. Technical Support Documents

Additional documentation in support of this RED are maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

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

These documents include:

Reregistration Eligibility Decision (RED) Document:

- *Reregistration Eligibility Decision for Phenol and Salts*, March 30 2009. Antimicrobials Division
- *Phenol/Sodium Phenate Reregistration Eligibility Decision*, September 30, 2009. Antimicrobials Division

Risk Assessment and Supporting Science Documents:

- *Occupational and Residential Exposure and Risk Assessment for the Existing Fogging Cleanroom Use of Phenol (Sporicidin)*, December 18, 2008. Antimicrobials Division. Dole, Timothy.
- *Occupational and Residential Exposure and Risk Assessment for the Duct Cleaning Use of Phenol (Sporicidin)*, December 18, 2008. Antimicrobials Division. Dole, Timothy.
- *Phenol/Sodium Phenate Summary*, September 15, 2004. Antimicrobials Division.
- *Overview of the Phenol/Sodium Phenate Preliminary Risk Assessment*, September 13, 2004. Antimicrobials Division.
- *Phenol RED Document*, September 10, 2004. Antimicrobials Division.
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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Phenol and Salts RED for a list of studies that the Agency plans to require.

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Appendix F. Product Specific Data Call-In

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

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Appendix G. Batching of Phenol and Salts Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching for phenol and salts at a later date.

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

A list of registrants sent the data call-in (DCI) will be posted at a later date.

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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

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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:

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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.

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