United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-07-009
September 2007

Reregistration Eligibility Decision for Copper 8-quinolinolate

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 Copper 8-quinolinolate. The Reregistration Eligibility Decision (RED) for Copper 8-quinolinolate was approved on September 26, 2007. 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 Copper 8-quinolinolate 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 Copper 8-quinolinolate are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0556 at: www.regulations.gov.

The Copper 8-quinolinolate RED was developed through EPA's public participation process, published in the Federal Register on July 11, 2007, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. 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.

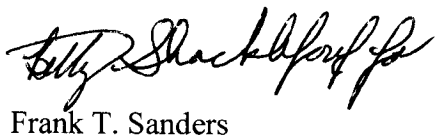
Please note that the Copper 8-quinolinolate risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to Copper 8-quinolinolate alone. This document 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 Copper 8-quinolinolate will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measure outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary to implement the identified 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 Copper 8-quinolinolate. 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 relevant to this reregistration decision, please contact the Chemical Review Manager, K. Avivah Jakob, at (703) 305-1328. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Adam Heyward at (703)-308-6422

Sincerely,



Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Copper 8-quinolinolate
List D
CASE 4026

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September 26, 2007

Attachment

Table of Contents

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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

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Copper 8-quinolinolate 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 Copper 8-quinolinolate that pose risks of concern. As a result of this review, EPA has determined that Copper 8-quinolinolate containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also required that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for copper 8-quinolinolate.

Copper 8-quinolinolate is an algaecide, bactericide and fungicide. Copper 8-quinolinolate is used as a material preservative in industrial textiles intended for the treatment of webbing, tenting, rope, canvas, leather, industrial cotton, industrial fabrics and clothing worn by the military. These textile uses of Copper 8-quinolinolate are intended only for military use. Other material preservation uses include in-can paint preservation; pulp and paperboard, kraft paper; and, adhesives and glues. Copper 8-quinolinolate is also used as a wood preservative intended for treatment of wood to be used as beams for indoor use, mushroom trays, produce picking trays/containers that may contain fruit (indirect food contact use), interior boat applications, wood used in greenhouse premises, equipment and containers, log homes, shingle roofs, siding, fences, decks, furniture, playground-equipment, sills & baseboards, and structural building lumber.

The Agency has concluded that the FQPA Safety Factor for copper 8-quinolinolate should be removed (equivalent to 1X) based on: (1) the toxicology data base is complete with respect to assessing the increased susceptibility to infants and children as required by FQPA for copper 8-quinolinolate; (2) there is no concern for developmental neurotoxicity resulting from exposure to copper 8-quinolinolate in the rat and rabbit prenatal developmental studies and 2-generation reproduction study; (3) there is no evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (4) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredient, copper 8-quinolinolate. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for copper 8-quinolinolate and any other substances**.** Copper 8-quinolinolate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that copper 8-quinolinolate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of copper 8-quinolinolate. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for copper 8-quinolinolate referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0556).

This document consists of six sections. Section I is the Introduction. Section II provides a Chemical Overview, a profile of the use and usage of copper 8-quinolinolate and its regulatory history. Section III, Summary of Copper 8-quinolinolate Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management and Reregistration, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

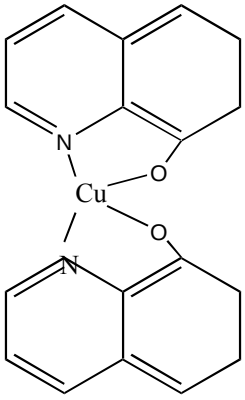
II. Chemical Overview

A. Regulatory History

Copper 8-quinolinolate was first registered as an active ingredient by the United States Environmental Protection Agency (EPA) on January 5, 1956. Currently, there are 27 products containing copper 8-quinilinolate as an active ingredient. Copper 8-quinolinolate is an algaecide, bactericide and fungicide. Copper 8-quinolinolate products are used in commercial/institutional premises and residential/public accesses areas. Copper 8-quinolinolate is used as a material preservative in industrial textiles intended for the treatment of webbing, tenting, rope, canvas, leather, industrial cotton, industrial fabrics and clothing worn by the military. These textile uses are intended only for military use. Other material preservation uses include in-can paint preservation; pulp and paperboard, kraft paper; and, adhesives and glues. Copper 8-quinolinolate is also used as a wood preservative intended for treatment of wood to be used as beams for indoor use, mushroom trays, produce picking trays/containers that may contain fruit (indirect food contact use), interior boat applications, wood used in greenhouse premises, equipment and containers, log homes, shingle roofs, siding, fences, decks, furniture, playground-equipment, sills & baseboards, and structural building lumber.

B. Chemical Identification

Technical Copper 8-quinolinolate



Copper-8 quinolate

Figure 1. Molecular Structure of Copper 8-quinolinolate

Common name: Copper 8-quinolinolate

Chemical name: Copper, bis(8-quinolinolato-N1,O8)-

Chemical family: Quinoline

Empirical formula: $C_{18}H_{12}$ Cu N_2O_2

CAS Registry No.: 10380-28-6

Case number: 4026

OPP Chemical Code: 024002

Molecular weight: 351.851

Other names: Copper oxine; 8-Quinolinol, copper(II) chelate; Bioquin; Bis(8-oxyquinoline) copper; Bis(8-quinolinolato)copper; Bis(8-quinolinolato-N(1),O(8)) copper; Cellu-quin; Copper 8-hydroxyquinoline; Copper oxinate; Copper oxyquinolate; Copper, bis(8-quinolinolato-N1, O8)-,; Copper-8; Cunilate 2472; Cupric 8-hydroxyquinolate; Dokivin; Fruitdo; Milmer; Oxine-Cu

Basic manufacturers: Tanabe U.S.A., Inc.; Osmose, Inc.; James Hardie Building Products, Inc.

Chemical properties: Copper 8-quinolinolate is an olive green crystalline powder that is odorless. Copper 8-quinolinolate has a melting point of 270 ^{o} C and decomposes below its melting point. The boiling point of copper 8-quinilinolate is undetermined and its vapor pressure can not be calculated. Copper 8-quinolinolate has a Log Kow of 3.14, a Log Koc of 6.69 and its solubility is 0.7mg/L at 25 ^{o} C. The henry law constant is 7.849 X 10 $^{-13}$ atm-m^{3}/mole. Copper 8-quinolinolate has a half life in air of 0.642 hours (measured against OH radical reaction) and its specific gravity is 1.63.

C. Use Profile

The following information is a description of the currently registered uses of copper 8-quinolinolate products and an overview of use sites and application methods. A detailed table of the uses of copper 8-quinolinolate eligible for reregistration is contained in Appendix A.

Type of Pesticide: Algaecide, Bactericide and Fungicide

Summary of Use:

Wood Preservative:
As a wood preservative copper 8-quinolinolate is intended for treatment of wood that is to be used as beams for indoor use, mushroom trays, produce picking trays/containers that may contain fruit (indirect food contact use), interior boat applications, wood used in greenhouse premises, equipment and containers, log homes, shingle roofs, siding, fences, decks, furniture, playground-equipment, sills & baseboards, and structural building lumber.

Materials Preservative:
Copper 8-quinolinolate is used as a material preservative in industrial textiles intended for the treatment of webbing, tenting, rope, canvas, leather, industrial cotton, industrial fabrics and clothing worn by the military. These textile uses are intended only for military use. Other material preservation uses include in-can paint preservation; pulp and paperboard, kraft paper; and adhesives & glues.

Target Pests: Bacterial ring rot (corynbacterium); brown powderpost beetles; decay; deterioration/spoilage bacteria; fungal rot/decay; fungi; fungus stain; furniture beetle; mold/mildew; powderpost beetle; rots; sapstain; stain; stain fungi; surface molds; termites; wood destroying insects; wood infesting insects; wood mold; wood rot/decay; wood rot/decay fungi; wood stain fungi

Formulation Types: Soluble concentrate, Ready-to-use

Method and Rates of Application:

Equipment for Antimicrobial Use: Copper 8-quinolinolate end-use products are added during the manufacturing process of treated articles and materials. Methods of material preservation application include dip, spray, or flow coat for textile preservation; Dispersion in solvent or aqueous systems for adhesives, glues and paints preservation; Brush, spray, short dip or application at the size-press for paper product preservation. For wood preservation, copper 8-quinolinolate end-use products are applied via dip, spray or flow coat.

Application Rates: For details about specific use sites for copper 8-quinolinolate, refer to Appendix A.

Materials Preservatives:
- Application rates can range from .24% to 1.0% active ingredient.

Wood Preservatives:
- Application rates can range from .11% to 3.3% active ingredient.

Use Classification: General use.

III. Summary of Copper 8-quinolinolate 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 Copper 8-quinolinolate. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0556, 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 Copper 8-quinolinolate 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 Copper 8-quinolinolate

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 Copper 8-quinolinolate can be found in the "Toxicology Chapter for Copper 8-quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007; and the "Preliminary Risk Assessment Chapter for the Copper 8-quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007. These documents are available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0556).

The Agency has reviewed all toxicity studies submitted for Copper 8-quinolinolate 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 gives a summary of the acute toxicity data and toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 2.

Table #1. Summary of Acute Toxicity Data for Copper 8-quinolinolte

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
Acute Toxicity				
870.1100 (§81-1)	Acute Oral- Rat Copper 8-quinolinolate purity 99.5%	42921501	LD_{50} > 5000 mg/kg M/F	IV
870.1200 (§81-2)	Acute Dermal- Rabbits Copper 8-quinolinolate purity 99.5%	42921502, 43558501	LD_{50} = 2000 mg/kg M/F	III

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.1300 (§81-3)	Acute Inhalation- Rat Copper 8-quinolinolate purity 96%	43611901	LC_{50} = 0.089 ± 0.031 mg/L M/F	III
870.2400 (§81-4)	Primary Eye Irritation- Rabbit, Copper 8-quinolinolate purity 98%	41678402	Corrosive	I
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit Copper 8-quinolinolate purity 99.7%	42921503	Non-Irritant	IV
870.2600 (§81-6)	Dermal Sensitization - Guinea pig Copper 8-quinolinolate purity 99.7%	42921504	Not a sensitizer.	N/A

NA = Not Applicable

Table #2. Dietary Toxicological Endpoints for Copper 8-quinolinolate

Exposure Scenario	Dose Used in Risk Assessment, UF	Target MOE, Uncertainty Factory (UF), Special FQPA Safety Factory (SF) for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49)	No appropriate endpoints were identified that represent a single dose effect. Therefore, this risk assessment is not required.		
Chronic Dietary (all populations)	NOAEL = 5 mg/kg/day	**FQPA SF** = **1** **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic RfD (cPAD)** = 0.05 mg/kg/day	Subchronic Toxicity in the Dog MRID 42986802 LOAEL = 50mg/kg/day, based on vomiting, decreased plasma protein and albumin, and reddened mucosa and hyperemia in the stomach and small intestine.
Carcinogenicity	Copper 8-quinolinolate has not been formally classified for carcinogenicity.		

Notes: UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

General Toxicity Observations

Acute Toxicity

Copper 8-quinolinolate exhibits low acute oral toxicity (Toxicity Category IV); moderate dermal toxicity (Toxicity Category III); and high inhalation toxicity (Toxicity Category II).

Copper 8-quinolinolate is classified as an eye corrosive (Toxicity Category I). For dermal irritation, Copper 8-quinolinolate is a low irritant (Toxicity Category IV) and it is not classified as a dermal sensitizer.

Developmental & Reproductive Toxicity

Developmental toxicity was not noted in either of the two available copper 8-quinolinolate developmental toxicity studies. The developmental toxicity data indicate that there is no evidence of primary developmental effects in either the rat or rabbit.

In a two-generation reproduction toxicity study, no significant compound-related effects were noted in the pregnancy rate, pre-coital time, duration of pregnancy and implantation sites/litter for rats fed copper 8-quinolinolate for two successive generations. The parental/systemic NOAEL was determined to be 250 ppm. The parental/systemic LOAEL was determined to be 2500 ppm based on increased liver weight in males. The reproductive toxicity NOAEL was determined to be 250 ppm. The LOAEL was determined to be 2500 based on a decreased mean number of live pups at birth and decreased litter weights observed at day 0 during lactation in the first generation.

Acute & Chronic Reference Dose (RfD)

An acute reference dose (RfD) value was not assigned for copper 8-quinolinolate. No appropriate endpoints were identified that represent a single dose effect for the acute dietary risk assessment. Therefore an acute dietary assessment was not conducted.

The chronic RfD value for copper 8-quinolinolate is 0.05 mg/kg/day for all populations. The chronic RfD was established by using the NOAEL of 5 mg/kg/day, which is based on a sub-chronic toxicity dog study that observed vomiting, decreased plasma protein and albumin, and reddened mucosa and hyperemia in the stomach and small intestine. An uncertainty factor of 100 was applied (10x inter-species extrapolation, 10x intra-species variation) and the hazard-based FQPA safety factor of 1 was applied.

Incidental Oral Exposure

The NOAEL for the short- and intermediate-term incidental oral endpoint is 200 mg/kg/day. The NOAEL is based on a rabbit prenatal developmental toxicity study, which observed clinical signs of toxicity and decreased body weight-gain in maternal rats at a dose of 800 mg/kg/day. For incidental oral exposures, the “target” margin of exposure (MOE), for Copper 8-quinolinolate is 100 (10x inter-species extrapolation, 10x intra-species variation) and the hazard-based FQPA safety factor of 1 was applied.

Dermal Exposure

The NOAEL for the short- and intermediate-term (ST/IT) dermal endpoint is 200 mg/kg/day. The NOAEL is based on a 28-day dermal toxicity study in the rat, which observed necrosis of thymic lymphocytes at a dose of 1000 mg/kg/day. The target MOE for ST and IT dermal exposure is 100 (10x inter-species extrapolation, 10x intra-species variation). An endpoint was not selected for long-term dermal exposure.

Inhalation Exposure

The NOAEL for the short-, intermediate-term and long-term (ST, IT, LT) inhalation endpoint is 5 mg/kg/day. The NOAEL is based on a sub-chronic dog toxicity study, which observed clinical signs of toxicity (vomiting, decreased plasma protein and albumin and reddened mucosa and hyperemia in the stomach and small intestine) at a dose of 50 mg/kg/day. For Copper 8-quinolinolate the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000 (10x inter-species extrapolation, 10x intra-species variation, 10x route extrapolation). In cases where inhalation endpoints are set using oral toxicity studies the Agency will consider requiring an inhalation toxicity study to confirm that the use of route-to-route extrapolation does not underestimate risk. The Agency determines the need for confirmatory inhalation data by evaluating the inhalation MOEs. For Copper 8-quinolinolate, if MOEs are greater then 100 there are no risks of concern. However, if MOEs are less than 1,000 confirmatory inhalation toxicity data are considered necessary to account for the use of route-to-route extrapolation. Since several inhalation MOEs are below 1,000 for Copper 8-quinolinolate, confirmatory data are required.

Carcinogenicity

Copper 8-quinolinolate has not been formally classified for carcinogenicity by the EPA. Copper 8-quinolinolate was examined for carcinogenicity in both rat (MRID 00083777) and mouse (MRID 43267201) studies. The National Toxicology Program has examined the 8-hydroxyquinoline moiety for carcinogenicity (NTP Technical Report no. 301). Additional studies not reviewed by the EPA but reviewed by Health Canada, Pest Management Regulatory Agency (PMRA) include a 3 week gavage and 50 week dietary carcinogenicity study in mice, a 2 year carcinogenicity study in B6C3F1 mice, and a 2 year carcinogenicity study in Fischer 344 rats.

In the mouse carcinogenicity study, Health Canada noted in their review that the lymphomas in the mouse are discounted based on the observations that (a) the tumors are not dose-related, (b) the tumors occur in only one sex, and (c) the tumors are not increased further at the next highest dose. Health Canada indicates in their review that the observed uterine tumors are outside historical control at the high dose. The incidences of tumors that are outside historical control occurred at a dose above the limit dose of 1000 mg/kg/day for carcinogenicity data. Therefore, the Agency believes that the biological significance of the tumors is questionable.

In the rat carcinogenicity study, interstitial cell tumors of the testes, 2 unilateral and 1 bilateral were observed in three males at the 761 mg/kg/day dose level. The study report indicates that this incidence was within historical control range for 'rats of this age in this laboratory.' However, only one set of historical control data were submitted that indicate benign interstitial cell tumor incidence of 10% (from examination of 70 male rats). In addition, only 10 rats at the high dose in the present study were examined histologically.

As noted by both the EPA and by Health Canada, the copper 8-quinolinolate carcinogenicity rat study has several significant deficiencies, including high mortality rates in all treatment groups, assessment of too few rats for carcinogenicity (only 30 animals/sex/dose), and inadequate historical control data. Therefore, the significance of the interstitial cell tumors is not known and cannot be determined from these data.

Mutagenicity Potential

For Copper 8-quinolinolate, three mutagenicity studies were submitted. In one study copper 8-quinolinolate was found to be weakly positive in an ames bacterial reverse mutation study (MRID 42963201). The test article was weakly mutagenic in some activated Salmonella strains at mild to moderate toxic concentrations**.**

In a micronucleus mutagenicity study (MRID 42962302) it was determined that the test material was negative for micronucleus induction in bone marrow cells of mice treated once at doses up to 7,500 mg/kg.

In the third mutagenicity study (MRID 42962303), unscheduled DNA synthesis (UDS) in hepatocytes (HPC) was tested in male rats. The study reported copper 8-quinolinolate negative in inducing unscheduled DNA synthesis in primary rat hepatocyte cultures for rats treated orally up to 3,000 mg/kg.

Endocrine Disruption Potential

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

been developed, copper 8-quinolinolate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The Agency has concluded that the FQPA Safety Factor should be removed (i.e., reduced to 1X) for Copper 8-quinolinolate 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 Copper 8-quinolinolate 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.

3. Population Adjusted Does (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The Agency has conducted a dietary exposure and risk assessment for the use of Copper 8-quinolinolate as a materials preservative in pulp and paper and adhesives.

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 Copper 8-quinolinolate because the use patterns are not expected to result in acute dietary exposure. Furthermore, no endpoints appropriate for a dietary risk assessment were identified in the toxicity database, which is largely complete. Therefore, Copper 8-quinolinolate does not pose as an acute dietary risk and an acute dietary risk assessment was not required.

b. Chronic PAD

Chronic dietary risk for Copper 8-quinolinolate 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 (0.05 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from a sub-chronic toxicity study in dogs in which the NOAEL (5 mg/kg/day) was determined. For the pulp and

paper use, the cPAD is 0.3% for adults and 0.9% for children. Therefore, there are no chronic dietary risks of concern from the pulp and paper use. The adhesive use was assessed for indirect food contact and the Agency determined that there are no chronic dietary concerns as a result of this use (% cPAD for adults is 0.6%, % cPaD for children is1.4%).

The Agency did not conduct a dietary risk assessment for the use of Copper 8-quinolinolate to treat wooden trays, which are used to grow mushrooms because it is believed that dietary exposures are not likely as a result of this use pattern. Mushrooms are typically grown on compost which must be supplemented in order to sustain growth of the mushrooms or fungi. The compost is typically not reused so even if some nominal leaching of Copper 8-quinolinolate into the compost occurred, it is not mobile based on the results of two soil studies. Moreover, the primitive nonvascular characteristics of mushrooms combined with widely used cultivation practices, make it unlikely use of Copper 8-quinolinolate to treat wooden mushroom trays will result in residues in mushrooms. Therefore, there are no dietary risks of concern for the use of Copper 8-quinolinolate to treat wooden trays.

4. Dietary Exposure Assumptions

The dietary risk assessment considered potential food exposures from treated pulp & paper and potential indirect food exposures from treated adhesives. In the absence of residue data, the Agency estimated antimicrobial residue levels that may occur in food that contacts treated pulp and paper products from the maximum application rates on Copper 8-quinolinolate 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 treated adhesives. Additional information can be found in the "Dietary Exposure Assessment of Copper 8-Quinolinolate Use of Indirect Food Contact Surfaces," dated June 28, 2007; and the dietary and exposure and risk section (4.2) of the "Preliminary Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007.

5. Dietary Risk Assessment

The Agency conducted a dietary exposure and risk assessment for the use of Copper 8-quinolinolate in pulp and paper and adhesive products. Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD (aPAD or cPAD) does not exceed the Agency's risk concerns. A summary of the chronic risk estimates are shown in Tables 3 & 4.

The Agency did not conduct a dietary risk assessment for the use of Copper 8-quinolinolate to treat wooden trays, which are used to grow mushrooms because it is believed

that dietary exposures are not likely as a result of this use pattern. The Agency reviewed two studies, which were conducted on non-aged soil and aged soil samples. Mushrooms are typically grown on compost which must be supplemented in order to sustain growth of the mushrooms or fungi. The compost is typically not reused so even if some nominal leaching of Copper 8-quinolinolate into the compost occurred, it is not mobile based on the results of two soil studies. Moreover, the primitive nonvascular characteristics of mushrooms combined with widely used cultivation practices, make it unlikely that use of Copper 8-quinolinolate to treat wooden mushroom trays will result in residues in mushrooms. Therefore, there are no dietary risks of concern for the use of Copper 8-quinolinolate to treat wooden trays.

a. Dietary Risk from Food & Indirect Food Contact

Copper 8-quinolinolate is used as a materials preservative in pulp and paper products and adhesives. An acute dietary assessment was not conducted for Copper 8-quinolinolate because the use patterns are not expected to result in acute dietary exposure and toxicity endpoints were not identified. Therefore, Copper 8-quinolinolate does not pose as an acute dietary risk.

Analysis of chronic dietary exposure to treated pulp and paper indicates that all risk estimates are below the Agency's level of concern for all population subgroups (< 0.3% of cPAD for adults and < 0.9% of cPAD for children). Therefore, there are no chronic dietary risks of concern for treated pulp and paper.

Table #3. Pulp & Paper Dietary Exposure and Risk

Dietary Concentration	Estimated Daily Intake (EDI)	Daily Dietary Dose (DDD): mg/kg/day	% cPAD (cPAD = 0.05 mg/kg/day)
10.0 µ g	Adult: 13.8 µg	Adult: 13.8 µg/70 kg = 0.000197 mg/kg/day	Adult: 0.000197 mg/kg/day ⁄ 0.05 mg/kg/day x 100 = 0.3%
	Child: 6.9 µg	Child: 6.9µg/15 kg = 0.00046 mg/kg/day	Child: 0.00046 mg/kg/day ⁄ 0.05 mg/kg/day x 100= 0.9%

Analysis of chronic indirect food contact exposure to treated adhesives indicates that all risk estimates are below the Agency's level of concern for all population subgroups (<0.6% of cPAD for adults and <1.4% of cPAD for children). Therefore, there are no chronic indirect food contact risks of concern for treated adhesives.

Table #4. Adhesives Indirect Food Contact Exposure and Risk

Dietary Concentration (ppb)	Estimated Daily Intake (EDI) µg/day	Daily Dietary Dose (DDD) mg/kg/day	% cPAD (cPAD) = o.05 mg/kg/day
7 ppb	Adult: 7µg/kg x 3000g = 21 µg/day Child: 7 µg/kg x 1500 g = 10.5 µg/day	Adult: 21 µg/day / 70 kg = 0.0003 mg/kg/day Child: 10.5 µg/day / 15kg/day = 0.0007 mg/kg/day	Adult: 0.0003 mg/kg/day ⁄ 0.05 mg/kg/day x100 =0.6% Child: 0.0007 mg/kg/day⁄ 0.05 mg/kg/day x 100=1.4%

b. Dietary Risk from Drinking Water

Copper 8-quinolinolate is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, a drinking water exposure assessment was not conducted.

6. Residential Risk Assessment

Based on registered use patterns from product labels, it has been determined that exposure to residential handlers or applicators can occur in a variety of residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by the Agency for assessment were evaluated using maximum application rates as stated on the product labels. The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food and drinking water. Exposure may occur during and after application methods including painting via brush/roller and airless sprayer. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose. Additional information can be found in the "Occupational and Residential Exposure Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007; and the "Preliminary Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential and occupational risks for Copper 8-quinolinolate are listed in Table 5.

For the residential handler assessment, a Margin of Exposure (MOE) greater than or equal to 100 is considered adequately protective for dermal exposures. The MOE of 100 includes an uncertainty factor (UF) of 10x for inter-species extrapolation and 10x for intra-species variation.

For inhalation exposure a target MOE of 1,000 was selected. The inhalation MOE of 1,000 includes an UF of 10x for inter-species extrapolation, 10x for intra-species variation and 10x for route-to-route extrapolation. For Copper 8-quinolinolate, an inhalation MOE greater than or equal to 100 is considered adequately protective for inhalation exposure. However if the inhalation MOE is less then 1,000 confirmatory inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation does not underestimate risk.

Table #5. Residential and Occupational Toxicological Doses and Endpoints for Copper 8-quinolinolate

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF* for Risk Assessment	Study and Toxicological Effects
Non-Dietary Risk Assessments			
Incidental Oral Short-Term (1-30 days) Intermediate-term (30-days – 6months)	**NOAEL (maternal)** = 200 mg/kg/day	**Target MOE = 100** (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF = 1**	Prenatal Developmental Toxicity Study in the Rat MRID 42986803 LOAEL = 800 mg/kg/day, based on clinical signs of toxicity and decreased body weight gain in maternal rats.
Dermal Short-Term (1 to 30 days) and Intermediate-term (30 days- 6 months)	**NOAEL** = 200 mg/kg/day	**Target MOE = 100** (10x inter-species extrapolation, 10x intra-species variation)	28-day dermal toxicity study in the rat MRID 42957802 LOAEL(systemic) = 1000 mg/kg/day, based on necrosis of thymic lymphocytes No evidence of dermal irritation from either this study or the acute dermal study
Dermal Long-Term (>6 months)	A long-term dermal endpoint is not required for copper 8-quinolinolate.		
Inhalation[a] (all durations)	**NOAEL** = 5 mg/kg/day	**UF = 1000** (10x inter-species extrapolation, 10x intra-species variation, 10x route extrapolation)	Subchronic Toxicity in the Dog MRID 42986802 LOAEL = 50mg/kg/day, based on vomiting, decreased plasma protein and albumin, and reddened mucosa and hyperemia in the stomach and small intestine.
Cancer	Copper 8-quinolinolate has not been formally classified as to carcinogenicity.		

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

[a] The inhalation absorption factor of 100% (default value, assuming oral and inhalation absorption are equivalent) should be used since an oral endpoint was selected for the inhalation exposure scenarios. If results are below an MOE of 1,000, a confirmatory inhalation study is warranted.

b. Residential Handlers

i. Exposure Assessment

Residential handler exposure to Copper 8-quinolinolate can occur through the treatment of wood surfaces and application of preserved paint via brush/roller or airless sprayer. For residential handlers, the representative uses assessed include treatments to wood surfaces (e.g.,

water repellents and coatings applied via brush, roller and low-pressure coarse spray). Additionally, handler exposures were assessed for the application of manufactured paint products containing Copper 8-quinolinolate as a preservative (paint brush/roller and airless sprayer). The EPA selected high-end representative use scenarios based on maximum application rates as stated on the product labels. The residential handler exposure scenarios assessed for the representative uses are shown in Table 6. The table also shows the maximum application rate associated with the representative use and the EPA Registration number for the corresponding product label.

Table #6. Representative Uses Associated with Residential Handler Exposure

Representative Use	Exposure Scenario	Application Method	EPA Reg. No.	Maximum Application Rate
Using Wood Preservative Coatings/ Water Repellents	ST Handler: Adult Dermal and Inhalation	Paint brush, Roller and Low-pressure coarse sprayer	1022-514 and 81819-1	0.675% ai ready-to-use (RTU) oil-based exterior coating for log homes, wood roofs, siding, fences, rough sawn lumber, new/old wood. 150-300 sq ft/gal. as one coat application.
Using Treated Paints/Coatings (in-can preservative)	ST Handler: Adult Dermal and Inhalation (aerosol particulates)[6]	Paint brush, Roller, Airless sprayer	Commercially-treated article preserved with 2829-136 (e.g., exterior house paint)	Solvent-based paint containing 1.0% ai incorporation to inhibit mold/mildew. (Paint use applications unspecified).

Note: Only EPA registered products with specified use directions/use applications are included in this table. Products listed were selected based on maximum use rates by application method.
ST = Short-term exposure
[6] Handler dermal and inhalation (to the particulates) exposure were assessed for Oxine-Copper using PHED unit exposures.

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 Residential Exposure SOPs (U.S. EPA, 1997a, 2001). The dermal and inhalation exposures from these techniques have been normalized by the amount of active ingredient handled and reported as unit exposures (UE), which are expressed as mg/lb of active ingredient handled.

Maximum application rates, related use information and Agency standard values were used to assess residential handler exposure. The residential handler scenarios were assumed to be of short-term duration (1-30 days).

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation risk assessments. An MOE greater than or equal to 100 is considered adequately protective for the dermal route of exposure.

For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However if the inhalation MOE is greater then 100 but less then 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation does not underestimate inhalation exposure risk. For Copper 8-quinolinolate the inhalation endpoint was set using oral toxicity data. When oral toxicity data are used to select an inhalation endpoint, as was done for Copper 8-quinolinolate, the Agency will consider requiring inhalation toxicity data to confirm that the use of route-to-route extrapolation does not underestimate potential risk.

The calculated short-term (ST) MOEs are above the target dermal MOE of 100 for all scenarios. Therefore, there are no dermal risks of concern for residential exposure. The inhalation MOEs are all above 100, indicating no risks of concern. However, the high-end scenario developed for the airless sprayer yielded a ST inhalation MOE above 100 (MOE of 278) but below 1,000. Because the inhalation MOE is below 1,000 for the airless sprayer scenario, an inhalation toxicity study is needed to confirm that there are no inhalation risks of concern. A summary of the residential handler exposures and risks are presented in Table 7.

Table #7. Short-Term Residential Handlers Exposures & MOEs

Exposure Scenario	Method of Application	Unit Exposure (mg/lb ai)		Application Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)		MOE (ST)	
		Dermal[a]	Inhalation[b]			Dermal[c]	Inhalation[d]	Dermal (Target = 100)[e]	Inhalation (Target = 1000)[f]
Using Wood Coatings	Low Pressure Sprayer	100	0.030	0.675% ai by weight	50 lbs (5 gal)	0.482	0.00015	415	33,333
Using Treated Paint	Brush/roller	230	0.284	1.0% ai by weight	20 lb s (2 gal)	0.657	0.0008	304	6,250
	Airless sprayer	79	0.83	1.0% ai by weight	150 lbs (15 gal)	1.69	0.018	118	278

a All dermal unit exposures represent ungloved replicates. The low pressure sprayer, brush/roller, and airless sprayer unit exposures represent short sleeve and short pant replicates.
b No respirator used by exposed individual.
c Dermal Daily Dose (mg/kg/day) = [dermal unit exposure (mg/lb ai) * application rate (0.00675 or 0.01) * quantity handled * dermal absorption factor (NA) / body weight (70 kg).
d Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * application rate (0.00675 or 0.01) * quantity handled * inhalation absorption factor 100% / body weight (70 kg).
e Dermal MOE = NOAEL (200 mg/kg/day) / Daily Dose. Target dermal MOE is 100.
f Inhalation MOE = NOAEL (5 mg/kg/day) / Daily Dose. Target inhalation MOE is 1000.

c. Residential Post-application

i. Exposure Assessment

Residential post-application exposures result when adults and children come in contact with Copper 8-quinolinolate in areas where pesticide end-use products have recently been applied (e.g., treated wood, treated textiles, hard surfaces), 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).

Post-application scenarios have been developed to encompass potential high-end exposure from various wood and materials preservative treatments. Representative post-application scenarios assessed include children contacting surface residues from Copper 8-quinolinolate treated wood (dermal and incidental oral exposure) and residues remaining on treated outdoor hard surfaces (dermal and incidental oral exposure to children). Scenarios were also developed for contact with residues on treated textiles such as tents and tarps (dermal exposure to adults and children and incidental oral exposure to children). Current product labels do not indicate that treated textiles are restricted for military/industrial use and, therefore a residential assessment was conducted for contact with residues on treated textiles as a conservative measure. The technical registrants of Copper 8-quinolinolate have indicated that as a textile preservative, the treated products are to be used only in military/industrial settings. Exposure of children to treated textiles is believed to be low, because the treated textiles are not intended for residential use. To address possible residential exposure to treated textiles, the registrants must update all end-use labels (that have treated tents/textiles as a use pattern) to state that treated textiles are for non-residential/military use only. By restricting the treated textile use pattern, residential exposure is unlikely. Further, the Agency believes that the conservative exposure estimates used in the dermal risk assessment are not pertinent to members of the military that may utilize treated tents and that exposures will be minimal and risks will not be of concern.

Typically, post-application exposures in residential settings are assumed to occur over a short-term duration (1 to 30 days) as episodic, not daily events. It is believed that the use patterns for Copper 8-quinolinolate will not result in any intermediate-term (IT) residential exposures and, therefore, IT post-application exposures were not assessed. Data sources and methodologies utilized for both the handler and post-application residential risk assessments include: the HED Residential Standard Operating Procedures (SOPs) (USEPA, 1997a) and the USEPA Exposure Factors Handbook (USEPA 1997b).

A number of Copper 8-quinolinolate end-use products are registered for wood preservative uses in pressure and non-pressure treatments of wood products intended for residential applications. As a result of these uses, there are potential post-application exposures to individuals exposed to Copper 8-quinolinolate treated wood in residential settings (home and farm).

Currently, there are no data that can be used to estimate either exposure to adults from inhalation of wood dusts during construction of wood decks or to children exposed to treated wood. Incidental ingestion exposure for adults is expected to be negligible and dermal contact for adults is expected to be lower than exposure for children crawling on wood decks. Because children are more likely than adults to contact wood surfaces using playground equipment (play-sets) and because children have a higher surface area to body weight ratio, they have been used to represent the maximum exposed individual. At present, there are no available data to assess the levels of Copper 8-quinolinolate residues in soil contaminated from treated wood (above ground fabricated components of decks or play-sets). Therefore, incidental ingestion and dermal exposures to children from contact with treated wood were estimated using surrogate data.

Data from the proprietary study, "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)"* (Bestari et al., 1999, MRID 455243-04, SIG Task Force #73154) was used as surrogate data to estimate screening-level exposures for the following pathways: outdoor residential dermal contact with Copper 8-quinolinolate treated wood products used in above-ground applications (e.g., residential play-sets, posts, decks, shingles, fencing, outdoor lumber, etc.); and outdoor residential incidental ingestion due to hand-to-mouth contact with pressure-treated wood products. The DDAC study measured dermal and inhalation exposures for various worker functions/positions for individuals handling DDAC-containing wood preservatives for non-pressure treatment application methods and for individuals that could then come into contact with the preserved wood. For the residential exposure assessment the Agency used the highest hand residue value obtained from the DDAC study (3.0 $\mu g/cm^2$). The Agency also used chemical-specific data from a leaching study on Copper 8-quinolinolate spray-treated hemlock-fir lumber (MRID 436370-01) as a comparison to the high-end surrogate residue value.

Table 8 presents the residential post-application scenarios evaluated by the Agency. These scenarios are considered to be representative of all possible post-application residential exposure scenarios.

Table #8. Representative Uses Associated with Residential Post-Application Exposure

Representative Use	Exposure Scenario	Application Method	EPA. Reg. No.	Maximum Application Rate
Contact with treated Textiles (i.e., outdoor-use treated tents/tarps, canvas exposed to the elements and prone to decay) Note: Textiles are not Clothing Apparel, Bedding or Home-goods	ST Post-application: Adult dermal; Child Incidental oral ingestion and Dermal	NA	Commercially-treated articles preserved with 2829-42; 2829-49; and 2829-112	0.7-1.0% ai used to treat canvas fabric

Environmental Outdoor Hard Surface Treatments (i.e., mold and mildew control treatments to exterior environmental surfaces)	ST Post-application: Child incidental oral ingestion and Dermal	NA	Commercial application done via Brush/Spray at residential sites with 1022-489; 1022-490; and 75675-1	0.1% ai treatment solution used on painted/varnished surfaces, concrete, brick, glass, tile, metals, plastic, wood, (paper)*, (leather)*, textiles and asphalt shingles. * - Treatments to these materials may indicate potential indoor uses. Clarification of labeling is needed.
Contact with treated Wood products (i.e., outdoor playsets, decks, wood structures)	ST Post-application: Child incidental oral ingestion and Dermal	NA	Commercially-treated wood preserved with 2829-135 and 2829-136, used for above-ground applications (via pressure and non-pressure methods)	1.0% ai used to treat wood via pressure methods resulting in an active ingredient retention of 0.02 lb/ft^3.

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted a residential post-application assessment for dermal and incidental oral exposure scenarios. An MOE greater than or equal to 100 is considered adequately protective for dermal and incidental oral exposures.

For the residential post-application risk assessment, MOEs are above the respective target MOEs (100 for ST dermal exposures, 100 for ST incidental oral) for all scenarios except for the following. The following residential post-application exposure scenarios are of potential concern:

- ST dermal exposure of children to treated textiles: $MOE_{100\% \text{ transfer}} = 3$ ($MOE_{5\% \text{ transfer}} = 50$)
- ST dermal exposure of adults to treated textiles: $MOE_{100\% \text{ transfer}} = 4$ ($MOE_{5\% \text{ transfer}} = 67$)

However, the Agency believes that the use of Copper-8-quinolinoate for the preservation of textiles is limited to military applications and that treated textiles will not be available to residents. Therefore, no residential exposure to treated textiles is expected. Further, the Agency believes that the conservative exposure estimates used in the dermal risk assessment are not pertinent to members of the military that may utilize treated tents and that exposures will be minimal and risks will not be of concern. To confirm the Agency's assumption that 5% or less

of Copper-8-quinolinoate will leach from the treated tent and be available for dermal exposure, a leaching study will be required. Labels will also need to specify that treated textiles are for use in military applications only.

There are no risks of concern for residential post-application dermal or incidental oral exposures to Copper 8-quinolinolate treated wood products. The dermal and incidental oral MOEs are above the target MOEs of 100 and, therefore, are not of concern.

Table 9 presents a summary of the residential post-application exposures and risk estimates for outdoor hard surfaces, textiles, and wood treated with Copper 8-quinolinolate.

Table #9. Residential Post-application Risks for Adults & Children

Exposure Scenario (short term)	Dermal MOE (Target 100)	Incidental Ingestion MOE (Target 100)
Child Contacting Treated Outdoor Hard Surfaces in Residential Setting	4,484	36,765
Child Contacting Treated Textiles	3 @ 100% transfer 50 @ 5% transfer	735 (mouthing canvas tent/tarp)
Adult Contacting Treated Textiles	4 @ 100% transfer 67@ 5% transfer	NA
Child Contacting Treated Wood	1,156 @ 3 ug/cm2 129 @ 27 ug/cm2	7,143 @ 3 ug/cm2 794 @ 27 ug/cm2

NA= Not applicable

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 a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure typically includes exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

Dietary and non-dietary aggregate assessments were conducted for Copper 8-quinolinolate. When selecting the exposure scenarios for the aggregate assessment, the use patterns of Copper 8-quinolinolate and the probability of co-occurrence were considered. The following use scenarios were selected for the dietary and non-dietary aggregate exposure assessments:

Aggregate Exposure Assessment-Dietary Scenarios for Adults

- Dietary exposure from treated pulp/paper
- Dietary exposure from adhesives containing Copper 8-quionolinolate

Aggregate Exposure Assessment- Dietary Scenarios for Children

- Dietary exposure from treated pulp/paper
- Dietary exposure to adhesives containing Copper 8-quinolinolate

Aggregate Exposure Assessment- Non-Dietary Scenarios for Children

- Incidental oral exposure to outdoor surfaces treated with Copper 8-quinolinolate
- Incidental oral exposure to treated tents/tarps
- Incidental oral exposure to treated wood products (maximum residue)
- Dermal exposure to outdoor hard surfaces treated with Copper 8-quinolinolate
- Dermal exposure to treated wood products (maximum residue)

Acute and Chronic Dietary Aggregate Risk

An aggregate dietary exposure and risk assessment was performed for the use of Copper 8-quinolinolate as a materials preservative in pulp/paper and in adhesives. The results indicate that 5% of the chronic Population Adjusted Dose (cPAD) is occupied from all dietary exposure sources for adults. For children, 11% of the cPAD is occupied from all dietary sources. These percentages are below 100% of the cPAD and, therefore, are not of concern.

Table #10. Aggregate Dietary Exposures & Risks (direct, indirect, and inert uses)

Population	Indirect Dietary Exposure (mg/kg/day)	cumulative % cPAD
Dose (mg/kg/day)		
Adult Population	0.00197 (paper) + 0.0003 (adhesive) = 0.0023	0.0023 mg/kg/day ⁄ 0.05 mg/kg/day x 100 = 4.6%
Children	0.0046 (paper) + 0.0007 (adhesive) = 0.0053	0.0053 mg/kg/day ⁄ 0.05 mg/kg/day x 100 = 10.6%

Short- and Intermediate-term Aggregate Risk

A short-term (ST) aggregate assessment for adults was not performed for Copper-8-quinolinolate due to the varying toxicity endpoints for the oral, dermal and inhalation studies. The episodic nature of likely exposures and the low probability of co-occurrence also supported the decision to not perform a ST aggregate assessment for adults. There are no intermediate-term scenarios for adults and therefore, adult exposures were not aggregated.

For toddlers, aggregation of incidental oral, dermal, and inhalation exposures was not performed across routes of exposure because toxicity endpoints of concern were derived from separate toxicity studies. However, it was possible to aggregate route specific exposures (e.g., incidental oral aggregate assessment and dermal aggregate assessment). An aggregate assessment was conducted for incidental oral exposures of children mouthing treated textiles with hand-to-mouth activities. The total MOE for incidental oral exposure (MOE = 373) is above the target MOE of 100 and therefore, not of concern.

Results of the short-term aggregate assessment for toddlers/children to incidental oral post applicator exposures are presented in Table 11.

Table #11. Short-term Aggregate Risk Assessment from Incidental Oral Exposures in Children

Exposure Routes	Exposure (mg/kg/day)	Margin of Exposure	Total MOE
Incidental oral aggregate			
-treat outdoor surfaces	0.00544	36,765	
-mouthing textile (tent/tarp)	0.272	735	
-surrogate hand residue (wood surfaces)	0.252	794	373

a: Aggregate MOE = 1/((1/MOE incid,oral) + (1/MOEincid,oral) + (1/MOE incid,oral)) where MOE = NOAEL (mg/kg/day) / absorbed daily dose (mg/kg/day) [Incidental oral NOAEL (maternal): 200 mg/kg/day].

An aggregate assessment was also conducted for dermal exposures to treated outdoor hard surfaces and lumber. The total MOE for dermal exposure (MOE = 125) is above the target MOE of 100 and therefore, is not of concern. Table 12 presents the results of short-term dermal aggregate exposure and risk for children from dermal contact with outdoor treated hard surfaces, and treated wood. The Margin of Exposure from children's dermal exposure from contact with treated textiles is alone of concern (MOE = 50 assuming 5% residue transfer), and thus was not included in the aggregate assessment.

Table #12. Short-term Aggregate Risks from Dermal Exposures in Children

Exposure Routes	Children	
	Exposure (mg/kg/day)	Margin of Exposure
Treated Outdoor hard surface	0.0446	4,484
Wood Products	1.55	129
TOTAL MOE		125

a: Aggregate MOE = 1/ ((1/MOEtreated hard) + (1/MOE wood products)) where MOE = NOAEL (mg/kg/day) / absorbed daily dose (mg/kg/day) [Dermal NOAEL (systemic): 200 mg/kg/day].

8. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Copper 8-quinolinolate is used as a material and wood preservative. Potential occupational handler exposure can occur in various use sites, which include food handling premises, commercial/industrial premises and applications in residential sites.

The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (metalworking fluid, paint, textiles, etc.) through either liquid pour or liquid pump methods. For the preservation of wood at treatment plants and lumber mills, the methods for treatment can vary (pressure/non-pressure), such that multiple worker functions were analyzed.

The representative uses assessed include the following various materials preservative and wood preservative applications: mixing and loading of product concentrates for materials

preservative incorporation into textile/paint/paper matrices (liquid pour/liquid pump of soluble concentrates); application of treated paint (paint brush/roller and airless sprayer) and protective wood coatings (low pressure sprayer); and applications to outdoor hard surfaces for mold remediation (brush/roller and low pressure sprayer).

a. Occupational Toxicity

The toxicological endpoints used in the occupational handler assessment of Copper 8-quinolinolate can be found in Table 5, "Residential and Occupational Toxicological Doses and Endpoints for Copper 8-quinolinolate," of this document.

b. Occupational Handler Exposure

Occupational risk for all potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. Occupational risk is assessed for exposure at the time of application (termed "handler" exposure). Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site and by the application rate required to achieve an efficacious dose.

The Agency evaluated representative scenarios using maximum application rates as recommended on Copper 8-quinolinolate product labels. To assess handler risk, the Agency used surrogate unit exposure data from both the proprietary Chemical Manufacturers Association (CMA) Antimicrobial Exposure Study (USEPA 1999: DP Barcode D247642) and the Pesticide Handlers Exposure Database (PHED) (USEPA 1998). For the occupational scenarios in which CMA data were insufficient, other data and methods were applied.

In lieu of chemical-specific data available regarding typical exposures to Copper 8-quinolinolate as a wood preservative, surrogate data were used to estimate exposure and risks. The blender/spray operator position was assessed using CMA unit exposure data and the remaining handler and post-application positions were assessed using data from the proprietary study, *"Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)"* (Bestari et al., 1999, MRID 455243-04). It is assumed that the workers at facilities using Copper 8-quinolinolate wood preservatives and handling the treated wood are performing similar tasks as those monitored in the DDAC study. Dermal and inhalation exposures for treated wood pressure treatment uses were derived from information in the exposure study sponsored by the American Chemistry Council (2002) entitled "*Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products*" (ACC, 2002).

The durations and routes of exposure evaluated for occupational exposure of Copper 8-quinolinolate include: short-term (ST) (1 to 30 days) and intermediate-term (IT- 30 days to 6 months) dermal route exposures; and, ST/IT and long-term (LT) (longer than 6 months) inhalation route exposures for occupational scenarios. A dermal end-point for LT exposure was not selected for Copper 8-quinolinolate.

Residential (non-occupational) handler scenarios were developed as ST dermal and ST inhalation exposures. Residential post-application scenarios included assessing child ST incidental oral and dermal contact with treated wood, treated articles and environmental surfaces.

For more information on the assumptions and calculations of the potential risks of Copper 8-quinolinolate to workers, see the Occupational Exposure Assessment (Section 7.0) in the "Preliminary Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007 and the "Occupational and Residential Exposure Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007. Based on the representative use patterns of Copper 8-quinolinolate, the exposure scenarios in Table 13 were assessed:

Table 13. Representative Exposure Scenarios Associated with Occupational Exposures to Copper 8-quinolinolate

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
Wood Preservatives (Use Site Category X)				
Non-pressure treatment of wood and wood products in wood treatment facilities	Handler Worker Functions • Diptank Operators • Blender/spray operators • Chemical operators Post-Application Worker Functions • Graders • Trim saw operators • Clean-up crews • Construction Workers	ST/IT/LT Handler & Post-application: Dermal and inhalation	3008-91	Diptank operators and Blender/spray operators: 2.3 % ai water-borne treatment solution used (1:15 v/v dilution of 34.18% ai product) Chemical operators and all other worker functions: 34.18% ai water-borne product concentrate handled.
Pressure treatment of wood and wood products in wood treatment facilities	Handler Worker Functions • Treatment assistant • Treatment operator Post-Application Worker Functions Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman	ST/IT/LT Handler & Post-application: Dermal and inhalation	2829-135; 2829-136	1.0 % ai solvent-borne treatment solution used (10% w/w solution of 10% ai product) via vacuum/empty-cell methods

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
General Preservation of wood in commercial sites (non-pressure treatment applications to wood including indirect food contact wood)	Brush/Spray and Dip methods employed for this use pattern	ST/IT Handler: Dermal and Inhalation	2829-135; 2829-136	Dip 1.0 % a.i. solvent-based treatment solution (applied at a rate of 10% w/w of 10 % a.i. product)
			1022-489; 75675-1	Brush 3.3% ai water-based treatment solution (1:3dilution of 10% ai product) for ground-contact wood
Wood Preservative Coatings/ Water Repellents	Paint brush, Roller and Low-pressure coarse sprayer	ST/IT Handler: Dermal and Inhalation	1022-504; 1022-514; 81819-1	0.675%-0.8% ai ready-to-use (RTU) water and oil-based exterior coatings for log homes, wood roofs, siding, fences, rough sawn lumber, new/old wood. 150-300 sq ft/gal. as one coat application.
Material Preservatives (Use Site Category VII)				
Paints/Coatings (in-can preservative incorporation)	Preservation of paint Liquid pour Liquid pump Commercial/ Professional painter Brush/Roller Airless sprayer	ST/IT/LT Handler: Dermal and Inhalation ST/IT Prof Painter: Dermal and Inhalation (aerosol particulate) [6]	2829-136 Treated article preserved with 2829-136 (e.g., exterior house paint)	1.0 % a.i. incorporation by volume of the material to be treated (10 % product by volume treated x 10 % a.i. in product) Note: Adhesives are incorporated at 0.1 % ai [Solvent-based]
Paper and Paperboard	Liquid pump (i.e., incorporation at the size press during manufacture of paper and paperboard sheets)	ST/IT/LT Handler: Dermal and Inhalation	2829-112	0.24% a.i. incorporation by weight of the material to be treated (3.2% product by weight of material treated x 7.5% a.i. in product) [Water-based]
	Brush/Spray and Dip impregnation methods employed for this use pattern		1022-489; 75675-1	0.4% ai water-based treatment solution impregnation (1:25 dilution of 10% ai products)

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
Textiles [Industrial-use and government-specified (e.g., military-issued) cloth/webbing/ropes used for tents/tarps, cotton duck/canvas, paper, paperboard for shoe construction]	Liquid pour Liquid pump (i.e., <u>incorporation</u> at the padder during textile processing) Brush/	<u>ST/IT/LT Handler:</u> Dermal and Inhalation	2829-42; 2829-49; 2829-112	0.7% ai (industrial-use) to 1.0 % ai (government-use) incorporation by weight of the material to be treated (10 % w/w of 10 % a.i. products for 2829-42 and 2829-49) [Solvent- & Water-based]
	Brush/Spray and Dip <u>impregnation</u> methods employed for this use pattern		2829-135; 2829-136; 60061-22	Mildew inhibitor to cotton duck, canvas, cotton webbing and rope <u>Dip:</u> 0.2% ai to 1.0 % ai (government-use); 1.0% ai as RTU (60061-22) [Solvent-based]
Material Preservatives (Use Site Category VII)				
Environmental Outdoor Hard Surface Treatments (i.e., mold and mildew control treatments to exterior environmental surfaces)	Brush/Spray Tank-type garden sprayer (i.e., Low pressure sprayer)	<u>ST/IT Handler</u>: Dermal and Inhalation	1022-489; 1022-490; 75675-1	0.1% ai water-based treatment solution (1:100 dilution of 10% ai product; 1:50 dilution of 5% ai product) used on paint/varnish, concrete, brick, glass, tile, metals, plastic, wood, (paper)*, (leather)*, textiles and asphalt shingles. * - Treatments to these materials may indicate potential indoor uses. Clarification of labeling is needed.

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
Food Handling/Storage Establishments, Premises and Equipment (Use Site Category II)				
Indoor Hard Surfaces Disinfection for Potato Ring Rot (e.g., potato processing planters, seed handling equipment, seed cutters, storage areas, truck/railcar transportation equipment.)	Spray- Low pressure spray non-mist nozzle 20 psi	ST/IT Handler: Dermal and Inhalation	1022-489; 1022-490; and 75675-1	0.05% ai water-based treatment solution (1:200 dilution of 10% ai product; 1:100 dilution of 5% ai product)

Note: Only EPA registered products with specified use directions/use applications are included in this table. Products listed were selected based on maximum use rates by application method.
ST = Short-term exposure, IT = Intermediate-term exposure, LT= Long-term exposure.
[6] Handler dermal and inhalation exposure (to aerosol particulates) were assessed for Copper 8-quinolinolate using PHED unit exposures.

c. Occupational Handler Risk Summary

The occupational handler risk assessment of Copper 8-quinolinolate includes both inhalation and dermal exposure scenarios. The target MOE for short- and intermediate-term dermal exposure is 100. The target MOE for short-, intermediate- and long-term inhalation exposure is 1,000.

Materials Preservation Use- Handler Risk Summary

The calculated dermal exposure MOEs are all above the target MOE of 100 with the use of gloves (personal protective equipment (PPE)). Dermal risks of concern were identified for six use scenarios when PPE (gloves) were not used by applicators (paper/paperboard preservation via liquid pump; paint preservation via liquid pump; textiles preservation via liquid pour; application of treated paint via airless sprayer; general wood preservative application via brush; and application of wood coating via low pressure sprayer). However, these dermal MOEs are greater then 100 for applicators with the addition of PPE (gloves). Therefore, the use of PPE gloves eliminates all risks of concern for these six use scenarios and there are no dermal risks of concern for workers.

For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However if the inhalation MOE is greater then 100 but less then 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation (use of oral toxicity data to set an inhalation endpoint) does not underestimate inhalation exposure risk.

All but one of the inhalation scenarios assessed indicate no risks of concern (MOEs greater then 100). The application of paint via an airless sprayer has an MOE of 83. Although the MOE of 83 is below the Agency target of 100, the Agency believes that this use does not pose as a risk of concern because the risk assessment is based on conservative exposure assumptions and the MOE is very close to the target of 100. Therefore, there are no inhalation risks of concern for this use scenario.

Three of the inhalation use scenarios assessed have MOEs below 1,000 and, therefore, trigger the need for an inhalation toxicity study to refine potential risks. For further information regarding the short-, intermediate and long-term risks associated with occupational handlers, refer to Table 14 below.

- Application of General Wood Preservative: Brush (ST/IT/LT Inhalation **MOE = 758**)
- Paper Preservation: Liquid Pump (ST/IT/LT Inhalation **MOE = 500**)
- Application of Treated Paint by Professionals: Airless Sprayer (ST/IT/LT Inhalation **MOE = 83**)

Table #14. Short-, Intermediate-, and Long-Term Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			Application Rate (% a.i. by weight)	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)[c]			MOE[d]		
		Baseline Dermal[a]	PPE-Gloves Dermal[b]	Inhalation			Baseline Dermal[a]	PPE-Gloves Dermal[b]	Inhalation	Baseline Dermal (Target MOE = 100)[a]	PPE-Gloves Dermal (Target MOE = 100)[b]	Inhalation[e] (Target MOE = 1000)
										ST/IT	ST/IT	ST/IT/LT
Wood Preservatives (Use Site Category X) *												
General Wood Preservative Application by Professionals	Brush	180	24	0.28	0.033	50 lbs	4.24	0.566	0.0066	47	353	758
Application of Wood Coatings by Professionals	Brush/ Roller	180	24	0.28	0.008	50 lbs	1.03	0.137	0.0016	194	1,460	3,125
	Low Pressure Sprayer	100	0.43	0.030	0.008	500 lbs	5.71	0.025	0.0017	35	8,000	2,941

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			Application Rate (% a.i. by weight)	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)[c]			MOE[d]		
		Baseline Dermal[a]	PPE-Gloves Dermal[b]	Inhalation			Baseline Dermal[a]	PPE-Gloves Dermal[b]	Inhalation	Baseline Dermal (Target MOE = 100)[a]	PPE-Gloves Dermal (Target MOE = 100)[b]	Inhalation[e] (Target MOE = 1000)
										ST/IT	ST/IT	ST/IT/LT
Material Preservatives (Use Site Category VII)												
Preservation of Paper and Paperboard	Liquid Pump	0.454	0.00454	0.000265	0.0024	(500 tons) 1,102,311 lbs	17.16	0.172	0.01	12	1,163	500
	Brush	180	24	0.28	0.004	50 lbs	0.514	0.069	0.0008	389	2,898	6,250
Preservation of Paint (in-can preservative)	Liquid Pour	50.3	0.135	0.00346	0.01	2,000 lbs	14.37	0.039	0.001	14	5,128	5,000
	Liquid Pump	0.454	0.00629	0.000403	0.01	10,000 lbs	0.649	0.0089	0.0006	308	22,472	8,333
Preservation of Textiles	Liquid Pour	50.3	0.135	0.00346	0.01	10,000 lbs	71.86	0.193	0.005	3	1,036	1,000
	Liquid Pump	0.454	0.00629	0.000403	0.01	10,000 lbs	0.649	0.0089	0.0006	308	22,472	8,333
Material Preservatives (Use Site Category VII)												
Application of Treated Paint by Professionals	Brush/ Roller	180	24	0.28	0.01	50 lbs	1.29	0.17	0.002	155	1,176	2,500
	Airless Sprayer	38	14	0.83	0.01	500 lbs	2.71	1.0	0.060	74	200	83
Commercial application to outdoor hard surfaces	Low Pressure Sprayer	100	0.43	0.030	0.001	100 lbs	0.143	0.00061	0.000043	1,399	327,869	116,280

Note: Other Occupational scenarios for Wood Preservatives are assessed separately in Section 6.4.
ST= Short-term; IT = intermediate-term, NA= No data available (or not applicable for dermal absorption factor).
Unit Exposure (UE) Data from CMA for most scenarios. PHED data used for Brush/Roller and Airless Sprayer.

a Baseline Dermal: Long-sleeve shirt, long pants, no gloves. It should be noted that the baseline dermal unit exposures for the preservation of paper, paint and textiles were from the cooling tower CMA data set because baseline (ungloved) dermal unit exposures are not available for the CMA data set on preservatives.

b PPE Dermal with gloves: baseline dermal plus chemical-resistant gloves. No gloved replicates available for CMA Low Pressure Spray scenario.

c Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) * absorption factor (NA for dermal; 100% (1.0) for inhalation) * application rate * quantity treated / Body weight (70 kg).

d MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where ST/IT Dermal NOAEL (systemic) = 200 mg/kg/day; ST/IT/LT Inhalation NOAEL = 5 mg/kg/day].

e For PHED data, a protection factor of 90% can be applied to UE values to represent use of organic vapor respirators as PPE. Any PHED Baseline inhalation painting scenarios (Brush/Roller or Airless Sprayer) with MOEs below the target of 1000 were also assessed for use of PPE.

Wood Preservative Use- Handler Risk Summary

Occupational handler exposure to Copper 8-quinolinolate may occur as a result of wood preservation. The calculated dermal exposure MOEs for wood preservation were all above the target of 100 and, therefore, there are no dermal exposure risks of concern for occupational handlers.

For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However if the inhalation MOE is greater then 100 but less then 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation (use of oral toxicity data to set an inhalation endpoint) does not underestimate inhalation exposure risk.

All of the inhalation scenarios assessed were not of concern (MOEs greater then 100). However, one of the inhalation scenarios has an MOE below 1,000 and, therefore, triggers the need for an inhalation toxicity study to confirm that there are no inhalation risks of concern. The following use scenario triggers the need for confirmatory inhalation toxicity data:

- Blender/ Spray Operators Adding Preservative to Wood Slurry: CMA Liquid Pump
  (ST/IT/LT Inhalation **MOE = 212**)

For further information regarding the short-, intermediate and long-term risks and MOEs for wood preservative blender/spray operators, chemical operators, diptank operators, and pressure treatment handlers refer to Tables 15, 16, 17, and 18.

Table #15. Short-term/Intermediate-term & Long-term Exposures and MOEs for Wood Preservative Blender/Spray Operators

Exposure Scenario	Dermal Unit Exposure[a] (mg/lb ai)	Inhalation Unit Exposure[b] (mg/lb ai)	Application Rate[c] (% ai in solution/ day)	Wood Slurry Treated[d] (lb/day)	Absorbed Daily Dose[e] (mg/kg/day)		MOEs[f]	
					Dermal	Inhalation	Dermal ST/IT Target=100	Inhalation ST/IT/LT Target = 1000
Occupational Handler								
CMA Liquid Pump	0.00629	0.000403	2.3	178,000	0.37	0.0236	540	**212**

ST = Short-term duration; IT =Intermediate-term duration; and LT = long-term.
a. Dermal unit exposure: Single layer clothing with chemical resistant gloves.
b. Inhalation unit exposure: Baseline, with no respirator.
c. The maximum application rate for both diptank and sapstain spray application methods is 2.3% ai solution based on product labeling (3008-91).
d. Wood slurry treated = (8 batches/day * 7,000 gallons/batch * 0.003785 m^3/gallon * 380 kg/m^3 * 2.2 lb/kg)
e. Absorbed Daily Dose = unit exposure (mg/lb ai) x App Rate (% ai/day as 2.3%; the ai weight fraction is 0.023) x Quantity treated (lb/day) x absorption factor (NA for dermal and 100% for inhalation) / BW (70 kg)
f. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/ /IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

Table #16. Short-term/Intermediate-term & Long-term exposures and MOEs for Wood Preservative Chemical Operators

Exposure Scenario[a] (number of volunteers)	Dermal UE[b] (mg/day)	Inhalation UE[b] (mg/day)	Conversion Ratio[c]	Absorbed Daily Doses[d] (mg/kg/day)		MOEs[e]	
				Dermal	Inhalation	Dermal ST/IT Target = 100	Inhalation ST/IT/LT Target = 1000
Occupational Handler							
Chemical Operator (n=11)	9.81	0.0281	0.0427	0.060	0.00017	3,333	29,412

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term

a. The exposure scenario represents a worker wearing either long-sleeved or short-sleeved shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves. Volunteers were grouped according to tasks they conducted at the mill.

b. Dermal and inhalation unit exposures are from Bestari et al (1999). Refer to Table B-1 in Appendix B for the calculation of the dermal and inhalation exposures. Inhalation exposure (mg/day) was calculated using the following equation: air concentration ($\mu g/m^3$) x inhalation rate (1.0 m^3/hr) x sample duration (8 hr/day) x unit conversion (1 mg/1000 μg). The inhalation rate is from USEPA, 1997a.

c. Conversion Ratio = 34.18% Oxine-Copper / 80% DDAC

d. Absorbed Daily dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.427) * absorption factor (NA for dermal and 100% for inhalation)/body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

Table #17. Short-term/Intermediate-term & Long-term Exposures and MOEs for Dip-tank Operator

Exposure Scenario[a] (number of replicates)	Dermal Unit Exposure[b] (mg DDAC/1% solution)	Inhalation Unit Exposure[b] (mg DDAC/1% solution)	App Rate (% a.i. in solution/ day)[c]	Absorbed Daily Doses[d] (mg/kg/day)		MOEs[e]	
				Dermal	Inhalation	Dermal ST/IT Target MOE = 100	Inhalation ST/IT/LT Target MOE = 1000
Occupational Handler							
Dipping, with gloves (n=7)	2.99	0.046	2.3	0.0982	0.00151	2,037	3,311

ST = Short-term duration; IT =Intermediate-term duration; and LT = long-term.

a. The exposure scenario represents a worker wearing long-sleeved shirts, cotton work trousers, and gloves. Gloves were worn only when near chemical, not when operating the diptank.

b. Dermal and inhalation unit exposures are from DDAC study (MRID 455243-04). Refer to Table B-2 in Appendix B for the dermal and inhalation unit exposure calculations. Inhalation exposure (mg) was calculated using the following equation: Air concentration (mg/m^3) x Inhalation rate (1.0 m^3/hr) x Sample Duration (8 hr). The inhalation rate is from USEPA, 1997a.

c. The maximum application rate for sapstain control dip application method is 2.3% ai solution (3008-91).

d. Absorbed Daily dose (mg/kg/day) = unit exposure (mg/1% ai solution) * percent active ingredient in solution (2.3) * absorption factor (NA for dermal and 100% for inhalation) / body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

Table #18. Short-term/Intermediate-term & Long-term Exposures and MOEs for Pressure Treatment Handlers

Exposure Scenario[a]	Unit Exposure[a] (µg As/ppm)		Application Rate (% ai solution)	Absorbed Daily Doses[b] (mg/kg/day)		MOEs[c]	
	Dermal	Inhalation		Dermal	Inhalation	Dermal ST/IT Target = 100	Inhalation ST/IT/LT Target=1000
Occupational Handler							
Treatment Operator (TO)	2.04	0.00257	1	0.291	0.000367	687	13,624
Treatment Assistant (TA)	0.24	0.000802	1	0.0343	0.000115	5,831	43,478

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term.

a. Unit exposure values are taken from CCA study as shown above and in Table 6.6.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) * [% Oxine-Copper in solution (1) * 10,000 (parts per million conversion)] * (0.001 mg/µg) * absorption factor (NA for dermal; 100% for inhalation) / Body weight (70 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

d. Occupational Post-application Risk Summary

Occupational handlers may have post-application exposure to Copper 8-quionlinolate by handling treated wood. Copper 8-quinolinolate is used industrially as a stand-alone preservative to control sapstain and protect against mold/mildew in softwood or hardwood lumber. It can also protect against insect damage for wood used in mainly above-ground use applications. Where ground-contact protection is needed, usually higher concentrations of preservative treatment solutions are used and applied via non-pressure methods. Occupational post-application risks are assumed to be negligible for all Copper 8-quinolinolate use patterns with the exception of the wood preservative scenarios.

Registered uses for Copper 8-quinolinolate include several wood preservative treatments as wood surface coatings (e.g., water repellents applied via brush, roller or spray) and impregnation into wood via non-pressure (e.g., non-pressure dipping/immersion) and pressure techniques (vacuum/empty-cell). The products can be used on many different types of wood including green or fresh cut/debarked lumber, poles, posts, and timbers; manufactured wood products such as logs (including for log home construction), plywood, and particle board (wood composites); dry lumber; and finished wood products such as millwork, shingles, shakes, siding, plywood and structural lumber. The majority of the products are intended for use at wood treatment facilities.

Chemical Operators/Graders/Millwrights/Trim Saw Operators/ Clean-up Crews

Post-application exposures to chemical operators, graders, millwrights, trim saw operators, and clean-up crews were assessed using surrogate data from the DDAC study (Bestari et al., 1999). This study examined individuals' exposure to DDAC while working with anti-sapstain chemicals and performing routine tasks at 11 sawmills/planar mills in Canada. Dermal and inhalation exposure monitoring data were gathered for each job function of interest using dosimeters and personal sampling tubes. These sample media were then analyzed for DDAC, and the results were reported in terms of mg DDAC exposure per person per day. The study reported average daily exposures for workers in various categories. Exposure data for individuals performing the same job functions were averaged together to determine job specific averages. Total exposures from 2 trim saw workers, 13 grader workers, 11 chemical operators, 3 millwrights, and 6 clean-up staff were used.

To determine Copper 8-quinolinolate exposures, the average DDAC exposures measured on individuals (in terms of total mg DDAC) were multiplied by a modification factor of 0.427 to account for the difference in percent active ingredient between Copper 8-quinolinolate and DDAC (34.18 % Copper 8-quinolinolate in the wood preservative product versus 80% DDAC in the comparative wood preservative product). The pounds (lb) of active ingredient handled by each person or the percent (%) active ingredient in the treatment solution was not provided for these worker functions.

Table 19 provides the short-, intermediate-, and long-term doses and MOEs for chemical operators, graders, millwrights, clean-up crews, and trim saw operators. For all worker functions, the dermal MOEs are above the target MOE of 100 for ST/IT durations assessed and, therefore, of no concern. For all worker functions, the inhalation MOEs are above the target MOE of 1,000 for ST/IT/LT durations and, therefore, are not of concern.

Table #19. Short-term/Intermediate-term & Long-term Exposures and MOEs for Wood Preservative Grader, Trim Saw, Millwright and Clean-Up

Exposure Scenario[a] (number of volunteers)	Dermal UE[b] (mg/day)	Inhalation UE[b] (mg/day)	Conversion Ratio[c]	Absorbed Daily Doses[d] (mg/kg/day)		MOEs[e]	
				Dermal	Inhalation	Dermal ST/IT Target = 100	Inhalation ST/IT/LT Target = 1000
Occupational Post-application							
Grader (n=13)	3.13	0.0295	0.0427	0.019	0.00018	10,526	27,778
Trim Saw (n=2)	1.38	0.061	0.0427	0.0084	0.00037	23,809	13,513
Millwright (n=3)	12.81	0.057	0.0427	0.078	0.00035	2,564	14,286
Clean-Up (n=6)	55.3	0.60	0.0427	0.337	0.0037	593	1,351

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term

a. The exposure scenario represents a worker wearing either long-sleeved or short-sleeved shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves. Volunteers were grouped according to tasks they conducted at the mill.

b. Dermal and inhalation unit exposures are from Bestari et al (1999). Refer to Table B-1 in Appendix B for the calculation of the dermal and inhalation exposures. Inhalation exposure (mg/day) was calculated using the following equation: air concentration (μg/m^3) x inhalation rate (1.0 m^3/hr) x sample duration (8 hr/day) x unit conversion (1 mg/1000 μg). The inhalation rate is from USEPA, 1997a.

c. Conversion Ratio = 34.18% Oxine-Copper / 80% DDAC

d. Absorbed Daily dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.427) * absorption factor (NA for dermal and 100% for inhalation)/body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

Construction Workers

Not enough data exists to estimate the amount of exposure associated with construction workers who install treated wood. In particular, values for the transfer coefficient associated with a construction worker handling the wood could not be determined. It is believed that the construction worker using a trim saw will have larger dermal and inhalation exposures than the installer, due to the amount of sawdust generated and the greater amount of hand contact that would be necessary to handle the wood when using a saw compared to installing the wood. Because the dermal and inhalation MOEs are well above the target of 100 for trim saw operators and handler exposure is expected to be greater for trim saw operation, risks of concern are not anticipated for construction workers installing treated wood.

Pressure Treatment Scenarios

Copper 8-quinolinolate wood preservatives may be used to treat wood and wood products using pressurized application methods, specifically empty-cell vacuum pressure techniques. Copper 8-quinolinolate is listed in the American Wood-Preservers' Association (AWPA) Book of Standards for treatment of several softwood species used in exposed, above-ground applications.

Chemical-specific exposure data are not available to asses the potential pressure treatment exposure of Copper 8-quinolinolate. Therefore, the assessment was based on surrogate chromated copper arsenate (CCA) data (ACC, 2002). Dermal and inhalation exposures for pressure treatment uses are derived from information in the exposure study sponsored by the American Chemistry Council (2002) entitled "*Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products*" (ACC, 2002). In this study, a treatment solution of CCA was approximately 0.5 percent active ingredient. The CCA exposure monitoring study is considered a valid surrogate source of data for pressure treatment applications and was therefore used in estimating exposure to Copper 8-quinolinolate.

The estimated dermal and inhalation post-application exposures and risks for Copper 8-quinolinolate pressure treatment uses are presented in Table 20. The calculated short- and intermediate-term (ST/IT) dermal MOEs are all above the target MOE of 100 and do not pose risks of concern. Also, the inhalation ST/IT/LT MOEs for all scenarios and durations are above the target MOE of 1,000 and, therefore, there are no post-application inhalation risks of concern.

Table #20. Short-term/Intermediate-term & Long-term Exposures and MOEs for Post-application Pressure Treatment Scenarios

Exposure Scenario[a]	Unit Exposure[a] (µg As/ppm)		Application Rate (% ai solution)	Absorbed Daily Doses[b] (mg/kg/day)		MOEs[c]	
	Dermal	Inhalation		Dermal	Inhalation	Dermal ST/IT Target = 100	Inhalation ST/IT/LT Target=1000
Occupational Post-application							
All Job Functions (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman)	0.74	0.00160	1	0.106	0.000229	1,887	21,834

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term.

a. Unit exposure values are taken from CCA study as shown above and in Table 6.6.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) * [% Oxine-Copper in solution (1) * 10,000 (parts per million conversion)] * (0.001 mg/µg) * absorption factor (NA for dermal; 100% for inhalation) / Body weight (70 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST/IT (systemic) NOAEL = 200 mg/kg/day for dermal and ST/IT/LT NOAEL = 5 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

9. Human Incident Data

The Agency reviewed the following information for human poisoning incidents related to Copper-8-quinolinolate use: (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 illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Information Center (NPIC)- NPIC 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) (1993-1996).

Eight definite or probable relationship cases submitted to the California Pesticide Illness Surveillance Program (1982-2004) were reviewed. The symptoms indicated in the cases were dermal, eye or inhalation irritation reactions. Dermal and eye exposure are the primary routes of exposure associated with these incidents. For eye contact, red, itchy eyes, blurred vision, photophobia, chemical conjunctivitis, and cornea abrasions have been reported. For dermal contact, red, rash, and contact dermatitis have been reported. For inhalation exposure, sore and burning throat and inhalation infection symptoms have been reported. There were no incidents

requiring hospitalization and no severe incidents associated with Copper 8-quinolinolate exposure have been reported.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. Copper 8-quinolinolate is used industrially as a stand-alone preservative to control sapstain and protect against mold/mildew in softwood or hardwood lumber. It can also protect against insect damage for wood used in mainly above-ground use applications. Where ground-contact protection is needed, usually higher concentrations of preservative treatment solutions are used and applied via non-pressure methods. The wood treatment uses of Copper 8-quinolinolate have potential for environmental exposure. Therefore, an ecological risk assessment was conducted for the wood treatment use scenarios. All other Copper 8-quinolinolate uses are considered to be indoor uses and to have minimal to no environmental exposure potential following use. Therefore, the material preservative uses were not assessed for ecological risk. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for Copper 8-quinolinolate use sites and any associated uncertainties.

For a detailed discussion of all aspects of the environmental risk assessment, refer to the Environmental Risk Assessment (Section 8.0) in the "Preliminary Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007; the "Ecological Hazard and Environmental Risk Assessment Chapter for the Copper 8-Quinolinolate Reregistration Eligibility Decision (RED) Document (Case No.: 4026)," dated June 27, 2007; and the "Environmental Fate Transport Assessment for Copper-8-Quinolinolate," dated June 28, 2007.

1. Environmental Fate and Transport

Copper 8-quinolinolate is hydrolytically stable at pH 5, 7 and 9. More than 80% of it is stable in aerobic and anaerobic soils. In aerobic soils its half-life is 16 weeks, but it may be over one year in anaerobic soils. It does not show any tendency to migrate from top soil. It is therefore likely to contaminate surface water through surface water run-off. Its degradation pathway appears to be aqueous photolysis with a half-life of 60 to 96 hours.

a. Bioaccumulation in Aquatic Organisms

The estimated log K_{ow} for Copper 8-quinolinolate is 2.5, which indicates that it is not likely to bioaccumulate in aquatic organisms such as fish. Therefore, bioaccumulation of Copper 8-quionlinolate in aquatic organisms is of no concern to the Agency.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. A summary of the submitted data is provided below.

a. Environmental Toxicity

Toxicity to Birds

Available data indicate that Copper 8-quinolinolate is slightly toxic to relatively non-toxic to birds on an acute oral bases and sub-acute dietary basis.

Toxicity to Terrestrial Animals

Based on the results of mammalian studies conducted to meet human toxicity data requirements, Copper 8-quinolinolate exhibits low acute oral toxicity (Toxicity Category IV); moderate dermal toxicity (Toxicity Category III); and high inhalation toxicity (Toxicity Category II). Copper 8-quinolinolate is classified as an eye corrosive (Toxicity Category I). For dermal irritation, Copper 8-quinolinolate is a low irritant (Toxicity Category IV) and it is not classified as a dermal sensitizer.

Toxicity to Aquatic Animals

On an acute basis, copper 8-quinolinolate is very highly toxic to freshwater fish; highly toxic to freshwater invertebrates; and very highly toxic to estuarine/marine invertebrates.

There are no acceptable acute toxicity data for estuarine/marine fish (OPPTS 850.1075) or estuarine marine shrimp (OPPTS 850.1035). There are also no chronic toxicity studies available for aquatic organisms. Therefore, potential risks to these species could not be assessed. Acute estuarine/marine fish data (850.1075), acute estuarine/marine shrimp data (850.1035), and acceptable chronic toxicity data are needed to fulfill data gaps. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Also, this data may remove uncertainties and may result in more accurate exposure estimations.

Toxicity to Plants

The use of Copper 8-quinolinolate as a wood treatment may result in chemical leachate from treated wood into the aquatic environment. As a result, non-target plant phytotoxicity testing is required. To evaluate the toxicity to aquatic plants, the Agency reviewed two marine diatom studies and a saltwater green algae study. However, additional data are needed to fully evaluate the toxicity of Copper 8-quinolinolate to aquatic plants, specifically: freshwater diatom (*Navicula pelliculosa*), blue-green cyanobacteria (*Anabeana flos-aquae*), and freshwater green alga (*Selenastrum capricornutum*). Other outstanding non-target aquatic plant toxicity tests are:

floating freshwater aquatic macrophyte duckweed (*Lemna gibba*) (OPPTS 850.4400), rooted freshwater macrophyte rice (*Oryza sativa*) (OPPTS 850.4225), and two tests on seedling emergence and vegetative vigor (OPPTS 850.4250). This data may remove uncertainties and may result in more accurate exposure estimations.

A summary of the submitted acute ecological toxicity data; avian sub-acute oral toxicity data; and aquatic plant toxicity data for Copper 8-quinolinolate are provided in Tables 21, 22, and 23, respectively.

Table #21. Acute Ecological Toxicity

Species	Chemical	% active ingredient (ai)	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID)
Birds (Acute Oral Toxicity)						
Bobwhite quail (*Colinus virginianus*)	Copper 8	99.5%	LD_{50} = 618	Slightly toxic	Yes (core) - 14-day test duration - 4-5 months of age	429271-01
Mallard duck (*Anas platyrhynchos)*	Copper 8	99.5%	LD_{50} = >2000 NOAEL = 2000	Relatively nontoxic	Yes (core) - 14-day test duration - 15 months of age	429271-02
Freshwater Fish (Acute Toxicity)						
Rainbow trout *Oncorhynchus-mykiss*)	Copper 8	100%	LC_{50} = 0.0089 NOEC = 0.0062	Very highly toxic	Yes (core) - 96-hr test duration - flow-through test system	428990-02
	Copper 8	80%	LC_{50} = 0.0097 NOAEC = 0.0071	Very highly toxic	Yes (core) - 96-hr test duration - static renewal test system	435637-01
Bluegill sunfish (*Lepomis macrochirus*)	Copper 8	100%	LC_{50} = 0.0216 NOAEC = 0.0108	Very highly toxic	Yes (core) - 96-hr test duration - flow-through test	428990-03

Species	Chemical	% active ingredient (ai)	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID)
					system	
Coho Salmon (*Oncorhynchus kisutch*)	Copper 8	100%	LC_{50} = 0.0139 NOAEC = 0.0066	Very highly toxic	Yes (core) - 96-hr test duration - flow-through test system	429024-01
Freshwater Invertebrates (Acute Toxicity)						
Waterflea *(Daphnia magna)*	Copper 8	98%	EC_{50} = 0.162 NOAEC = < 0.036	Highly toxic	Yes (core) - 48-hr test duration - flow-through test system	432284-01
Estuarine/Marine Organisms (Acute Toxicity)						
Eastern oyster (*Crassostrea virginica*)	Copper 8	100%	LC_{50} = 0.0363 EC_{50} = 0.0111 NOAEC = 0.003	Very highly toxic	Yes (core) - 48-hr test duration - static test system	428990-04

Table #22. Sub-acute Oral Toxicity to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (ppm)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Birds (Sub-acute Oral Toxicity)					
Bobwhite quail (*Colinus virginianus)*	Copper 8 99.5%	LC_{50} (diet) = 3248 NOAEC = 1300	Slightly toxic	Yes (core) - 8-day test duration - 14 days of age	429271-03
Mallard duck (*Anas platyrhynchos)*	Copper 8 99.5%	LC_{50} (diet) = >5200 NOAEC = 2600	Relatively nontoxic	Yes (core) - 8-day test duration - 10 days of age	429271-04

Table #23. Toxicity to Aquatic Plants

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Aquatic Plants				
Marine diatom (*Nitzschia punctata*)	Copper 8 100%	EC_{50} = 0.0073	No (supplemental) - 5-day test duration - static test system - NOEC not determined	429024-04
Marine diatom (*Skeletonema costatum*)	Copper 8 98%	EC_{50} = 0.0019 NOEC = < 0.0007	Yes (core) - 5-day test duration - static test system	430735-01
Saltwater Green alga (*Dunaliella tertiolecta)*	Copper 8 100%	EC_{50} = 0.0154 NOEC = 0.009	Yes (core) - 5-day test duration - static test system	429024-05

b. Ecological Exposure and Risk

For the ecological exposure and risk assessment, the Agency has evaluated Copper 8-quinolinolate wood preservative use scenarios. Wood preservative uses are considered to be "outdoor uses," which are considered during reregistration. As discussed earlier, all other Copper 8-quinolinolate uses are considered to be indoor uses and to have minimal to no environmental exposure potential following use.

The EPA performed an environmental risk assessment using estimated environmental concentrations (EECs) for Copper 8-quinolinolate, which were developed by modeling the release of Copper 8-quinolinolate from a dock into water. Toxicity values were also used to develop risk quotients (RQs) for comparison to levels of concern (LOCs). The modeling used in the ecological assessment is a conservative representation of all Copper 8-quinolinolate wood preservative use scenarios, including antisapstain use.

The EPA calculated the leaching of Copper 8-quinolinolate from a dock into water. It was assumed that 4% of the total applied Copper 8-quinolinolate would leach from the wood into the water. The retention rate of the wood was assumed to be 22 $\mu g/cm^2$. The length and width of the dock was assumed to be 30 meters and 10 meters, respectively, and the thickness of the wood was assumed to be 0.1 meters. The number of poles underneath the dock was assumed to be 18 and the dimensions of the poles were assumed to be 2 meters (length) x 0.15 meters (width) x 0.15 meters (height). The poles were assumed to be 0.5 meters inserted into the sediment. Based on these specifications, Copper 8-quinolinolate EECs were calculated for water body sizes ranging from 1 acre foot to 24 acre feet. The highest EEC calculated for the smallest

body of water (1 acre foot) was 0.00226 mg Copper 8-quinolinolate per liter of water. The calculated EEC for a slightly larger body of water (6 acre feet) is 0.00038 mg Copper 8-quinolinolate per liter of water. For details on the calculations conducted to arrive at this EEC as well as the uncertainties and limitations of the calculations, consult the memo "Estimated Environmental Concentrations for Copper 8-Quinolinolate (Cu8Q) from Treated Wood Used to Build Docks," dated October 9, 2007.

Levels of concern (LOCs) were not exceeded for fish, freshwater invertebrates, the eastern oyster or aquatic plants in bodies of water 6 acre feet in size or greater. Risks to endangered freshwater fish and the eastern oyster as well as risks to aquatic plants were of concern in bodies of water 1 acre foot in size or less. However, it is unlikely that a dock of the size used in the calculations for EEC will be present on a body of water less than 6 acre feet in size. Therefore, the risks to aquatic organisms from Copper 8-quinolinolate appear to be low.

Avian & Mammalian Species

Based on available avian toxicity data for Copper 8-quinolinolate, the various wood treatments are not expected to be acutely toxic to avian & mammalian species.

Aquatic Organisms

To develop risk quotients (RQs), the estimated environmental concentrations (EECs) determined by modeling were compared to the most sensitive endpoint for each taxa. Acute LOCs (0.5) were not exceeded for freshwater fish (RQ of 0.254), freshwater aquatic invertebrates (RQ of 0.014), or the eastern oyster in bodies of water 6 acre feet in size or greater. However, risks to endangered freshwater fish and the eastern oyster (RQ is 0.204**)** were of concern in bodies of water 1 acre foot in size or less. Since it is unlikely that a dock of the size used in the calculations for EEC will be present on a body of water less than 6 acre feet in size, the risks to aquatic organisms from Copper 8-quinolinolate appear to be low (RQs of 0.2).

There were no acceptable acute toxicity studies for estuarine/marine fish (OPPTS 850.1075/ (72-3a) or estuarine marine shrimp (OPPTS 850.1035/(72-3c). Therefore, the acute aquatic estuarine/marine species assessment is incomplete due to lack of toxicity data.

The need for chronic freshwater fish and invertebrate studies are triggered based on acute toxicity. However, there are no acceptable chronic toxicity studies available for aquatic organisms. Estuarine/marine chronic toxicity studies for fish and invertebrates are needed to fulfill guideline requirements. Therefore, the chronic aquatic toxicity assessment for estuarine/marine species could not be assessed due to lack of data.

Plants

The LOCs (1) were not exceeded for aquatic plants in bodies of water 6 acre feet in size or greater (RQ of 0.2). However, risks to aquatic plants were of concern in bodies of water 1 acre foot in size or less (RQ of 1.189. It is unlikely that a dock of the size used in the calculations

for EEC will be present on a body of water less than 6 acre feet in size and, therefore, risks to aquatic organisms from Copper 8-quinolinolate appear to be small. Additional plant toxicity data could further refine this risk assessment.

Non-target Insects (Honeybee)

Honeybees could potentially be exposed to pesticide residues if treated wood is used to construct hives or hive components. These residues may be toxic to the bees or result in residues in honey or other hive products intended for human use/consumption. Therefore, a special honeybee study is required for all wood preservative uses unless a statement prohibiting the use of treated wood in hive construction is added to the label such as, "Wood treated with Copper 8-quinolinolate shall not be used in the construction of beehives." This study is a combination of Guidelines 171-4 and 850.3030 (see information regarding residue data requirements for uses in beehives in the residue chemistry section of 40 CFR part 158). Numbers of bees used in this study and methods for collection/introduction of bees into hives, feeding, and observations for toxicity and mortality should be consistent with those described in OPPTS Guideline 850.3030, "Honey Bee Toxicity of Residues on Foliage." The toxicity portion of this study is in lieu of the honeybee contact LD50 test.

Additional information regarding the Copper 8-quinolinolate ecological assessment can be found in the "Preliminary Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026)," dated June 28, 2007; the "Ecological Hazard and Environmental Risk Assessment Chapter for the Copper 8-quinolinolate Reregistration Eligibility Decision (RED) Document (Case No. 4026)," dated June 27, 2007; and the "Estimated Environmental Concentrations for Copper 8-Quinolinolate (Cu8Q) from Treated Wood Used to Build Docks," dated October 9, 2007.

Please refer to Table 24 for a comprehensive list of the identified ecological risk quotients for the antisapstain use of Copper 8-quinolinolate.

Table #24. Ecological Risk Quotients for Antisapstain Use

Taxa/Endpoint	Estimated Environmental Concentrations (ECCs) Low to High Dilution	Risk Quotients (RQs)
Acute Freshwater Fish *Endpoint: 0.0089 mg/L*	0.00226 mg/L (1 acre foot) 0.0038 mg/L (6 acre foot)	0.254 0.043
Acute Freshwater Aquatic Invertebrate *Endpoint: 0.162 mg/L*	0.00226 mg/L (1 acre foot) 0.0038 mg/L (6 acre foot)	0.014 < 0.00
Acute Aquatic Estuarine/Marine Species-Eastern Oyster *Endpoint: 0.0111 mg/L*	0.00226 mg/L (1 acre foot) 0.0038 mg/L (6 acre foot)	0.204 0.034
Acute Aquatic Plant Toxicity *Endpoint: 0.0019 mg/L*	0.00226 mg/L (1 acre foot) 0.0038 mg/L (6 acre foot)	1.189 0.2

c. Risk to Listed Species

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The material preservative uses for Copper 8-quinolinolate fall into this category.

The preliminary analysis for wood treatment uses indicates that there is a potential for Copper 8-quinolinolate use to overlap with listed species. Since the dock model is only intended as a screening-level model, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations, further refinement of the model and risk assessment is necessary before any regulatory action is taken regarding the wood treatment uses of Copper 8-quinolinolate. A more refined assessment is warranted to include direct, indirect and habitat effects. Also, clear delineation of the action area associated with the proposed uses of Copper 8-quinolinolate, and the best available information on the temporal

and spatial co-location of listed species with respect to the action area should be included in a more refined assessment. Due to these circumstances, the Agency defers making an endangered species effect determination for the wood treatment uses of Copper 8-quinolinolate until additional data and modeling refinements are available. At that time, the environmental exposure assessment for the wood treatment uses of Copper 8-quinolinolate will be revised, and the risks to Listed Species will be considered. Registrants are responsible for amending all Copper 8-quinolinolate antisapstain wood preservative product labels to incorporate the required antisapstain use label language. The antisapstain label statement is expected to decrease possible leaching risks associated with antisapstain use products.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing Copper 8-quinolinolate as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing Copper 8-quinolinolate.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient Copper 8-quinolinolate. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient Copper 8-quinolinolate, the Agency has sufficient information on the human health and ecological effects of Copper 8-quinolinolate to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that Copper 8-quinolinolate-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. Label changes are described in Section V. Appendix A summarizes the uses of Copper 8-quinolinolate that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of Copper 8-quinolinolate and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of Copper 8-quinolinolate, the Agency has determined that Copper 8-quinolinolate products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measure identified in this document, the Agency may take regulatory action to address the risk concerns from the use of Copper 8-quinolinolate. If all changes outlined in this document are incorporated into the product labels, then all current risks for Copper 8-quinolinolate will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, the EPA worked with stakeholders and the public to reach the regulatory decision for Copper 8-quinolinolate. The EPA released its preliminary risk assessment for Copper 8-quinolinolate for public comment on July 11, 2007. The Agency received no comments during the 60-day public comment period on the Copper 8-quinolinolate risk assessment and supporting science documents, which closed on September 10, 2007.

C. Regulatory Position

The Agency has determined that if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to Copper 8-quinolinolate are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to Copper 8-quionolinolate from all possible sources.

a. Determination of Safety to U.S. Population

The Agency has determined that Copper 8-quinolinolate, with amendments and changes specified in this document, meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of Copper 8-quinolinolate. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of Copper 8-quinolinolate.

An acute dietary risk assessment was not conducted for Copper 8-quinolinolate because the use patterns are not expected to result in acute dietary exposure and toxicity endpoints were not identified. Therefore, Copper 8-quinolinolate does not pose as an acute dietary risk.

The Agency conducted an aggregate dietary exposure and risk assessment for the pulp and paper uses as well as the adhesive uses of Copper 8-quinolinolate. The results of the total aggregate dietary exposure and risk indicate that for adults 5% of the cPAD is occupied from all dietary exposure sources; and for children 11% of the cPAD is occupied from all dietary sources. These risk estimates are less then 100% of the cPAD and, therefore, are below the Agency's level of concern.

For toddlers, an aggregate assessment of incidental oral, dermal, and inhalation exposures was not performed across routes of exposure because toxicity endpoints of concern were derived from separate toxicity studies. However, the Agency did aggregate route specific exposures for incidental oral scenarios and dermal scenarios for toddlers/children. An aggregate assessment was conducted for incidental oral exposures of children mouthing treated textiles with hand-to-mouth activities. An aggregate assessment of dermal exposures of children to treated outdoor hard surfaces and lumber was also performed. The total aggregate MOEs for incidental oral exposure (MOE = 373) and for dermal exposure (MOE = 125) are above the target MOE of 100 and are not of concern.

Copper 8-quinolinolate is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, a drinking water exposure assessment was not conducted because Copper 8-quinolinolate is not expected to come into contact with or be exposed to drinking water.

b. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of Copper 8-quinolinolate, with changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased susceptibility to the toxic effects of Copper 8-quinolinolate residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from Copper 8-quinolinolate residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for Copper 8-quinolinolate based on: (1) the toxicology database is complete with respect to assessing the increased susceptibility to infants and children as required by FQPA; (2) there is no concern for developmental neurotoxicity resulting from exposure to Copper 8-quinolinolate in the rat and rabbit prenatal developmental studies and the 2-generation reproduction study; (3) there is no evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (4) the risk assessment does not underestimate the potential exposure for infants and children.

c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all 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 FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, Copper 8-quinolinolate may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of Copper 8-quinolinolate. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for Copper 8-quinolinolate. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

D. Regulatory Rationale

The Agency has determined that Copper 8-quinolinolate is eligible for reregistration provided that additional required data confirm this decision, the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the uses of Copper 8-quinolinolate. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

The chronic dietary risks from Copper 8-quinolinolate residues on food or possible indirect food contact, estimated using conservative measures, are below the Agency's level of concern for the treated pulp/paper and adhesive uses. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

Copper 8-quinolinolate is not expected to come into contact with or be exposed to drinking water and, therefore, the Agency did not conduct a drinking water exposure assessment. Copper 8-quinolinolate is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, no mitigation measures are necessary at this time.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler dermal and inhalation risks were assessed for the use of Copper 8-quinolinolate wood preservative coatings and water repellents (applied via brush, roller and low pressure coarse spray); and application of manufactured paint products containing Copper 8-quinolinolate as a preservative (applied via paint brush/ roller and airless sprayer).

When oral toxicity data are used to select an inhalation endpoint, as was done for Copper 8-quinolinolate, it is Agency policy to consider requiring inhalation toxicity data to confirm that the use of route-to-route extrapolation does not underestimate potential risk. A target inhalation MOE of 1,000 was selected for Copper 8-quinolinolate because the inhalation endpoint was based on an oral NOAEL. The high-end inhalation scenario developed for the airless sprayer yielded a short-term (ST) inhalation MOE above 100 (MOE of 278) but below 1,000. Because the inhalation MOE is below 1,000 for the airless sprayer scenario, a confirmatory inhalation toxicity study is needed to further refine the inhalation risk assessment for the residential handler in-can paint preservative airless sprayer use.

ii. Post-Application Risk Mitigation

For the residential post-application assessment, representative scenarios were assed for contact with surface residues from wood treated with Copper 8-quinolinolate (dermal and incidental oral exposure to children); and residues remaining on treated outdoor hard surfaces (dermal and incidental oral exposure to children). Dermal and incidental oral exposures were also assessed for contact with treated tents/textiles. The short-term MOEs for dermal contact with treated tents (materials preservative use) are of concern for both adults and children (ST dermal MOEs of 3 for children and 50 for adults with a 100% transfer factor; ST dermal MOEs of 4 for children and 67 for adults with a 5% transfer factor).

The technical registrants of Copper 8-quinolinolate have indicated that as a textile preservative, Copper 8-quinolinolate is to be used only in military/industrial settings. To address the dermal risks of concern, the registrants must update all end-use labels (that have treated tents/textiles as a use pattern) to state that treated textiles are for non-residential/military use only. By restricting the treated textile use pattern, residents will not be exposed to treated tents/textiles, eliminating all residential post-application dermal risks of concern.

The Agency believes that the use of Copper-8-quinolinoate for the preservation of textiles is limited to military applications and that treated textiles will not be available to residents. Therefore, no residential exposure to treated textiles is expected. Further, the Agency believes that the conservative exposure estimates used in the dermal risk assessment are not pertinent to members of the military that may utilize treated tents and that exposures will be minimal and risks will not be of concern. To confirm the Agency's assumption that 5% or less of Copper-8-quinolinoate will leach from the treated tent and be available for dermal exposure, a leaching

study will be required (GL 875.2300). As previously mentioned, end-use labels will also need to specify that treated textiles are for use in military applications only.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

Occupational handler dermal risks of concern were identified for six use scenarios when personal protection equipment (PPE) (gloves) were not used (paper/paperboard preservation via liquid pump; paint preservation via liquid pour; textiles preservation via liquid pour; application of treated paint via airless sprayer; general wood preservative application via brush; and application of wood coating via low pressure sprayer). To mitigate the dermal risks of concern for occupational handlers, workers must wear chemical resistant gloves while handling Copper 8-quinolinolate products. The use of chemical resistant gloves (PPE) eliminates all risks of concern for these six use scenarios (MOEs well above the target of 100 with the use of PPE), eliminating all dermal risks of concern for workers. All end-use labels, with these uses, must be amended to include language stating that PPE must be used by workers.

Three of the occupational inhalation use scenarios have MOEs below 1,000 (Application of general wood preservative via brush, MOE of 758; Paper preservation via liquid pump, MOE of 500; Application of treated paint via airless sprayer, MOE of 83). Confirmatory inhalation toxicity data are needed to refine the occupational inhalation MOEs for these three exposure scenarios. Because the inhalation endpoint was based on an oral NOAEL, a target inhalation MOE of 1,000 was selected to determine if confirmatory inhalation toxicity data are needed. For inhalation MOEs below the target of 1,000, it is Agency policy to request confirmatory inhalation toxicity data to refine potential risks.

The application of paint via an airless sprayer has an MOE of 83. Although the MOE of 83 is below the Agency target of 100, the Agency believes that this use does not pose as a risk of concern. Because the risk assessment is based on conservative exposure assumptions and the MOE is very close to the target of 100, the Agency believes that there are no inhalation risks of concern. Therefore, mitigation is not needed for this use pattern. However, as mentioned previously, a confirmatory inhalation toxicity study is needed to further refine the inhalation risk assessment for the residential and occupational handler in-can paint preservative airless sprayer use scenarios because the MOEs are below 1,000.

ii. Post-Application Risk Mitigation

Occupational post-application exposures are expected to be negligible and, therefore, there are no occupational post-application risks of concern. Mitigation measures are not necessary at this time.

2. Environmental Risk Management

The EPA performed an environmental risk assessment using estimated environmental concentrations (EECs) for Copper 8-quinolinolate, which were developed by modeling the

release of Copper 8-quinolinolate from a dock into water. Toxicity values were also used to develop risk quotients (RQs) for comparison of levels of concern (LOCs). The modeling used in the ecological assessment is a conservative representation of all Copper 8-quinolinolate wood preservative use scenarios. Levels of concern (LOCs) were not exceeded for fish, freshwater invertebrates, the eastern oyster or aquatic plants in bodies of water 6 acre feet in size or greater. Risks to endangered freshwater fish and the eastern oyster as well as risks to aquatic plants were of concern in bodies of water 1 acre foot in size or less. However, it is unlikely that a dock of the size used in the calculations for EEC will be present on a body of water less than 6 acre feet in size. Therefore, the risks to aquatic organisms from Copper 8-quinolinolate appear to be low.

Several ecological species risk assessments for Copper 8-quinolinolate are incomplete or could not be conducted due to data gaps or outstanding data. There were no acceptable acute toxicity studies for estuarine/marine fish (OPPTS 850.1075) or estuarine/marine shrimp (OPPTS 850.1035). Therefore, the acute aquatic estuarine/marine species assessment is incomplete due to lack of toxicity data. A chronic aquatic toxicity assessment for estuarine/marine species could not be conducted due to chronic toxicity data gaps. The plant toxicity risk assessment is also incomplete due to outstanding plant toxicity data.

It should be noted that there are a number of uncertainties and limitations with the fate and environmental modeling for the preliminary environmental risk assessment. Extrapolating risk conclusions from the pond scenario used in the environmental modeling may either underestimate or overestimate potential exposures and risks. Numerous uncertainties exist with the modeling used since environmental properties are likely to be regionally specific because of local hydrogeological conditions. Further, any alteration in water quality parameters may impact the environmental behavior of the pesticide. Additionally, there are pertinent data (wood leaching) that are lacking. Such data would be useful in refining this preliminary risk assessment.

Information, including wood leaching, would help to refine the ecological risk assessment. Also, such data may remove uncertainties and may result in more accurate exposure estimations. As previously mentioned acute estuarine/marine fish data (850.1075), acute estuarine/marine shrimp data (850.1035), acceptable chronic toxicity data, and plant toxicity data are needed to fulfill data gaps. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Please refer to Section V of this RED document for further details regarding the manufacturing use data requirements.

The following statement must be added to all product labels because the acute toxicity to fish, aquatic invertebrates, and estuarine/marine species are less then 1.0 mg/L:

> This product is toxic to fish, aquatic invertebrates, oysters and shrimp. 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.

Registrants are responsible for amending all Copper 8-quinolinolate antisapstain wood preservative product labels to incorporate the required antisapstain use label language. The following statement must be placed on all antisapstain products to decrease leaching risks:

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

To address exposure to non-target insects, a special honeybee study is required for all wood preservative uses unless a statement prohibiting the use of treated wood in hive construction is added to the label such as, "Wood treated with Copper 8-quinolinolate shall not be used in the construction of beehives." This study is a combination of Guidelines 171-4 and 850.3030 (see information regarding residue data requirements for uses in beehives in the residue chemistry section of 40 CFR part 158). Numbers of bees used in this study and methods for collection/introduction of bees into hives, feeding, and observations for toxicity and mortality should be consistent with those described in OPPTS Guideline 850.3030, "Honey Bee Toxicity of Residues on Foliage." The toxicity portion of this study is in lieu of the honeybee contact LD50 test.

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 Copper 8-quinolinolate. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

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

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

The screening level assessment conducted for the wood treatment uses of Copper 8-quinolinolate indicates that there is a potential for use of this chemical to overlap with listed species and that a more refined assessment is warranted to include indirect, direct, and habitat effects. Further, while materials preservative uses are historically viewed as providing little to no contribution to environmental burdens, the wide spectrum of materials preservative and other uses of Copper 8-quinolinolate are such that the Agency cannot make a no effects determination at this time. The revised labeling that is required in order for products to be considered eligible for reregistration, is expected to provide some level of mitigation until such time as a full endangered species assessment is possible.

b. General Risk Mitigation

Copper 8-quinolinolate end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing Copper 8-quinolinolate specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users

adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that Copper 8-quinolinolate is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. To implement the risk mitigation measure, the registrants must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below (Table 26). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For Copper 8-quinolinolate 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

For end-use products containing the active ingredient Copper 8-quinolinolate, the registrant needs to submit the following items for each product.

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

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

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

Within eight months from the receipt of the PDCI:

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

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

3. Five copies of the draft label incorporating all label amendments outlined in Table 26 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.

Please contact Marshall Swindell at (703) 308-6341 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
Marshall Swindell
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
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of Copper 8-quinolinolate has been reviewed and determined to be substantially complete. 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.

Residential & Occupational Handler Confirmatory Data

Confirmatory inhalation toxicity data are needed to refine the residential handler inhalation MOE of 278 and for the occupational handler inhalation MOE of 83 for the in-can paint preservative airless sprayer use scenarios. Because the inhalation endpoint was based on an oral NOAEL, a target inhalation MOE of 1,000 was selected to determine if confirmatory inhalation toxicity data are needed. For inhalation MOEs above 100 but below 1,000, it is Agency policy to request confirmatory inhalation toxicity data to refine potential risks. A confirmatory inhalation toxicity study is needed to further refine the inhalation risk assessment for the residential and occupational handler in-can paint preservative airless sprayer use scenarios because the MOEs are below 1,000.

Three of the occupational inhalation use scenarios also have MOEs below 1,000 (Application of general wood preservative via brush, MOE of 758; Paper preservation via liquid pump, MOE of 500; Application of treated paint via airless sprayer, MOE of 83). Confirmatory inhalation toxicity data are needed to refine the occupational inhalation MOEs for these three exposure scenarios. Because the inhalation endpoint was based on an oral NOAEL, a target inhalation MOE of 1,000 was selected to determine if confirmatory inhalation toxicity data are needed. For inhalation MOEs below the target of 1,000, it is Agency policy to request confirmatory inhalation toxicity data to refine potential risks.

Also, to confirm the Agency's assumption that 5% or less of Copper-8-quinolinoate will leach from treated tents, and be available for dermal exposure, a leaching study will be required (GL 875.2300).

Surrogate data were taken from the proprietary CMA antimicrobial exposure study (USE EPA 1999: DP Barcode D247642). Most of the CMA data are of poor quality and, therefore, the Agency requests that confirmatory monitoring data be generated to support the values used in the occupational and residential risk assessments and to further refine these assessments. The following confirmatory monitoring data are needed: dermal exposure-indoor & outdoor data (875.1200 & 875.1100, respectively), and inhalation exposure-indoor & outdoor data (875.1400 & 875.1300, respectively). Product use information (875.1700) and description of human activity data (875.2800) are also needed to further define the exposure scenarios being supported and to further refine the assessments.

Environmental Fate and Ecological Exposure Confirmatory Data (Wood Treatment Use)

Several ecological species risk assessments for Copper 8-quinolinolate are incomplete or could not be conducted due to data gaps or outstanding data. Confirmatory environmental fate and ecological exposure data are needed to remove uncertainties and the data may result in more accurate exposure estimations. The data will also allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps.

Table 25 provides an outline of the requested confirmatory data for Copper 8-quinolinolate.

Table #25. Confirmatory Data for Copper 8-quinolinolate

Guideline Study Name	New OPPTS Guideline Number
Human Health Confirmatory Data	
Inhalation Toxicity Data	870.3465
Indoor Surface Residue Dissipation Study	875.2300
Dermal exposure-indoor & outdoor data	875.1200 & 875.1100
Inhalation exposure-indoor & outdoor data	875.1400 & 875.1300
Product Use Information	875.1700 & 875.2700
Description of Human Activity Data	875.2800
Environmental Fate & Ecological Exposure Confirmatory Data	
Estuarine/marine shrimp acute study	850.1035
Estuarine/marine fish acute study	850.1075
Freshwater rooted macrophyte rice seedling emergence	850.4225
Freshwater rooted macrophyte rice vegetative vigor	850.4250
Freshwater floating macrophyte duckweed	850.4400
Freshwater diatom	850.5400
Blue-green cyanobacteria	850.5400
Freshwater green alga	850.5400
Wood leaching study (AWPA E11-06),	AWPA Method E11-06, Standard Method of Determining the Leachability of Wood Preservatives Immersed in Water, AWPA, 2006
Residues in honey/beeswax and toxicity of treated wood residues to bees *(This test can be waived provided that labels are amended as outlined for wood preservative use)*	Combination of Guideline 860.1500 and 850.3030

2. Labeling for Technical and Manufacturing Use Products

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

applicable policies. The Technical and MP labeling should bear the labeling contained in Table 26, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The 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. A product-specific data call-in will be issued at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 26, Label Changes Summary Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measure outlined in Section IV of the Copper 8-quinolinolate RED. The following table describes how language on the labels should be amended.

Table #26. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
All End Use Products		
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish, aquatic invertebrates, oysters and shrimp. 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 Intended for Occupational Use		
PPE Requirements	"Applicators must wear chemical resistant gloves while handling or applying Copper 8-quinolinolate."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
For all antisapstain end-use products	"Antisapstain treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events."	This language is to be included in the Environmental Hazards section of the label
Directions For Use		
End Use Products Intended for Textile Preservation (or end use products that are preserved textiles, such as tents)	"Treated textiles, preserved with Copper 8-quinolinolate, are to be used only in military or industrial settings. Treated textiles are for non-residential/military use only."	

End Use Products Intended for Wooden Tray Preservation (Treated Wooden Trays)	"Treated wooden trays are only to be used to grow mushrooms. The trays are not to be used to store or transport mushrooms, fruits, or vegetables."	

VI. APPENDICES

Appendix A. Table of Use Patterns for Copper 8-quinolinolate

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials preservatives				
Textiles Canvas, burlap, rope, twine, cotton duck, cotton webbing, twill, and cardboard	Soluble concentrate: Reg. 1022-489 Reg. 1022-490 Reg. 1022-493 Reg. 1022-492 Reg. 2829-42 Reg. 2829-44 Reg. 2829-49 Reg. 2829-112 Reg. 2829-135 Reg. 2829-136 Reg. 60061-17 Reg. 75675-1	Dip, spray, or flow coat	Water based solution: Dilute 1:20 to 1:50 in water for .25% to .75% of copper depending upon severity of service. Immerse completely the object to be treated in the solution for 15 to 30 seconds. Allow sufficient time for the treated objects to dry prior to any further processing. For objects that cannot be immersed, liberal applications by flooding, rolling or, brushing. Oil based solution: 1 volume to 5 volumes of petroleum oil (or other organic solvent) dip for 15 seconds to 10 min. depending on the tightness of the weave.	None stated
	Ready to use: Reg. 60061-18 Reg. 60061-22			
Adhesives and glues	Soluble concentrate: Reg. 10829-8	Dispersing in solvent or aqueous systems	It is recommended that levels from 0.015 to 0.1% by weight of copper 8-quinolinolate be used for the protection of adhesives and glues based on the weight of the finished product, to protect the product while in the can.	None stated
Paints	Soluble concentrate: Reg. 10829-8	Dispersing in solvent or aqueous systems	Copper 8-quinolinolate should be used at levels from 0.1% to 1.0% based on the volume of the finished product. The median level of 0.5% to 0.75% is most generally used and has remained free from mold after two years under conditions where ordinary paint becomes contaminated after 60 days of exposure.	None stated
Paper products	Soluble concentrate: Reg. 1022-490 Reg. 1022-489 Reg. 2829-44 Reg. 707-302	Brush, spray or short dip	Dilute 1:20 to 1:50 for .25% to .75% of copper depending upon severity of service.	None stated
	Soluble concentrate:	Applied at the size	Incorporate a minimum of 3.2% of product by weight into the	None stated

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg. 2829-112	press	sheet to deposit 0.45% copper as metal.	
Wood preservatives				
Wood used in above ground service, ground contact service	Soluble concentrate: Reg.1022-489 Reg.1022-490 Reg. 2829-137	Dip spray or flow coat	Above Ground Service: For mild conditions, apply liberally by brush or spray at 1:20 use dilution in water. For severe conditions, dip for a minimum of three minutes. For Ground contact Service: For mild conditions, apply by dipping for 12 – 48 hours at a 1:10 dilution in water. For severe service, use a 1:4 use dilution in water and dip for 12-48 hours	None stated
Wood preservation (shingles, siding, millwork, timber, furniture, poles, posts, decks, playground equipment, window sills and frames, fascia boards, log homes, roofs, old weathered wood, new porous wood)	Soluble concentrate: Reg. 3008-91 Reg.1022-476 Reg. 1022-503 Reg. 1022-492 Reg. 1022-493 Reg. 2829-135 Reg. 2829-136 Reg. 60061-17 Reg. 81819-1 Reg. 75675-1	Dip, spray, or flow coat	Base strength: 1 gallon to 150-250 gallons of water Stronger than base strength: 1 gallon to 30-50 gallons of water	None stated
	Ready to use: Reg. 1022-505 Reg. 1022-504 Reg. 1022-491 Reg: 1022-514 Reg. 60061-18 Reg. 60061-22		The most effective treatment is obtained with pressure treating or extended soaking where deep penetration and high absorption are obtained. With spraying or brushing, multiple flowing coats should be applied	
Wood used in greenhouse premises, equipment and containers (indirect food contact)	Soluble concentrate: Reg. 1022-476 Reg. 1022-490 Reg. 1022-503 Reg. 3008-91	Dip, spray, or flow coat	Base strength: 1 gallon to 150-250 gallons of water Stronger than base strength: 1 gallon to 30-50 gallons of water	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Wood used in greenhouse premises, equipment and containers (indirect food contact) (Wood in contact with fruit, vegetables, and other food stuffs, includes boxes and bins, mushrooms trays, pallets, nursery trays, flats, stakes and fences)				
	Ready to use: Reg. 1022-505 Reg. 1022-504 Reg. 1022-491 Reg: 1022-514		The most effective treatment is obtained with pressure treating or extended soaking where deep penetration and high absorption are obtained. With spraying or brushing, multiple flowing coats should be applied.	
Lumber (2 inch thick or less) sapstain control	Soluble concentrate: Reg.1022-476 Reg. 1022-503 Ready to use: Reg. 3008-91	Dip, spray, or flow coat	Base strength: 1 gallon to 150-250 gallons of water Stronger than base strength: 1 gallon to 30-50 gallons of water	None stated
Food handling/storage establishments, premises and equipment				
Potato processing, storage and transportation facilities	Soluble concentrate: Reg.1022-489 Reg. 1022-490 Reg. 75675-1	Spray Applicator	Pre-clean area and allow to air dry before applying. Dilute 1:100-200 in water with careful agitation to lessen foaming. Spray all surfaces with a non-mist type nozzle set at approx. 20 psi.	Although not phototoxic to cut seed potatoes, DO NOT treat the potato seed surfaces.

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

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Copper 8-quinolinolate. These requirements apply to Copper 8-quinolinolate 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
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

3. **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.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY				
830.1550	61-1	Product Identity and Composition		42922701 43532901 43563001 46346401 46438601 46835201
830.1600 830.1620 830.1650	61-2 A	Starting Materials and Manufacturing Process		43532901 43563001 46346401 46438601 46835201
830.1670	61-2 B	Formation of Impurities		43532901 43563001 46346401 46438601 46835201
830.1700	62-1	Preliminary Analysis		42922701 46438601 46835201
830.1750	62-2	Certification of Limits		46346401 46438601 46835201
830.1800	62-3	Analytical Method		43532901 43563001 46346401 46438601 46835201

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.6302	63-2	Color		42922701 43532901 46346401 46438601
830.6303	63-3	Physical State		42922701 43532901 46346401 46438601
830.6304	63-4	Odor		42922701 43532901 46346401 46438601
830.7200	63-5	Melting Point		42922701 43532901 46346401 46438601
830.7220	63-6	Boiling Point		42922701 43532901 46346401 46438601
830.7300	63-7	Density		42922701 43532901 46346401 46438601
830.7840 830.7860	63-8	Solubility		42922701 43532901 46346401 46438601
830.7950	63-9	Vapor Pressure		42922701 43532901 46346401 46438601

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7370	63-10	Dissociation Constant in Water		42922701 43532901 46346401
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		42922701 43532901 46346401
830.7000	63-12	pH		42922701 43532901 46346401
830.6313	63-13	Stability		42922701 43532901 46346401 46438601
830.6314	63-14	Oxidizing/Reducing Action		42922701 43532901 46346401
830.6315	63-15	Flammability		46438601
830.6316	63-16	Explodability		42922701 43532901 46346401
830.6317	63-17	Storage Stability		43532901 43563001
830.7100	63-18	Viscosity		46438601
830.6320	63-20	Corrosion Characteristics		46438601
ECOLOGICAL EFFECTS				
850.2100	71-1 A	Avian Acute Oral Toxicity Test - Quail/duck		42927101 42927102

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.2200	71-2 A	Avian Acute Dietary - Quail		42927103 42927104
850.2200	71-2 B	Avian Acute Dietary – Duck		42927104
850.1075	72-1 A	Fish Acute Toxicity - Bluegill		42899003
	72-1 A	Fish Acute Toxicity - Salmon		42902401
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout		42899002 43563701
850.1010	72-2 A	Acute Aquatic Invertebrate Toxicity		43228401
850.1075	72-3 A	Estu/Mari tox. Fish		Data gap
850.1055	72-3 B	Estu/Mari tox. Mollusk		42899004
850.1035	72-3 C	Estu/Mari tox. Shrimp		42902402
850.1300	72-4 A	Early Life Stage Fish		42902403
850.1400	72-4 B	Life Cycle Invertebrate		42899005
	72-5	Life cycle Fish		43109701
850.1735	73-1	Whole sediment, Acute invertebrates, freshwater		Data gap
850.1740	73-2	Whole sediment, Acute invertebrates, marine		Data gap
	122-1 B	Vegetative vigor		42902404

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.4400	122-2	Aquatic plant growth		42902404 42902405 43073501
850.4225	123-1 A	Seedling emergence, rice		Data Gap
850.4250	123-1 B	Vegetative Vigor, rice		Data Gap
850.5400	123-2	Acute algal dose-response toxicity - 3 species		42902404 42902405 43073501
850.3030	141-2	Honey Bee toxicity of residues in foliage		Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat		42921501 42962305
870.1200	81-2	Acute Dermal - Rabbit		42921502 43558501
870.1300	81-3	Acute Inhalation – Rat		43611901 41678401
870.2400	81-4	Acute Eye Irritation - Rabbit		41678402
870.2500	81-5	Acute Skin Irritation - Rabbit		42921503
870.2600	81-6	Dermal Sensitization		42921504
	82-2	21 Day Dermal Rabbit/rat		42957802

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3100	82-1 A	90 Day feeding-Rodent		42957801 42986801 42937301 43572401
870.3150	82-1 B	90 Day feeding-Non-rodent		42986802
870.3465	82-4	90 Inhalation-rat		Data Gap
870.4100	83-1 A	Chronic Toxicity-Rodent		00083777
870.4100	83-1 B	Chronic Toxicity-Non-rodent		00099606
870.4200	83-2 B	Oncogenicity-Mouse		43267201 43267202
870.3700	83-3 A	Prenatal Developmental Toxicity - Rat		41063702 42986803
870.3700	83-3 B	Prenatal Developmental Toxicity – Rabbit		41063701
870.3800	83-4	Reproduction and fertility effects - Rat		00079233 43267202
870.5100	84-2 A	Bacterial Reverse Mutation Test - Ames		00248746 42962301 42962302 42962303
870.5375	84-2 B	In Vitro Mammalian Chromosome Aberration Test		42962302
870.5550	84-4	Other Genotoxic Effects		42962303 42962306
870.7485	85-1	General Metabolism		42962304 42962305

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
ENVIRONMENTAL FATE				
	160-5	Chemical Identity		42922701
835.2120	161-1	Hydrolysis of Parent and Degradates		42899001
835.2240	161-2	Photodegradation – Water		42925501
	162-1	Aerobic Soil Metabolism		42925502 43677301
835.1230	163-1	Leaching and Absorption/desorption		42925503 42925504 43620602 43620603 43667001
OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.2400	133-3	Dermal Exposure		45524304
875.2500	133-4	Inhalation Exposure		45524304
875.1300	232	Inhalation Exposure-Outdoor		455021101
875.1400	234	Inhalation Exposure-Indoor		455021101
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity		42922701

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
860.1200	171-3	Directions for Use		Data Gap
860.1500	171-4 K	Crop Field Trials		Data Gap

Appendix C. Technical Support Documents

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

The docket initially contained the June 28, 2007 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

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 Copper 8-quinolinolate, 09/26/2007

Revised Risk Assessment and Supporting Science Documents:

- Revised Risk Assessment Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026), 9/18/2007
- Revised Occupational and Residential Exposure Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026), 9/17/2007
- Revised Ecological Hazard and Environmental Risk Assessment Chapter for the Copper 8-Quinolinolate Reregistration Eligibility Decision (RED) Document Case No.: 4026, 10/24/2007
- Estimated Environmental Concentrations for Copper 8-Quinolinate (Cu8Q) from a treated wood used to build docks, 10/9/2007

Preliminary Risk Assessment and Supporting Science Documents:

- Preliminary Risk Assessment for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026), 6/28/2007
- Toxicology Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026), 6/28/2007
- Occupational and Residential Exposure Chapter for Copper 8-Quinolinolate (Oxine-Copper) in Support of the Reregistration Eligibility Decision (RED) Document for the Copper Salts (RED Case 4026), 6/28/2007

- Product Chemistry Science Chapter for Copper 8-Quinolinolate or Copper Oxine, 6/28/2007
- Dietary Exposure Assessment of Copper 8-Quinolinolate Use of Indirect Food Contact Surfaces, 6/28/2007
- Environmental Fate Transport Assessment for Copper 8-Quinolinolate, 6/28/2007
- Ecological Hazard and Environmental Risk Assessment Chapter for the Copper 8-Quinolinolate reregistration Eligibility Decision (RED0 Document (Case No.: 4026), 6/27/2007
- Incident Report Associated with Copper 8-Quinolinolate, 5/3/2007

Appendix D. Citations Considered to be Part of Data Base Supporting the Reregistration Decision (Bibliography)

1. MRID Studies

MRID #	Citation
00083777	Mulligan, T.; Banas, D.A. (1976). Final Report: Two-year Dietary Administration in the Rat: Project No. 854-104. (Unpublished study received May 20, 1981 under 42567-1; prepared by Hazleton Laboratories America, Inc., submitted by La Quinoleine S.A., c/o Regst. Consulting, Pacifica, Calif.; CDL: 245397-G).
00099606	Mulligan, T.; Voelker, R. (1976). Final Report: Two-year Dietary Toxicity Study in Dogs: Project No. 854-103. (Unpublished study received Dec 8, 1978 under 42567-1; prepared by Hazleton Laboratories America, Inc., submitted by La Quinoleine S.A., c/o Registration Consulting Associates, Pacifica, CA; CDL:237444-A).
00248746	Peirce, M.; Simmon, V. (1981) Microbiological Genotoxicity Assays of Copper-8-quinolinolate: Active Ingredient in Woodtreat: Study No. 3002-7. Final rept. (Unpublished study received Nov 3, 1982 under 453-281; prepared by Genex Corp., submitted by Wood Treating Chemicals, Dept. of Koppers Co., Inc., St. Louis, MO; CDL:248746-A)
0079233	Mulligan, T.; Durloo, R. (1975). Final Report: A Two Generation Reproduction Study in Rats: Project No. 854-105. (Unpublished study received May 20, 1981 under 42567-1; prepared by Hazleton Laboratories America, Inc., submitted by La Quinoleine S.A., c/o Regst. Consulting, Pacifica, Calif.; CDL: 245397-F).
41063701	Ridgway, P. (1987). K37 (Copper 8-Hydroxyquinolate): rabbit teratology dose ranging study: Project ID: AKJ/5/87. Unpublished study prepared by Toxicol Laboratories Ltd.
41063702	Ridgway, P. (1987). K37 (Copper 8-Hydroxyquinolate): Rabbit Teratology Study: Project ID: AKJ/6/87. Unpublished study prepared by Toxicol Laboratories Ltd. 106 p.
41678401	Imamura, T.; Biederman, K.; Thevenaz, P. (1990) 4-Hour Acute In- halation Study with RO 17-0099/000 in Rats, Final Report: Lab

Project Number: RCC 246475. Unpublished study prepared by RCC Research and Consulting Company Ag. 110 p.

41678402 Ullman, L.; Porricello, T.; Janiak, T. (1990) Primary Eye Irritation Study with RO 17-0099/000 (copper 8 quinolinolate) in Rabbits: Lab Project Number: RCC 273115. Unpublished study pre- pared by RCC Research and Consulting Company Ag. 47 p.

42899001 A. Kesterson, B.A. and Brenda Lawrence, 1993. Hydrolysis of [14C]Oxine Copper at pH 5, 7 and 9, Study performed by PTRL East Inc., Richmond, KY. Final Report # 1244.

42899002 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to Rainbow Trout, *Oncorhynchus mykiss*, Under Flow-Through Test Conditions: Lab Project Number: J9006014A. Unpublished study prepared by Toxikon Environmental Sciences. 43p.

42899003 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to Bluegill, *Lepomis macrochirus*, Under Flow-Through Test Conditions: Lab Project Number: J9006014B.Unpublished study prepared by Toxikon Environmental Sciences. 44p.

42899004 Ward, G.; Davis, J. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to Embryos and Larvae of the Eastern Oyster, *Crassostrea virginica*, Under Static Test Conditions: Lab Project Number: J9006014I. Unpublished study prepared by Toxikon Environmental Sciences. 45p.

42899005 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Chronic Toxicity to the Water Flea, *Daphnia magna*, Under Flow-Through Test Conditions: Lab Project Number: J9006014F. Unpublished study prepared by Toxikon Environmental Sciences. 52p.

42902401 Carr, K.; Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to Coho Salmon, *Oncorhynchus kisutch*, Under Flow-Through Test Conditions: Lab Project Number: J9006014C. Unpublished study prepared by Toxikon Environmental Sciences. 44p.

42902402 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to the Mysid, *Mysidopsis bahia*, Under Flow-Through Test Conditions: Lab Project Number: J9006014J.Unpublished study prepared by Toxikon Environmental Sciences. 42p.

42902403 Lintott, D.; Ward, G. (1993) Oxine Copper (Copper 8

Quinolinolate): Toxicity to Embryos and Lavae of the Rainbow Trout,*Oncorhynchusmykiss*, Under Flow-Through Test Conditions: Lab Project Number: J9006014E. Unpublished study prepared by Toxikon Environmental Sciences. 64p.

42902404 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Toxicity to the Saltwater Alga, *Nitzschia punctata*, Under Static Test Conditions: Lab Project Number: J9006014M. Unpublished study prepared by Toxikon Environmental Sciences. 46p.

42902405 Ward, G. (1993) Oxine Copper (Copper 8-Quinolinolate): Acute Toxicity to the Saltwater Green Alga, *Dunaliella tertiolecta*, Under Static Test Conditions: Lab Project Number: J9006014L. Unpublished prepared by Toxikon Environmental Sciences. 46p.

42921501 Buser, S. (1990). Determination of the Acute Oral Toxicity of Ro 17-0099/000 (Copper 8-Quinolinolate TGAI) in the Rat: Lab Project Number: B-157'235: 032A90Z. Unpublished study prepared by F. Hoffmann-La Roche Ltd. 37 p.

42921502 Buser, S. (1990). Determination of the Acute Dermal Toxicity of Ro 17-0099/000 (Copper 8-Quinolinolate TGAI) in the Rat: Lab Project Number: B-157'234. Unpublished study prepared by F. Hoffmann-La Roche Ltd. 21p.

42921503 Ullmann, L.; Porricello, T. (1993). Primary Skin Irritation Study with Ro 17-0099/000 (Copper 8-Quinolinolate) in Rabbits (4-Hour Semi-Occlusive Application on Intact and Abraided Skin): Lab Project Number: 213344. Unpublished study prepared by Research & Consulting Co., AG. 29 p.

42921504 Ullmann, L.; Kups, A. (1988). Contact Hypersensitivity to Ro 17-0099/000 (Copper 8-Quinolinolate) in Albino Guinea Pigs (Maximization Test): Lab Project Number: 213333. Unpublished study prepared by Research & Consulting Co., AG. 46 p.

42922701 Freyre, J.; Griffon, G. (1990) Oxine Copper (Ro 17-0099/000): Product Identity and Disclosure of Ingredients: Lab Project Number: F-0200. Unpublished study prepared by La Quinoleine S.A. 28 p.

42927101 Hakin, B.; Rodgers, M.; Grutzner, I. (1991) Ro 17-0099/000 (Copper 8-Quinolinolate): Acute Oral Toxicity (LD50) to the Bobwhite Quail: Lab Project Number: HLR 184-901854: RCC 284253. Unpublished study prepared by Huntingdon Research Centre Ltd.; RCC UMWELTCHEMIE AG. 53p.

42927102 Hakin, B.; Rodgers, M.; Grutzner, I. (1991) Ro 17-0099/000 (Copper 8-Quinolinolate): Acute Oral Toxicity to Mallard Duck: Lab Project Number: HLR 185-901733: RCC 284264. Unpublished study prepared by Huntingdon Research Centre Ltd.; RCC UMWELTCHEMIE AG. 38p.

42927103 Hakin, B.; Rodgers, M.; Grutzner, I. (1991) Ro 17-0099/000 (Copper 8- Quinolinolate): Dietary Toxicity (LC50) to Bobwhite Quail: Lab Project Number: HLR 187-901685: RCC 279854. Unpublished study prepared by Huntingdon Research Centre Ltd.; RCC UMWELTCHEMIE AG. 39p.

42927104 Hakin, B.; Rodgers, M.; Grutzner, I. (1991) Ro 17-0099/000 (Copper 8-Quinolinolate): Dietary Toxicity (LC50) to the Mallard Duck: Lab Project Number: HLR 186-901684: RCC 274228. Unpublished study prepared by Huntingdon Research Centre Ltd.; RCC UMWELTCHEMIE AG. 39p.

42925501 Dr. S. Dennis, 1991. Ro 17-0099/022 (14C-Copper 8 Quinolinolate) Photodegradation Studies in Aqueous Solution. Study Performed by Metabolism Section (RES), Switzerland, Project #: RES-MET Q13

42925502 Dennis, S. (1991) Ro 17-0099/022: Laboratory Aerobic Soil Metabolism (of Copper 8-Quinolinolate): Lab Project Number: RES-MET Q101. Unpublished study prepared by Dr. R. Maag Ag. 59 p.

42925503 Dr. S. Sack. 1991. Ro 17-0099/022: Laboratory Non-Aged Leaching Study. Study Performed by Metabolism Section Department of Registration and Environmental Studies (RES), Switzerland. Project #: RES-MET Q102

42925504 Dr. S. Sack, 1991. Ro 17-0099/022: Laboratory Non-aged Leaching Study. Study Performed by Metabolism Section Department of Registration and Environmental Studies (RES). Switzerland. Project# RES-MET Q103

42937301 Buser, S. (1983). A 13-Week Toxicity Study with Ro-17-0099/000 (Copper 8-Quinolinolate) in Mice p.o. (Feed Admix): Lab Project Number: RRB 104 777: 62 A 81: 104 777. Unpublished study prepared by F.Hoffmann-La Roche & Co. Ltd. 135 p.

42957801 Coleman, M.; Taupin, P. (1990). K-37 (Copper 8-Quinolinolate):

13-Week Oral (Dietary) Rangefinding Study in the Mouse: Lab Project Number: TOM/1/90. Unpublished study prepared by Toxicol Labs, Ltd. 211 p.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In (DCI) at a later date. See Chapter V of the Copper 8-quinolinolate RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

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

Appendix G. Batching of Copper 8-quinolinolate Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching for Copper 8-quinolinolate at a later date.

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.

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

    b. 84-1 Clarification of Label Improvement Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

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

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

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.