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United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-07-003
September 2007

Reregistration Eligibility Decision for Copper and Zinc Naphthenate Salts

(Case 3099)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the wood and materials preservatives copper and zinc naphthenate salts. The Reregistration Eligibility Decision (RED) for the naphthenate salts was approved on September 28, 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 the naphthenate salts and their associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for the naphthenate salts are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0589 at: www.regulations.gov.

The naphthenate salts RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, 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 naphthenate salts risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to the naphthenate salts alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required

responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that the naphthenate salts will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary to implement this mitigation measure. 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 the naphthenate salts. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Diane Isbell at (703) 308-8154. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION
For Naphthenate Salts (Copper and Zinc)

List C

Case 3099

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September 28, 2007

Attachment

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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

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ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the copper and zinc naphthenate salts and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required database supporting the use patterns of currently registered products and additional information received from stakeholders 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 and zinc naphthenate salts that pose risks of concern. As a result of this review, EPA has determined that naphthenate salt-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.

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I. Introduction

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

This document presents the EPA decision regarding the reregistration eligibility of the registered uses of the naphthenate salts. There are two active ingredients in the naphthenate salts case: copper naphthenate (PC Code 023102); and zinc naphthenate (PC Code 088301).

The naphthenate salts are used predominantly in industrial and commercial wood preservation for non-pressure (dip/brush/spray) and pressure treatments (vacuum/full-cell) to protect against fungal rot, decay, termites and wood-boring insects in unfinished wood and various fabricated wood products. These preservatives are also used for remedial treatments to in-service poles (internal/external surfaces at ground or below-ground level via brush/trowel, mechanical injection or bandage wrap). Treated wood is specified for exterior above-ground, ground-contact, below-ground and fresh or salt water contact use applications. The naphthenate salts are also used as protective wood preservative surface treatments when applied to bare seasoned wood. Copper and zinc naphthenates are also used for commercial/industrial materials preservation of cellulose-based cordage/textiles. Textile preservation is limited to industrial textiles and certain government-issued (military specified) treatments for cellulose-based cotton, canvas, tentage/tarps, ropes, cordage and nets. Products are used as fungistats to control rot and mildew and are registered for impregnation by dip (primarily), or by spray and brush surface treatment. Residential use of the naphthenate salts is limited to exterior wood preservation and materials preservative in cellulose-based textiles/cordage intended for exterior-use only, including non-apparel industrial-use textiles.

The Agency has concluded that the FQPA Safety Factor for copper and zinc naphthenate salts should be removed (equivalent to 1X) based on the fact that there are no food use tolerances for these chemicals and indirect food contact is not expected from the current uses of these chemicals.

Risks summarized in this document are those that result only from the use of the active ingredients, copper and zinc naphthenate. 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. EPA has not made a common mechanism of toxicity finding for naphthenic acid and any other substances**.** Copper and zinc naphthenate do not appear to produce a toxic metabolite produced by other substances, unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity. For the purposes of this action, therefore, EPA has not assumed that copper and zinc naphthenate have 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 and zinc naphthenate. 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 and zinc naphthenate 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-2007-0589).

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 and zinc naphthenate and their regulatory history. Section III, Summary of Copper and Zinc Naphthenate 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.

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II. Chemical Overview

A. Regulatory History

Copper naphthenate was first registered as an active ingredient on October 29, 1951 and zinc naphthenate was first registered on November 26, 1975. There are 38 registered copper naphthenate products and 11 registered zinc naphthenate products. The naphthenate salts are used in combination as a wood preservative and a materials preservative.

There are no direct or indirect food uses associated with the naphthenate salts. There is however, one tolerance exemption for residues of copper naphthenate when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops only (40 CFR 180.920). This tolerance was reassessed previously in a separate review of the inert tolerance and is not reconsidered in this document. No more than 2.5% copper naphthenate can be present, and products containing copper naphthenate can only be applied before the edible portions of plants begin to form.

B. Chemical Identification

Copper Naphthenate

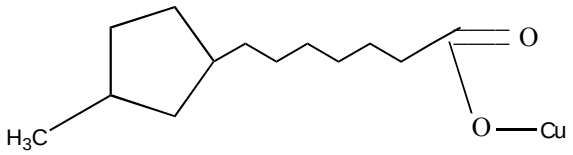

Figure 1. Molecular Structure of Copper Naphthenate

Common name: Copper Naphthenate

Chemical name: Naphthenic acids, copper salts

Chemical family: Naphthenate salts

Empirical formula: $C_{13}H_{23}CuO_2$

CAS Registry No.: 1338-02-9

Case number: 3099

OPP Chemical Code: 023102

Molecular weight: 274.87

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Other names: Copper naphthenate, naphthenic acids, copper salts, Troysan, and Copper Uversol

Basic manufacturers: OMG Americas INC
OMG Bellville Limited
IBG Manufacturing
Merichem Chemicals & Refinery Services LLC

Chemical properties: Copper Naphthenate is a green-black viscous liquid with a burnt, hydrocarbon-like odor. Copper Naphthenate is a liquid and, therefore, has no melting point. It has a boiling point of 121^0C, and decomposition begins around 257^o C. Copper Naphthenate has a log K_{ow} of 4.1 at 20^oC.

Zinc Naphthenate

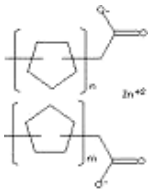

Figure 2. Molecular Structure of Zinc Naphthenate

Common name: Zinc Naphthenate

Chemical name: Naphthenic acids, zinc salts

Chemical family: Naphthenate salts

Empirical formula: R-C=O-Zn-O-C=O-R, where R = various alkyl and cycloalkyl groups

CAS Registry No.: 12001-85-3

Case number: 3099

OPP Chemical Code: 088301

Molecular weight: Variable, between 365-665

Other names: Naphthenic acids, zinc salts, zinc naphthenate

Basic manufacturers: OMG Americas Inc.
OMG Bellville Limited
IBC Manufacturing

Chemical properties: Zinc Naphthenate is a light brown solid (TGAI) or viscous liquid (MUP) with a hydrocarbon-like odor. Zinc Naphthenate has a log K_{ow} of 1.0 – 1.2 at 20^{o}C.

C. Use Profile

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

Type of Pesticide: Fungicide, insecticide, miticide, microbiocide/microbiostat, algaecide and herbicide

Summary of Use:

Materials Preservatives:
For use as a materials preservative for rope, burlap, canvas, cellulosic materials, cordage/rope/twine, fabrics, boat coverings and sails, truck covers, fabrics, nets (not fish nets), seines, tents, awnings, textiles, particle board, insulation board, and other wood base fiber and particle materials tarpaulins.

Wood Preservative:
Copper and zinc naphthenate products are used as wood preservatives on lumber, timbers, posts, poles, fences, pickets, fence rails, all exterior wood exposed to moisture or weather; wood pilings, wood decks/porches, wood flooring, wood shingles, wood siding, wood sills, wood steps, wood flower boxes, outdoor wood furniture, green house flats, green house benches, landscaping material, ladders, millwork, decks, docks/piers, doors, beverage cases, boat hulls, boats, wood frames/shingles/siding/sills, and wood beehives.

Target Pests: Fungal rot, decay, mildew, termites, and wood-boring insects.

Formulation Types: Emulsified concentrate, soluble concentrate, paste and ready-to-use solution.

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Method and Rates of Application:

Impregnation is the primary method of application for both copper and zinc naphthenate. Other application methods include rollers, brushes, sprayers, mops, caulk guns, scoops, trowels, as well as tanks and low pressure equipment for application to aquatic structures such as boats, marinas, docks, piers, bridge members, and timbers.

An 8% copper naphthenate solution should be used at a level of 5 to 50 percent and applied as a dip or brush treatment to wood such as fence posts, patio decking, ladders, millworks, greenhouse benches, and similar items. Lumber items should be totally immersed in the ready to use solution for a period of 3 seconds to 3 minutes depending on the absorption required or they may be sprayed or brushed until run off occurs. The wood should then be drained of excess solution and allowed to air dry until all solvent has evaporated and the wood is free of odor.

Fabric such as cotton duck should be immersed in the ready to use solution, passed through suitable squeeze rolls and dried by festooning or passing over dry can. It is recommended that 0.4% to 0.8% copper naphthenate or 0.5% to .10% zinc naphthenate be deposited in the treated fabric. Higher levels are recommended for those areas where extensive weathering and/or leaching are commonplace.

Both copper and zinc naphthenate are readily soluble in mineral spirits and may be combined with standard solvent soluble water repellents such as petroleum waxes and/or resins. The products should not be used where they may be in contact with food or agricultural products.

Application Rates: For details about specific use sites for the naphthenate salts, refer to Appendix A.

Use Classification: General use.

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III. Summary of the Naphthenate Salts 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 the naphthenate salts. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0589, 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 naphthenate salts risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

1. Toxicity of the Naphthenate Salts

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 1. Further details on the toxicity of the naphthenate salts can be found in the "Naphthenate Salts: Toxicology Chapter in support of the Reregistration Eligibility Decision (RED) Document," dated July 12, 2007; "Naphthenate Salts: Preliminary Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document," dated July 12, 2007; and "Review Memorandum: Naphthenate Salts (Zinc/Copper) – Endpoint Selection Report," dated April 16, 2007. These documents are available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0589).

The Agency has reviewed all toxicity studies submitted for naphthenate salts and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements.

Major features of the toxicology profile are presented below. The naphthenate salts exhibit moderate to low acute dermal and oral toxicity (toxicity categories III (dermal, copper and zinc) and IV (oral, zinc). Acute oral toxicity for copper naphthenate was not determined in conducted studies. The naphthenate salts exhibit low inhalation toxicity (toxicity categories III and IV). In addition, the naphthenate salts are not considered to be an eye irritant (toxicity category III). However, copper naphthenate is considered to be a moderate dermal irritant and zinc naphthenate is considered to be a severe dermal irritant (toxicity categories II and III, respectively). Copper naphthenate is not a dermal sensitizer; however, zinc naphthenate is considered a primary skin irritant and a possible dermal sensitizing agent.

Table 1. Acute Toxicity Profile for Copper/Zinc Naphthenate

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral- Rat purity 45.4% -copper naphthenate	00266172	LD_{50} > 501 mg/kg	III
870.110 (§81-1)	Acute Oral- Rat purity 58% -copper naphthenate	433342402	Not determined	N/A
870.1100 (§81-1)	Acute Oral- Rat purity 60%- zinc naphthenate	00244277	LD_{50} > 2000 mg/kg	IV
870.1200 (§81-2)	Acute Dermal- Rabbit purity not determined – copper naphthenate	41140710	LD_{50} > 2000 mg/kg	III
870.1200 (§81-2)	Acute Dermal- Rabbit Purity 60%-zinc naphthenate	00244277	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute Inhalation- Rabbit Purity technical- copper naphthenate	41486301	LC_{50} > 2.966 mg/L	III
870.1300 (§81-3)	Acute Inhalation- Rabbit Purity 60%- zinc naphthenate	00244277	LC_{50} > 11.6 mg/L	IV
870.2400 (§81-4)	Primary Eye Irritation- Rabbit purity 80% -copper naphthenate	00260891	Redness cleared on day 4	III
870.2400 (§81-4)	Primary Eye Irritation- Guinea pig purity 60% -zinc naphthenate	00244277	Redness cleared on day 2	III
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit purity technical –copper naphthenate	41140710	Moderate Irritant	III
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit 60% -zinc naphthenate	00244277	Moderate to Severe Irritant	II
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 58 % - copper naphthenate	41140710	Not a sensitizer.	No
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 60 % - zinc naphthenate	00244277	Primary skin irritant/possible sensitizing agent	No

Notes: LC = Lethal Concentration; LD = Lethal Dose; NA = Not Applicable

General Toxicity Observations

Dietary

Based on registered uses, no dietary exposure to naphthenate salts is anticipated and no toxicological dietary endpoints were identified. Therefore, no dietary assessment has been conducted.

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Incidental Oral

The NOAEL for the short- and intermediate-term (1 – 30 days) incidental oral endpoint is 30 mg/kg/day, based on a developmental toxicity study in the rat (copper naphthenate). The NOAEL is based on decreased body weight and food consumption at 100 mg/kg/day. The target margin of exposure (MOE) is 100 (10X for inter-species extrapolation and 10X for intra-species variation).

Short- and Intermediate-term Dermal

The short-term dermal LOAEL is 100 mg/kg/day, which is based on a dermal toxicity study in the rabbit (zinc naphthenate). The LOAEL is based on erythema, edema, and desquamation at 100 mg/kg/day. The target MOE, for short-term dermal exposures is 30 (3X for inter-species extrapolation, 3X for intra-species variation, and 3X for use of a LOAEL).

The intermediate-term dermal NOAEL is 100 mg/kg/day, based on a dermal toxicity study in the rabbit (zinc naphthenate). The NOAEL is based on reductions in body weight observed at 300 mg/kg/day. The target MOE, for intermediate-term dermal exposures is 100 (10X for inter-species extrapolation and 10X for intra-species variation).

In a 90-day dermal toxicity study using copper naphthenate, no irritation or systemic effects were observed. Therefore, a dermal toxicity endpoint was not identified for copper naphthenate. The toxicity endpoints identified above only apply to zinc naphthenate. No dermal risk assessment is needed for copper naphthenate but an assessment is required for zinc naphthenate.

Short- Intermediate- and Long-term Inhalation

The short-, intermediate-, and long-term inhalation endpoint is based on an oral developmental toxicity study in the rat, with a NOAEL of 30 mg/kg/day. The target MOE for the naphthenate salts is 100 for all exposure durations (10X for inter-species extrapolation and 10X for intra-species variation). An additional 10x uncertainty factor was applied to determine the need for confirmatory inhalation toxicity data. This was done because the inhalation endpoint is based on an oral toxicity study requiring route-to-route extrapolation.

Carcinogenicity

There are no data from which to derive a carcinogenicity classification of copper or zinc naphthenate. There are summary data only for calcium naphthenate; however, calcium naphthenate has no registrations as a pesticidal active ingredient.

Mutagenicity

The Agency considers all of the submitted mutagenicity studies to be unacceptable, but upgradable, if the test material purity is provided for these studies. In the studies submitted for copper naphthenate, no mutagenic effects were seen. Mutagenicity studies were also submitted

for zinc naphthenate and included a mouse lymphoma assay (MRID 41400701), chromosome aberration test (MRID 41400702) and an unscheduled DNA synthesis (UDS) study (MRID 41400703). In the mouse lymphoma mutagenesis assay, zinc naphthenate caused an increase in mutant frequency in the presence of microsomal S9. There was also a greater increase in small colonies versus large colonies with exposure to zinc naphthenate as opposed to what was seen with copper naphthenate exposure. In the chrosomal aberration test using Chinese hamster ovary cells, zinc naphthenate caused an increase in chromosomal aberrations with increasing concentrations of zinc naphthenate. In the unscheduled DNA assay, zinc naphthenate did not show effects at any concentration tested.

Developmental/Reproductive

In a prenatal developmental toxicity study (MRID 41615101), Copper naphthenate (purity assumed to be 100%) in corn oil, was administered by gastric intubation to 4 groups of 25 rats/dose by gastric intubation at dose levels of 0, 30, 100, or 300 mg/kg/day, respectively, from gestation days (GD) 6 to 15. Maternal toxicity was noted in the 100 and 300 mg/kg/day groups in the form of decreases in body weight and food consumption. Evaluation of developmental toxicity revealed an increase in the mean number of early resorptions only, however the mean litter size of the treated and control groups was comparable. Therefore, these increases were considered to be of no biological significance. The maternal NOAEL is 30 mg/kg/day and the maternal LOAEL is 100 mg/kg/day. The developmental; toxicity NOAEL was determined to be greater than or equal to 300 mg/kg/day and the developmental toxicity LOAEL was greater than 300 mg/kg/day, the highest dose tested.

In another developmental toxicity study (MRID 41615002), Zinc naphthenate (purity assumed to be 100%) in corn oil, was administered via oral gavage to 4 groups of 25 female rats/dose at dose levels of 0, 50, 250, or 500 mg/kg/day from gestation days (GD) 6 to 15. The only observed clinical sign of maternal toxicity was a dose-related increase in staining around the mouth and anogenital area in the 250 and 500 mg/kg/day groups. This staining may be due to the increased intake of the pigmented chemical**.** The maternal NOAEL was greater than or equal to 500 mg/kg/day (HDT), and the maternal LOAEL was greater than 500 mg/kg/day. The developmental toxicity NOAEL is greater than or equal to 500 mg/kg/day (HDT) with a developmental toxicity LOAEL greater than 500 mg/kg/day.

In a study conducted by the U.S. Army (Angerhofer et al., 1991), zinc naphthenate was administered by gavage to groups (33/dose) of pregnant Sprague-Dawley rats at doses of 0, 94, 188, and 938 mg/kg/day from days 6 through 15 of gestation. Clinical signs of toxicity were observed in maternal rats at the 938 mg/kg/day dose and included brown staining in the urogenital area, red nasal and oral exudate, generalized alopecia, and lethargy. Body weight was significantly decreased on day 10 of dosing but was not otherwise affected in treated female rats compared to vehicle control. Total resorptions were increased at the 938 mg/kg/day dose as well as resorptions/dam. Average fetal body weight was decreased at 938 mg/kg/day. There was no clear dose relationship observed for fetal variations. Consequently, the developmental LOAEL is 938 mg/kg/day based on reduced mean fetal body weight. The developmental NOAEL is 118 mg/kg/day.

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Endocrine Disruption

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

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

2. Dietary Risk Assessment

Based on registered uses, no dietary exposure to naphthenate salts is anticipated and no toxicological dietary endpoints were identified. Therefore, no dietary assessment has been conducted.

3. Residential Risk Assessment

Residential exposure from the naphthenate salts can occur when these active ingredients are used as a wood preservative or through contact with treated textiles (e.g., treated canvas tents or tarps) or treated wood. 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. Based on the application methods, the naphthenate salts have been assessed for the residential applicator (or "handler") and post application exposure. For additional information, please refer to "Occupational and Residential Exposure Chapter for Copper and Zinc Naphthenates in Support of the Reregistration Eligibility Decision (RED) Document for the Naphthenate Salts (RED Case 3099)," dated July 10, 2007.

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a. Residential Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential and occupational risks for the naphthenate salts are listed in Table 2.

An MOE greater than or equal to 100 is considered adequately protective for the incidental oral route of exposure. The MOE of 100 includes 10x for inter-species extrapolation, 10x for intra-species variation. The target MOE of 30 is considered protective for short-term dermal exposure; the MOE of 30 includes 3x for inter-species extrapolation, 3x for intra-species variation and 3x for the use of LOAEL. For intermediate-term dermal exposure, an MOE of 100 is considered protective based on 10X for inter-species extrapolation and 10x for intra-species variation. For all durations of inhalation exposure, an MOE of 100 is considered protective, and includes the following uncertainty factors: 10x inter-species extrapolation and 10x intra-species variation. An additional 10x uncertainty factor was applied to determine the need for confirmatory inhalation toxicity data. This was done because the inhalation endpoint is based on an oral toxicity study requiring route-to-route extrapolation.

Since the irritation and systemic effects on which the dermal toxicity endpoints are based were not observed in a 90-day dermal toxicity study using copper naphthenate these endpoints only apply to zinc naphthenate. No dermal risk assessment is needed for copper naphthenate but an assessment is required for zinc naphthenate.

Table 2. Residential and Occupational Toxicological Doses and Endpoints for the Naphthenate Salts

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE and UF for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days); Intermediate-term (30-days – 6 months)	**NOAEL** = 30 mg/kg/day	**Target MOE = 100** (UF =10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – Rat (Copper Naphthenate) MRID 41615101 Maternal NOAEL = 30 mg/kg/day, based on decreased body weight and food consumption at 100 mg/kg/day.
Short-Term Dermal [a] (1 to 30 days) (residential and occupational) **Zinc Naphthenate Only**	**LOAEL**= 100 mg/kg/day ***Dermal Irritation:*** (22,222 µg/cm^2) [a]	**Target MOE = 30** (UF =3x inter-species extrapolation, 3x intra-species variation, 3x for use of LOAEL)	90-day Dermal Toxicity- Rabbit (Zinc Naphthenate) MRID 41515001 LOAEL (dermal) = 100 mg/kg/day, based on erythema, edema, and desquamation at 100 mg/kg/day

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE and UF for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (30 days- 6 months) (residential and occupational) **Zinc Naphthenate Only**	**NOAEL**= 100 mg/kg/day (Systemic Toxicity)	**Target MOE = 100** (UF =10x inter-species extrapolation, 10x intra-species variation)	90-day Dermal Toxicity- Rabbit (Zinc Naphthenate) MRID 41515001 NOAEL = 100 mg/kg/day, based on reductions in body weight gain observed at 300 mg/kg/day.
Dermal Long-Term (>6 months)	A long-term dermal endpoint is not required for the Naphthenate Salts (Copper, Zinc).		
Inhalation [b] (all durations) (residential and occupational)	**NOAEL**= 30 mg/kg/day	**Target MOE = 100** (UF = 10x inter-species extrapolation, 10x intra-species variation) An additional 10x route extrapolation UF is used to determine if inhalation toxicity data is needed)	Developmental Toxicity – Rat (Copper Naphthenate) MRID 41615101 Maternal NOAEL = 30 mg/kg/day, based on decreased body weight and food consumption at 100 mg/kg/day.
Cancer	The Naphthenate Salts (Copper, Zinc) have not been formally classified as to carcinogenicity. No cancer data available.		

Notes: UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, and MOE = margin of exposure.

[a] The short-term dermal toxicity endpoint has been converted to an exposure per area of skin in order to assess the potential for dermal irritation effects. The following equation was used for deriving the short-term dermal endpoint in $\mu g/cm^2$: (100 mg[a.i.]/kg[rabbit] x 2.0 kg[body weight of rabbit] x 1000 μg/mg) / 9 cm^2 [area of rabbit exposed] = 22,222 $\mu g/cm^2$. Assumptions involved in this calculation include body weight of the rabbit and area of skin exposed. No systemic toxicity assessed for ST dermal exposure.

b. Residential Handlers

i. Exposure Assessment

Residential exposure can occur through the application of naphthenate salts preservative coatings via paintbrush or sprayer. Post-application exposures can occur from incidental oral ingestion (children) contact with treated surfaces including preserved wood and outdoor-use textiles (e.g., treated canvas tents or tarps). EPA selected high-end scenarios for each use site for the residential handler exposure assessment. These scenarios are listed below:

- Painting with a low pressure sprayer
- Painting with a brush/roller

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There were no chemical-specific exposure data to assess paint application with a brush roller or airless sprayer. Therefore, dermal and inhalation exposures were assessed for these scenarios using the Pesticide Handlers Exposure Database (PHED) data presented in the Office of Pesticide Program's Health Effects Division's (HED) Residential SOPs (USEPA, 1998). A summary of the PHED database is presented in Appendix A.

Maximum application rates, related use information and Agency standard values were used to assess residential handler exposure. For example, it was conservatively assumed that a resident applies 5 gallons of product per day using a low pressure sprayer and 2 gallons of paint per day using a brush/roller. 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 exposure assessments. A MOE greater than or equal to 30 is considered adequately protective for the residential exposure assessment for the dermal route of exposure. An MOE of 100 is considered adequately protective for the residential inhalation route of exposure.

All of the inhalation MOEs for residential handlers are above the target MOE of 100 and, therefore, are not of concern. For the residential handler dermal risk assessment, dermal MOEs are below the target of 30 and, therefore, are of concern (MOE of 17 for low pressure sprayer, MOE of 25 for paint brush). A summary of the residential handler exposures and risks are presented on Tables 3 and 4.

Table 3. Residential Handler Inhalation Risk Summary (Short-Term Duration)

Method of Application	Unit Exposure (mg/lb a.i.)[a]	Application Rate	Quantity Handled/ Treated per Day	Absorbed Daily Dose (mg/kg/day)[b]	MOE (Target = 100)[c]
Low Pressure Sprayer	0.030	25% a.i. by weight	42.5 lbs/day (5 gal/day)	0.0045	6,700
Brush/roller	0.284	25% a.i. by weight	17 lbs/day (2 gal/day)	0.017	1,800

a No respirator used by exposed individual.
b Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb a.i.) * application rate (0.25) * quantity handled (lbs/day) * inhalation absorption factor 100% / body weight (70 kg).
c Inhalation MOE = NOAEL (30 mg/kg/day) / Daily Dose. Target inhalation MOE is 100.

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Table 4. Residential Handler Dermal Risk Summary (Short-Term Duration)

Method of Application	Unit Exposure (mg/lb a.i./cm^2)[a]	Application Rate	Quantity Handled/ Treated per day	ST Absorbed Daily Dose (mg/cm^2)[b]	MOE[c] ST Dermal Irritation (Target = 30)
Low Pressure Sprayer	0.124	25% a.i. by weight	42.5 lbs/day (5 gal/day)	5.3	17
Brush/roller	0.213	25% a.i. by weight	17 lbs/day (2 gal/day)	3.6	25

a All dermal unit exposures represent ungloved replicates. The low pressure sprayer and brush/roller unit exposures represent short sleeve shirt and short pant replicates.

b Dermal Daily Dose (mg/cm^2) = [(PHED *hand* unit exposure (mg/lb a.i.)/surface area of adult hand (820 cm^2)] * application rate (0.25) * quantity handled (lbs).

c Dermal MOE = ST Dermal Irritation concentration (22.222 mg/cm^2) / Daily Dose. Short-term target dermal MOE is 30.

c. Residential Post-application

i. Exposure Assessment

Residential post-application dermal exposures result when adults and children come in contact with naphthenate salts in areas where pesticide end-use products have recently been applied (e.g., treated wood, textiles such as canvas tents or rope), or when children incidentally ingest the pesticide residues through mouthing the treated end products/treated articles (i.e., hand-to-mouth or object-to-mouth contact). The residential post-application scenarios considered for the naphthenate salts are from contacting treated textiles (adult/child dermal and incidental oral exposure to children) and contacting treated wood (adult/child dermal and incidental oral exposures to children). It should be noted that because naphthenate salts have a relatively low vapor pressure, post-application inhalation exposures were not assessed.

After naphthenate salts have been applied in a residential setting, there is potential for short-term dermal exposure to adults and children contacting treated wood or textiles such as canvas tents, or rope treated with naphthenate salts. In addition, there is potential for children to have short-term incidental oral exposure through hand-to-mouth transfer with treated wood or textiles. A number of conservative assumptions were used in assessing post-application risks including maximum application rates from naphthenate salt product labels.

For short-term dermal exposure and incidental oral exposure to children to textiles treated with naphthenate salts, the Agency assumed the following.

- For both the dermal and incidental oral exposure, the canvas tent cloth textile is assumed to be medium weight Army Duck Canvas (12 oz/yd^2) with a density of 408 g/m2 (40.8 mg/cm^2) [This density estimate is based on a weight specification chart from an internet source of exported canvas textile (Bharat Textiles, 2007)].

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- For both the dermal and incidental oral exposure, the product is applied at a rate of 11 % percent a.i. by weight to the textile (based on a recommended maximum application rate of 1.2% copper metal by weight).

- For the dermal exposure assessment, no data were available from which a transfer factor could be estimated. Potential doses were calculated using a conservative percent transfer of 100%, which assumes that all residues are transferable from textile surfaces to the skin. Because the calculated MOE was less than the target MOE for ST exposure, a less conservative estimate of dermal exposure was also calculated assuming a transfer factor of 5%.

- For the dermal exposure assessment, a conservative approach assumed that adults and children are sleeping inside a treated tent with no bedding between body and tent floor surfaces, wearing short pants/tee-shirt or just undergarments. The protection factor inhibiting exposure to naphthenate salts in the tent fabric from clothing is 50% based on PHED protection factor for a single layer of clothing, including long pants, short sleeved shirt, shoes, and socks (USEPA 1998).

- For the incidental oral exposure assessment, the saliva extraction efficiency was 50% (USEPA, 2000 and 2001).

- For the incidental oral exposure assessment, the surface area of textile mouthed by toddlers is 20 cm^2 (professional judgment).

- For the incidental oral exposure assessment, toddlers (3 years old) are used to represent the 1 to 6 year old age group. For three-year olds, the median body weight is 15 kg (USEPA, 1997a).

- The highest hand residue value from the available study (3.0 $\mu g/cm^2$) was used for this assessment.

- The palmar surface area of 3 fingers of a toddler, 20 cm^2, was used to estimate hand-mouthing as opposed to whole hand mouthing (USEPA, 2001).

- The rate of hand-to-mouth activity for outdoor playing is 7 events per hour based on Freeman et. al (2001) at the 95th percentile.

- The exposure time (ET) is 2 hours and is consistent with the Agency's CCA assessment for time playing outdoors. Although the 2 hour duration represents "outdoor" time, it is used as a conservative estimate for playing on decks and playsets.

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ii. Post-Application Risk Assessment

Based on the registered use patterns, toxicological criteria and potential for exposure, the Agency has conducted dermal and incidental oral exposure assessments. A MOE greater than or equal to 30 is considered adequately protective for the residential post-application exposure assessment for the dermal route of exposure. The MOE of 30 includes 3x for inter-species extrapolation, 3x for intra-species variation, and 3x for the use of a LOAEL. An MOE greater or equal to 100 is considered adequately protective for incidental oral exposures to children that could occur when children contact treated surfaces such as wood or textiles. The residential post-application risk assessment assesses short-term (1-30 days) exposure for adults and children.

As mentioned earlier, since the irritation and systemic effects were not observed in a 90-day dermal toxicity study using copper naphthenate these endpoints only apply to zinc naphthenate. No dermal risk assessment is needed for copper naphthenate but an assessment is required for zinc naphthenate.

Table 5 presents a summary of the short-term residential post-application exposures and risk estimates for children and adults contacting treated textiles. The MOE is below the short-term target of 30 for the 100% transfer factor scenario but is not of concern using the 5% transfer factor assumption. The MOEs are 10 at 100% dermal transfer and 200 at 5% dermal transfer.

Table 5. Short-term Residential Post-application Dermal Risk Summary for Children and Adults Contacting Treated Textiles.

Weight Fraction of Product (% a.i.)	Fabric Density (mg/cm^2)	Fraction Transferred to Skin	Protective Factor	Exposure Dose (mg/cm^2) [a]	MOE[b]
					Short Term (Target = 30)
11%	40.8	100%	50%	2.2	**10**
11%	40.8	5%	50%	0.11	**200**

[a] Potential exposure for ST is expressed as mg a.i. per cm^2 of exposed skin. Equation used to estimate exposure is presented above.
[b] MOE = NOAEL/exposure estimate [Where: ST and IT NOAEL = 22.222 mg/cm^2].

Table 6 shows the potential daily oral dose and oral MOE for toddlers mouthing treated textiles such as canvas tents or tarps. The short-term MOE is 10, which is below the short-term target MOE of 100, indicating a potential risk concern.

Table 6: Short-term Incidental Oral Risk Summary for Toddlers Mouthing Treated Textiles

Weight of Textile (g/m^2)	Concentration on Textile[a] (mg/cm^2)	Surface Area Mouthed (cm^2/day)	Saliva Extraction Efficiency	Potential Daily Dose[b] (mg a.i./kg/day)	ST Incidental Oral MOE (Target MOE = 100)[c]
408	4.5	20	50%	3	**10**

a. Concentration on textile (mg/cm^2) = (Weight fraction a.i. in clothing) * (weight of textile, g/m^2) * (1,000 mg/g) * (0.0001 m^2/cm^2)
b. Potential Daily Dose (mg/kg/day) = (concentration on textile, mg/cm^2) * (surface area mouthed, cm^2/day) * (saliva extraction efficiency) / (body weight, 15 kg).
c Oral MOE = NOAEL (mg/kg/day) / Potential Daily Dose [Where short-term incidental oral NOAEL = 30 mg/kg/day]. Target MOE = 100.

For the post-application exposure to lumber treated with naphthenate salts, the Agency evaluated the following scenarios.

- Dermal contact by children with naphthenate salts-treated wood products for above-ground uses [e.g., residential playground equipment (playsets), posts, decks, shingles, fencing, outdoor lumber, etc.]; and

- Incidental ingestion by children due to hand-to-mouth contact with naphthenate salts-treated wood products.

Because children are more likely than adults to contact wood surfaces using playground equipment (playsets), and because children have a higher surface area to body weight ratio, they represent the maximum exposed individual. Incidental ingestion exposure for adults is expected to be negligible and dermal contact for adults is expected to be lower than children for crawling on wood decks.

No chemical-specific residential post-application studies are available for naphthenate salts. However, 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 be used as surrogate data to estimate screening-level exposures for the following pathways: outdoor residential dermal contact with naphthenate salts-treated wood products used in above-ground applications (e.g., residential playsets, 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.

Potential risks resulting from adult/child residential dermal contact with wood treated with naphthenate salts are assessed using the range of worker residue data for hands available in the DDAC study. Hand sampling was performed using cotton gloves as dosimeters. The data in Table 7 were used to approximate the residues transferred from treated wood to skin. No other data are available (e.g., no surface wood wipe data). The data from the job descriptions

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presented below from the DDAC study were chosen because of the worker contact with dry treated lumber.

The MOEs for adults and children dermal contact with naphthenate salts-treated wood range from 7,400 – 37,000 which are above the target MOE of 30 and are not of concern. Additional information can be found in the Occupational and Residential Exposure Assessment for the Naphthenate Salts, dated July 10, 2007.

There is potential for short-term incidental oral contact with naphthenate salts-treated wood for toddlers from hand to mouth activity. As discussed above, the DDAC study was used to estimate risks to toddlers from incidental oral exposures. The short-term incidental oral exposures are shown in Table 7 below. The MOEs are above the target of 100 and are not of concern to the Agency. Additional information can be found in the Occupational and Residential Exposure Assessment for the Naphthenate Salts, dated July 10, 2007.

Table 7. Residential Post-application Short-term Incidental Oral Exposures to Naphthenate Salts-treated Wood Products

Hand Residue Concentration from DDAC Study ($\mu g/cm^2$)	Finger Surface Area (cm^2)	Exposure Frequency for Outdoor Playing (events/hr)	Saliva Extraction Factor	Exposure Time (hrs/day)	Average Daily Oral Dose [a] (mg/kg/day)	ST Oral MOE (Target MOE = 100)[b]
3.0	20	7	50%	2	0.028	1,100

[a]Average Daily Oral Dose (mg/kg/day) = [hand $_t$ (3 $\mu g/cm^2$) x Hand SA (20 cm^2) x SEF (50% as 0.50) x Frequency (7 events/hr) x Exposure Time (2 hrs/day) x 0.001 mg/µg] / BW (15 kg)
[b]MOE = NOAEL (mg/kg/day) / daily dose (mg/kg/day). For incidental oral exposures, the ST NOAEL is 30 mg/kg/day. Target MOE = 100.

4. 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.

Since the irritation and systemic effects were not observed in a 90-day dermal toxicity study using copper naphthenate these endpoints only apply to zinc naphthenate. No dermal risk assessment is needed for copper naphthenate but an assessment is required for zinc naphthenate.

Short-Term Aggregate Exposures and Risks

The following lists summarize all of the potential non-dietary sources of naphthenate salts exposures for adults and children in residential settings.

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Adult naphthenate salts exposure sources:

- Applying wood preservative/water repellent coatings in residential settings;
- Applying materials preservatives to cellulose-based fibers/textiles in residential settings;
- Post-application exposures to treated outdoor-use wood; and
- Post-application exposures to treated outdoor-use textiles.

Child naphthenate salts exposure sources:

- Post-application exposure to treated outdoor-use wood; and
- Post-application exposures to treated outdoor-use textiles.

Scenarios considered for the aggregate assessment include: short-term inhalation exposure by adult handlers and short-term dermal and incidental oral post-application exposure by children from contact with treated lumber.

Because the endpoints for the short-term dermal and incidental oral routes of exposure were based on route-specific (dermal and oral animal studies) resulting in different effects, separate route-specific aggregate assessment are appropriate. However, only one exposure scenario was identified for each route of exposure. Accordingly, evaluation of aggregate risk as outlined in the OPP guidance for aggregate risk assessment (September 1, 2000, Standard Operating Procedure (SOP) for Incorporating Screening Level Estimates of Drinking Water Exposure into Aggregate Risk Assessments) is not required for the naphthenate salts.

5. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. The naphthenate salts are used as an antimicrobial pesticide as a wood preservative and a materials preservative for non-apparel textiles (tents, awnings, canvas products) and cordage such as ropes, twine, nets. Potential occupational exposure can occur in various use sites, which include commercial/industrial premises, and applications conducted at a residential site.

Occupational handlers of naphthenate salts include handlers applying naphthenate salts directly to outdoor-use textiles (e.g., canvas for tarps and tents and rope); handlers pouring naphthenate salts liquid preservative for textile preservation during manufacturing; wood preservative handlers for pressure- and non-pressure treated wood; and application to in-service utility poles.

a. Occupational Toxicity

The toxicological endpoints used in the occupational handler assessment of the naphthenate salts can be found in Table 2, “Residential and Occupational Toxicological Doses and Endpoints for Naphthenate Salts”, of this document.

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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.

Zinc naphthenate dermal irritation exposures and risks were not estimated for occupational handler exposures. These risks are addressed using personal protective equipment (PPE) requirements already existing on labels. The level of PPE required is based on the toxicity of the end-use product.

To minimize dermal exposures, the minimum PPE required for mixers, loaders, and applicators who use products containing concentrations of zinc naphthenate that result in classification of category I, II, or III for skin irritation potential will be long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of zinc naphthenate in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential. These changes to product labels, if necessary, will occur during the product reregistration process.

The Agency evaluated representative scenarios using maximum application rates listed on naphthenate salts 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) and the Pesticide Handlers Exposure Database (PHED), (USEPA, 1998). The occupational exposure to naphthenate salts was assessed based on the anticipated duration of exposure. Specifically, short-term (1 to 30 days), intermediate-term (30 days to 6 months), or long-term (longer than 6 months) exposure durations were evaluated in the risk assessment. The representative occupational handler scenarios included in Table 9 were assessed to determine dermal and inhalation exposures.

For more information on the assumptions and calculations of potential risks associated with the use of naphthenate salts to workers, see the Occupational Exposure Assessment titled "Occupational and Residential Exposure Chapter for Copper and Zinc Naphthenates in Support of the Reregistration Eligibility Decision (RED) Document for the Naphthenate Salts (RED Case 3099)," dated July 10, 2007.

<u>Low Pressure Spray Applications</u>

For the low pressure spray scenarios (application to outdoor-use textiles and general preservation of wood), the occupational PHED dermal and inhalation unit exposure values for a

handler pouring a pesticide and applying it via a low pressure sprayer (handwand) were used (PHED Scenario 32). The unit exposure values of 100 mg/lb a.i. for ungloved dermal, 0.43 mg/lb a.i. for gloved replicates, and 0.030 mg/lb a.i. for inhalation represent a handler treating low and mid-level targets, generally below the waist (greenhouse benches and shrubs) while wearing a single layer of clothing. The quantity handled depends on the material that is being treated. The following values were used for the different materials based on standard Agency assumptions:

- *Textiles*: 85 lbs (10 gal of ready-to-use product with a density of 8.5 lb/gal); and
- *Application of general wood preservative or coating*: 425 lbs of fluid (50 gallons of ready-to-use product with a density of 8.5 lb/gal).

Roller/brush Applications

For roller/brush scenarios (application to outdoor-use textiles, general preservation of wood and application to in-service wood poles), the occupational PHED dermal and inhalation unit exposure values for paintbrush applications (PHED Scenario 22) were used (single layer of clothing, no respirator). The dermal unit exposures are 180 mg/lb a.i. for ungloved replicates and 24 mg/lb a.i. for gloved replicates. The inhalation exposure value is 0.28 mg/lb a.i. For the roller/brush application scenarios, it was assumed that 42.5 lbs of treatment fluid (approximately 5 gallons with a density of 8.5 lb/gal) are used based on standard Agency assumptions.

It should be noted that no data were identified on exposures to handlers applying product to in-service poles and similar members using a trowel, caulking gun, or pre-manufactured bandage. Exposures for these scenarios were assumed to be represented by the assessment done using unit exposure data for the brush/roller use scenario.

Liquid Pour Applications

For the liquid pour scenario (associated with open-loading in preparation of automated application via dip/spray mechanism for preservation of textiles and similar materials), the CMA dermal unit exposure value of 0.135 mg/lb a.i. (gloved data) and inhalation unit exposure value of 0.00346 mg/lb a.i. for liquid pour of preservative were used. For the liquid pour scenario, it was assumed that 10,000 lbs of textiles are treated per day in open-loading systems based on standard Agency assumptions (USEPA, 2005).

The values are based on two replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. Since no baseline dermal (ungloved) unit exposure data are available for preservative uses in textiles, the baseline dermal exposures were evaluated using the cooling tower CMA data (50.3 mg/lb ai).

Liquid Pump Applications

For the liquid pump scenario (associated with closed-delivery in preparation of automated application via dip/spray mechanism for preservation of textiles and similar materials), the CMA dermal unit exposure value of 0.00629 mg/lb a.i. (gloved data) and inhalation unit exposure value of 0.000403 mg/lb a.i. for liquid pump of preservative were used.

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The values are based on two replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. Since no baseline dermal (ungloved) unit exposure data are available for preservative uses in textiles, the baseline dermal exposures were evaluated using the cooling tower CMA data (0.454 mg/lb ai). For the liquid pump scenario, it was assumed that 10,000 lbs of textiles are treated per day in closed-delivery systems based on Agency standard assumptions (USEPA, 2005).

Airless Spray Applications

For the airless spray scenario, the occupational PHED dermal and inhalation unit exposure values for airless sprayer application (PHED scenario 23) were used (single layer of clothing). The dermal unit exposures are 38 mg/lb a.i. for ungloved replicates and 14 mg/lb a.i. for gloved replicates. The inhalation exposure value is 0.83 mg/lb a.i. For this application scenario, it was assumed that 425 lbs of ready-to-use treatment fluid (approximately 50 gallons of with a density of 8.5 lb/gal) are used based on Agency standard assumptions.

Diptank Operators

Exposures to diptank operators were also assessed using surrogate data from the DDAC study (Bestari et al., 1999). The diptank scenario assessment was conducted differently than for the other job functions because the concentration of DDAC in the diptank solution was provided. The exposure data for diptank operators wearing gloves were converted into unit exposures in terms of mg a.i. for each 1% of concentration of the product. For the naphthenate salts, the application rates range from 25% to 32%. Dermal and inhalation unit exposures were 2.99 and 0.046 mg/1% solution, respectively. The air concentrations presented in the DDAC study were converted to unit exposures using an inhalation rate of 1.0 m^3/hr (light activity) and a sample duration of 8 hrs/day. Based on the use patterns for the naphthenate salts, the exposure scenarios in Table 8 were assessed.

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Table 8. Representative Exposure Scenarios Associated with Occupational Exposures to Naphthenate Salts

Representative Use	Method of Application	Exposure Scenario	Representative EPA Reg. No.	Maximum Application Rate
Material Preservatives				
Direct application to outdoor-use textiles (e.g., canvas used for tarps and tents; ropes, nets)	• (Dipping) [a] • Low-pressure spray • Brush/roller	Handler: IT dermal; ST/IT/LT inhalation	1022-409 (spray)	25% a.i. by weight, ready-to-use (RTU)
			60061-16; 60061-19 (brush)	22% a.i. by weight, ready-to-use (RTU)
Incorporation into textiles during industrial manufacturing	• Liquid pour (associated with automated dip/spray) [b] • Liquid pump (associated with automated dip/spray) [b]		43437-3; 43437-4	11% a.i. by weight (1.2% copper by weight) deposition in treated canvas textile. Incorporation during manufacturing.
Wood Preservatives				
Non-pressure treatment of wood and wood products in wood treatment facilities	<u>Handler Worker Functions</u> • Diptank Operators • Blender/spray operators • Chemical operators <u>Post-Application Worker Functions</u> • Graders • Trim saw operators • Clean-up crews • Construction workers	Handler: IT dermal; ST/IT/LT inhalation Post-application: IT dermal; ST/IT/LT inhalation	1022-409; 1022-522; 9630-31.	<u>Blender/spray operators:</u> 25% a.i. in solution used (RTU product 1022-409); and for wood composite use a 1.4% a.i. solution (1022-522) [i.e., 3% (0.03) w/w * 45.4% a.i. in product = 1.4 % a.i.]. <u>Diptank operators:</u> 25% a.i. RTU (1022-409) and 32% a.i. use-solution (9630-31) [i.e., 1:2 v/v use dilution * 63% a.i. in product = 31.5 ~32 % a.i.]. <u>All other worker functions:</u> 25% a.i. in product (RTU product 1022-409)
Pressure treatment of wood and wood products in wood treatment facilities	<u>Handler Worker Functions</u> • Treatment assistant • Treatment operator <u>Post-Application Worker Functions</u> • Tram setter, stacker	Handler: IT dermal; ST/IT/LT inhalation Post-application: IT dermal;	43437-4	13% a.i. by weight in treatment solution (89% a.i. in product diluted with 7 parts solution by volume) [c]

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Representative Use	Method of Application	Exposure Scenario	Representative EPA Reg. No.	Maximum Application Rate
	operator, loader operator, supervisor, test borer, and tallyman	ST/IT/LT inhalation		
General preservation of wood/lumber in commercial sites (non-pressure treatment applications) [d,e]	• Brush/roller • Airless sprayer [d] • Low-pressure sprayer	Handler: IT dermal; ST/IT/LT inhalation	7424-1; 1022-409	25% a.i. in solution used (RTU products)
Application to in-service utility poles, pilings, posts, and other standing timbers	• Brush, trowel, or caulking/grease gun [f] • Pre-manufactured bandage [f]	Handler: IT dermal; ST/IT/LT inhalation	75341-5 (Highest Use Rate for exterior surface treatments)	20% a.i. by weight in applied product (RTU).

a Handler exposures during dipping/immersion operations for textiles are assumed to be comparable to diptank operations for wood. Therefore this scenario is not directly assessed. Refer to the non-pressure treatment (diptank operator) scenario as representative.

b Exposures to handlers during preparation of dipping solution were assessed assuming a liquid pour (open-loading) or operation of a liquid pump (closed-delivery) associated with automated (large-scale) dipping of textiles in an industrial setting. However, based on the label use instructions, it is possible that manual dipping may also be used for preservation of textiles (e.g., via preparation of small-scale dipping solution by pouring product into a small receptacle and manually dipping textiles). Exposures that may occur as part of manual dipping activity are not assessed here.

c Application rate calculations where concentrated product is diluted assume that the densities of product and solution are approximately equivalent; actual densities of product and solution may vary somewhat.

d The label indicates that applications to existing homes can be made through brush or spray. The airless sprayer method was selected because it is based on applying preservative to the outside of a house in the same manner as one would use an airless paint sprayer, not an aerosolized paint sprayer. It was also assumed that a low-pressure sprayer could be used for applications involving smaller amounts of product or area treated.

e Immersion of wood/lumber is another use application that may occur at commercial sites outside of wood treatment facilities; however, exposures for this scenario are assumed to be subsumed by the non-pressure treatment (diptank operator) scenario.

f No data were identified on exposures to handlers applying products to exterior surfaces of in-service poles using a trowel, or to interior surfaces using a caulking gun or mechanical pump injection, (nor data on other remedial-treatment products such as pre-manufactured bandages/wraps); exposures were assessed using unit exposure data for a brush use scenario as representative of all remedial use patterns. The product selected for this assessment (EPA Reg. No. 75341-5) has the highest use rate for exterior surface treatments where commercial applications can be made by brush (20% ai). A remedial product for use only in filling interior cavities (pre-drilled holes) of poles has a higher application rate of 28% ai (EPA Reg. No. 75341-12) but unit exposure data are unavailable to assess this application method (caulking gun) so the 20% a.i. product is used.

c. Occupational Handler Risk Summary

The occupational handler risk assessment for the antimicrobial uses of the naphthenate salts includes both inhalation and dermal exposure scenarios. The target MOE for intermediate-term dermal handler exposures is 100. The target MOE for short-, intermediate- and long-term inhalation handler exposures is 100.

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For occupational handlers, seven scenarios have dermal risks of concern when no PPE is used; however the risks from these seven scenarios are mitigated if handlers wear gloves. The seven remaining scenarios indicate potential dermal risks of concern when handlers wear gloves.

Since the irritation and systemic effects were not observed in a 90-day dermal toxicity study using copper naphthenate these endpoints only apply to zinc naphthenate. No dermal risk assessment is needed for copper naphthenate but an assessment is required for zinc naphthenate.

For the naphthenate salts, 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 the naphthenate salts, 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 necessary to account for the use of route-to-route extrapolation. Since the MOEs for several scenarios are below 1,000 for the naphthenate salts, confirmatory data are needed.

The occupational handler scenarios are summarized in tables 9 through 14 below. There are several dermal exposure scenarios that present risks of concern for zinc naphthenate (MOE < 100). One scenario is of concern for inhalation exposures (use of airless sprayers to treat existing wood structures) unless a respirator is used. Detailed information on the occupational handler scenarios can be found in the Occupational Exposure Assessment titled "Occupational and Residential Exposure Chapter for Copper and Zinc Naphthenates in Support of the Reregistration Eligibility Decision (RED) Document for the Naphthenate Salts (RED Case 3099).," dated July 10, 2007.

Table 9. Intermediate-Term Dermal Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application			Application Rate (% a.i. by weight)	Quantity Handled/ Treated per day	Dermal Absorbed Daily Dose (mg/kg/day)[c]		IT Dermal MOE[d] (Target MOE = 100)	
		Baseline Dermal[a]	PPE-Gloves Dermal[b]			Baseline Dermal	Glove PPE	Baseline Dermal	Glove PPE
Material Preservatives									
Preservation of outdoor-use textiles	Low-pressure sprayer	100	0.43	25%	85 lbs	30	0.13	3	770
	Brush/roller	180	24	22%	42.5 lbs	24	3	4	33
	Liquid pour	50.3	0.135	11%	10,000 lbs	790	2	0.13	50
	Liquid pump	0.454	0.00629	11%	10,000 lbs	7	0.11	14	910
Wood Preservatives									
General preservation of wood	Brush/roller	180	24	25%	42.5 lbs	27	4	4	25
	Airless sprayer	38	14	25%	425 lbs	58	21	2	5

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Exposure Scenario	Method of Application			Application Rate (% a.i. by weight)	Quantity Handled/ Treated per day	Dermal Absorbed Daily Dose (mg/kg/day)[c]		IT Dermal MOE[d] (Target MOE = 100)	
		Baseline Dermal[a]	PPE-Gloves Dermal[b]			Baseline Dermal	Glove PPE	Baseline Dermal	Glove PPE
Material Preservatives									
	Low-pressure sprayer	100	0.43	25%	85 lbs	30	0.13	3	770
	Low-pressure sprayer	100	0.43	25%	85 lbs	30	0.13	3	770
Application to in-service utility poles	Brush	180	24	20%	42.5 lbs	22	3	5	33

[a]Baseline Dermal: Long-sleeve shirt, long pants, and no gloves. It should be noted that the baseline dermal unit exposures (liquid pour/liquid pump) for the preservation of 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.
[c]Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) * absorption factor (NA for dermal) * application rate * quantity treated / Body weight (70 kg).
[d]MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where IT dermal NOAEL = 100 mg/kg/day].

Table 10: Short- and Intermediate-Term Inhalation Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application	Inhalation Unit Exposure (mg/lb a.i.)	Application Rate (% a.i. by weight)	Quantity Handled/ Treated per day	Inhalation Absorbed Daily Dose (mg/kg/day)[a]	Inhalation ST/IT MOE[b] (Target MOE = 100)	
Material Preservatives							
Preservation of outdoor-use textiles	Low-pressure sprayer	0.03	25%	85 lbs	0.009	3,300	
	Brush/roller	0.28	22%	42.5 lbs	0.04	750	7,500 (PPE)
	Liquid pour	0.00346	11%	10,000 lbs	0.05	600	6,000 (PPE)
	Liquid pump	0.000403	11%	10,000 lbs	0.0063	4,800	
Wood Preservatives							
General preservation of wood	Brush/roller	0.28	25%	42.5 lbs	0.043	700	7,000 (PPE)
	Airless sprayer	0.83	25%	425 lbs	1.3	23	230 (PPE)
	Low-pressure sprayer	0.03	25%	85 lbs	0.009	3,300	
Application to in-service utility poles	Brush/roller	0.28	20%	42.5 lbs	0.034	880	8,800 (PPE)

ST= Short-term; IT = intermediate-term;

[a]Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) * absorption factor (100% (1.0) for inhalation) * application rate * quantity treated / Body weight (70 kg).
[b]MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where ST/IT/LT Inhalation NOAEL = 30 mg/kg/day].

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Table 11. Short- and Intermediate-term Exposures and MOEs for Wood Preservative Blender/Spray Operators

	Dermal Unit Exposure[a] (mg/lb ai)	Inhalation Unit Exposure[b] (mg/lb ai)	Application Rate[c] (% ai by weight)	Wood Slurry Treated[d] (lb/day)	Absorbed Daily Dose[e] (mg/kg/day)		MOEs[f]	
					Dermal	Inhalation	Dermal IT Target=100	Inhalation ST/IT Target = 100
CMA Liquid Pump	0.00629	0.000403	1.4 (wood composites)	177,000	0.22	0.0143	450	2,100
			25 (non-pressure mix/load)		4	0.255	25	120

ST = Short-term duration; IT =Intermediate-term duration.

a. Dermal unit exposure: Single layer clothing with chemical resistant gloves.

b. Inhalation unit exposure: Baseline, with no respirator.

c. The maximum application rate is 1.4% a.i. solution for particle board composite based on product labeling (1022-522); and maximum application rate is 25% a.i. RTU for representative non-pressure treatment mixing/loading (1022-409).

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 (1.4% or 25% a.i. by weight as 0.014 or 0.25) 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 IT NOAEL = 100 mg/kg/day for dermal and ST/ /IT/LT NOAEL = 30 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1000 for inhalation exposure.

Table 12. Short- and Intermediate-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]			MOEs[e]	
				Dermal	Inhalation	Dermal IT Target = 100	Inhalation ST/IT Target = 1000
Chemical Operator (n=11)	9.81	0.0281	0.3125	0.044	0.00013	2,300	240,000

ST = Short-term duration; IT = Intermediate-term duration

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, 1997.

c. Conversion Ratio = 25% Naphthenate Salts / 80% DDAC (based on EPA Reg. No. 1022-409 for 25% a.i. RTU product).

d. Absorbed Daily dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.3125) * absorption factor (NA for dermal and 100% for inhalation)/body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where IT NOAEL = 100 mg/kg/day for dermal and ST/IT/LT NOAEL = 30 mg/kg/day for inhalation]. Target MOE is 100 for dermal and 100 for inhalation exposure.

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Table 13. Short- and Intermediate-Term Exposures and MOEs for Diptank Operators

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 IT Target MOE = 100	Inhalation ST/IT Target MOE = 100
Dipping, with gloves (n=7)	2.99	0.046	32 and 25	1.07-1.37	0.016-0.021	70-90	1,400-1,900

ST = Short-term duration; IT =Intermediate-term duration;

a. The exposure scenario represents a worker wearing long-sleeved shirts, cotton work trousers, and gloves. Gloves were worn only when near the 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, 1997.

c. The typical high-end and maximum application rates for dip application method are 25% (1022-409) and 32% a.i. (9630-31) solutions.

d. Absorbed Daily dose (mg/kg/day) = unit exposure (mg/1% a.i. solution) * percent active ingredient in solution (25 or 32) * absorption factor (NA for dermal and 100% for inhalation) / body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where IT NOAEL = 100 mg/kg/day for dermal and ST/IT/LT NOAEL = 30 mg/kg/day for inhalation]. Target MOE is 100 for dermal exposure and 1,00 for inhalation exposure.

Table 14. Short- and Intermediate -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 IT Target = 100	Inhalation ST/IT Target=100
Treatment Operator (TO)	2.04	0.00257	13	4	0.0048	25	6,300
Treatment Assistant (TA)	0.24	0.000802	13	0.446	0.0015	220	20,000

ST =Short-term duration; IT = Intermediate-term duration..

a. Unit exposure values taken from CCA study and are shown in Table 6.6. It is assumed that the dermal and inhalation exposure to As (per ppm of a.i.) is representative of exposure to Naphthenate Salts.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) x [% Naphthenate Salts in solution (13) x 10,000 (parts per million conversion)] x (0.001 mg/µg) x absorption factor (NA for dermal, 100% for inhalation) / Body weight (70 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where IT dermal NOAEL = 100 mg/kg/day and ST/IT/LT inhalation NOAEL = 30 mg/kg/day]. Target MOE is 100 for dermal exposure and 100 for inhalation exposure.

d. Occupational Post-application Exposure and Risk Summary

Occupational handlers may be exposed to the naphthenate salts by handling non-pressure treated wood and pressure treated wood. All other uses of the naphthenate salts are expected to result in negligible post-application exposure.

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The naphthenate salts are used in products that are intended to preserve wood through non-pressure treatment and pressure treatment methods. It can be applied as a sapstain control to freshly-cut wood. As very little chemical specific data were available regarding typical exposures to the naphthenate salts as a wood preservative, surrogate data were used to estimate exposure 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 a DDAC study (Bestari et al., 1999). All post-application job functions have been combined into one data set because for most activities the sample size from the study was small.

The following scenario has MOEs that are less than 100 for dermal or inhalation exposure and have remaining risks that are of concern:

- handling pressure treated wood (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman).

All other post-application exposures to naphthenate salts are not of concern. The dermal and inhalation exposure scenarios exceed the target MOE of 100 when handlers were wearing short sleeve shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves and, therefore, are not of concern.

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). The DDAC study examined individuals' exposure to DDAC while working with antisapstain 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. Dosimeters and personal air sampling tubes were analyzed for DDAC. Exposure data for individuals performing the same job functions were averaged together to determine job specific averages. Monitoring was conducted using 2 trim saw workers, 13 grader workers, 11 chemical operators, 3 millwrights, and 6 clean-up staff. A summary of the data are shown in Table 15 below.

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Table 15. Post-application Exposures and MOEs for Wood Preservative Graders, Millwrights, Trim Saw Operators, and Clean-Up Crews

Exposure Scenario[a] (number of volunteers)	Dermal UE[b] (mg/day)	Inhalation UE[b] (mg/day)	Conversion Ratio[c]			MOEs[e]	
				Dermal	Inhalation	Dermal IT Target = 100	Inhalation ST/IT Target = 100
Grader (n=13)	3.13	0.0295	0.3125	0.014	0.00013	7,100	230,000
Trim Saw (n=2)	1.38	0.061	0.3125	0.0062	0.00027	16,000	110,000
Millwright (n=3)	12.81	0.057	0.3125	0.057	0.00025	1,800	120,000
Clean-Up (n=6)	55.3	0.60	0.3125	0.25	0.0027	400	11,000

ST = Short-term duration; IT = Intermediate-term duration;

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, 1997.

c. Conversion Ratio = 25% Naphthenate Salts / 80% DDAC (based on EPA Reg. No. 1022-409 for 25% a.i. RTU product).

d. Absorbed Daily dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.3125) * absorption factor (NA for dermal and 100% for inhalation)/body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily dose [Where IT NOAEL = 100 mg/kg/day for dermal and ST/IT NOAEL = 30 mg/kg/day for inhalation]. Target MOE is 100 for dermal and 100 for inhalation exposure.

There is no chemical-specific data on post-application exposure to wood that has been pressure treated with naphthenate salts. Therefore, 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. According to the CCA study, workers wore cotton long-sleeved shirts and cotton trousers (or one-piece cotton coveralls) over the whole-body dosimeters ("plus additional shirts or jackets per typical practice at Site B") and chemical-resistant or work gloves, when appropriate. The post-application job functions (tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman) have been combined into one data set to represent post-application activities because for most activities the sample size is small ($5 \leq n \leq 15$). There are dermal risks of concern for workers handling pressure treated wood that has been treated with naphthenate salts, the results of the analysis are shown in Table 16 below.

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Table 16. Post-application Scenarios Related to Naphthenate Salts Pressure Treated Wood Use

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 IT Target = 100	Inhalation ST/IT Target=100
All Job Functions (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman)	0.74	0.00160	13	1.37	0.0030	70	10,000

ST = Short-term duration; IT = Intermediate-term duration;

a. Unit exposure values taken from CCA study and are shown in Table 6.6. It is assumed that the dermal and inhalation exposure to As (per ppm of a.i.) is representative of exposure to Naphthenate Salts.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) x [% Naphthenate Salts in solution (13) x 10,000 (parts per million conversion)] x (0.001 mg/µg) x absorption factor (NA for dermal, 100% for inhalation) / Body weight (70 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where IT dermal NOAEL = 100 mg/kg/day and ST/IT inhalation NOAEL = 30 mg/kg/day]. Target MOE is 100 for dermal exposure and 100 for inhalation exposure.

6. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to naphthenate salts. EPA consulted the following sources of information for human poisoning incidents related to naphthenate salts use: (1) OPP Incident Data System (IDS) - The Office of Pesticide 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; (4) National Poison Control Centers (PCC) (1993-1996); and (5) Published Scientific Literature on Incidents.

Since 1992, only one incident associated with copper or zinc naphthenate alone has been recorded. The incident report noted a strong odor and adverse health effects were reported following residential application of copper naphthenate containing wood preservative. However, no clear symptoms were described in the report. Some incidents associated with exposure to end-use products containing copper and/or zinc naphthenate have been reported. Although the naphthenates are known to be skin irritants in rabbits, not many skin related incidents have been reported. The reported complaints primarily consist of itchy skin rashes following dermal exposure. Inhalation of vapors of pesticides containing copper naphthenate have been reported to cause nausea, head ache, dizziness, sore throat, dry throat, chest tightness and coughing. It is

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not known if the symptoms reported reflect exposure to naphthenate, the solvent vehicle in the products, volatilized copper, or if the exposure to a strong odor in the compound is perceived as toxic.

The most common symptoms reported for cases of ocular exposure were eye irritation/burning. Eye pain and swelling of eyes also been reported in some cases. No incidents associated with oral exposure have been reported.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The naphthenate salts have several registered use sites that could result in environmental exposures. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for the naphthenate salts 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) in the "Naphthenate Salts: Preliminary Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document.," dated July 12, 2007; the "Ecological Hazard and Environmental Risk Assessment Chapter for Naphthenate Salts Reregistration Eligibility Decision (RED) Document," dated July 17, 2007; and the "Environmental Fate Science Chapter on: Copper Naphthenate," dated July 11, 2007 and the "Environmental Fate Risk Assessment of Zinc Naphthenate for the Reregistration Eligibility Decision (RED)," dated July 11, 2007.

1. Environmental Fate and Transport

The available data for the naphthenate salts indicate that these compounds are very stable in water under aerobic and abiotic conditions, with an estimated half life of more than three months and are highly to moderately immobile in soils with an estimated K_{oc} of over 3000. The naphthenate salts are not highly water soluble, have a low vapor pressure (~ 10^{-4} mm Hg), and have an air/water partition coefficient (estimated Henry Law Constant) of ~ 9.804x 10^{-6}. For these reasons, the naphthenate salts are likely to evaporate from water surfaces to a high degree and likely to contaminate surface water by way of soil run-off. Copper and zinc naphthenate are likely to persist in water and soils around the treated wood.

The estimated log K_{ow} for copper and zinc naphthenate is 4.17. This K_{ow} indicates that the naphthenate salts may be bioaccumulative in aquatic organisms such as fish. Estimated half life of copper naphthenate in air is 8.9 hours. It is anticipated that zinc naphthenate may have a similar value. Neither copper nor zinc naphthenate are likely to be persistent in air.

Laboratory studies on southern yellow pine using copper and zinc naphthenate treated wood stakes has shown that copper and zinc naphthenate leach from non-pressure and pressure treated wood. For both copper and zinc naphthenate, the rates of leaching from the non-pressure and pressure treated wood are highest in pH 5 and lowest at pH 9. The rate of copper and zinc naphthenate that leach from the treated wood is shown below in Table 17.

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Table 17. Rates of Leaching from Non-Pressure Treated and Pressure Treated Wood

	Copper Naphthenate (Amount of Leachate)	Zinc Naphthenate (Amount of Leachate)
Non-pressure Treated Wood	pH 5 = 0.047 ppm/cm^2 /day pH 9 = 0.00048, ppm/cm^2/day	pH 5 = 0.112 ppm/cm^2 /day pH 9 = 0. 0026, ppm/cm^2 /day
Pressure Treated Wood	pH 5 =0.03 ppm/cm^2/day pH 9 = 0.00029 ppm/cm^2/day	pH 5 = 0.019 ppm/cm^2 /day pH 9 = 0.0012 ppm/cm^2 /day

a. Bioaccumulation in Aquatic Organisms

There is no data available to determine if the naphthenate salts are likely to bioaccumulate in aquatic organisms. The following data are needed to determine the bioaccumulation potential of the naphthenate.

- fish bioconcentration study (850.1730).

2. Ecological Risk

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

a. Environmental Toxicity

Toxicity to Birds

To evaluate the acute toxicity to birds, the Agency reviewed two acute oral toxicity studies for the naphthenate salts. These acute oral toxicity studies on the bobwhite quail indicate that the naphthenate salts are relatively nontoxic on an acute oral basis.

The subacute toxicity for the naphthenate salts was determined from four studies conducted on the bobwhite quail and the mallard duck. The results of these studies indicate that the naphthenate salts are relatively nontoxic to avian species through subacute dietary exposure.

Toxicity to Terrestrial Animals

Based on the results of mammalian studies conducted to meet human toxicity data requirements, the naphthenate salts acute toxicity profile is presented in Table 18 below.

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Table 18. Acute Toxicity to Mammalian Species

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral- Rat purity 45.4% -copper naphthenate	00266172	LD_{50} > 501 mg/kg	III
870.110 (§81-1)	Acute Oral- Rat purity 58% -copper naphthenate	433342402	Not determined	N/A
870.1100 (§81-1)	Acute Oral- Rat purity 60%- zinc naphthenate	00244277	LD_{50} > 2000 mg/kg	IV
870.1200 (§81-2)	Acute Dermal- Rabbit purity not determined – copper naphthenate	41140710	LD_{50} > 2000 mg/kg	III
870.1200 (§81-2)	Acute Dermal- Rabbit Purity 60%-zinc naphthenate	00244277	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute Inhalation- Rabbit Purity technical- copper naphthenate	41486301	LC_{50} > 2.966 mg/L	III
870.1300 (§81-3)	Acute Inhalation- Rabbit Purity 60%- zinc naphthenate	00244277	LC_{50} > 11.6 mg/L	IV
870.2400 (§81-4)	Primary Eye Irritation- Rabbit purity 80% -copper naphthenate	00260891	Redness cleared on day 4	III
870.2400 (§81-4)	Primary Eye Irritation- Guinea pig purity 60% -zinc naphthenate	00244277	Redness cleared on day 2	III
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit purity technical –copper naphthenate	41140710	Moderate Irritant	III
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit 60% -zinc naphthenate	00244277	Moderate to Severe Irritant	II
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 58 % - copper naphthenate	41140710	Not a sensitizer.	No
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 60 % - zinc naphthenate	00244277	Primary skin irritant/possible sensitizing agent	No

Toxicity to Aquatic Animals

On an acute basis, the naphthenate salts are moderately toxic to freshwater fish and highly toxic to freshwater invertebrates. No data are available to assess the toxicity of the naphthenate salts to estuarine and marine organisms. Data are needed to evaluate the risks to these species.

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Toxicity to Plants

No data are available to assess the toxicity of the naphthenate salts to aquatic plants. The following data are needed to evaluate the risks to these species: freshwater green alga (*Selenastrum capricornutum*); freshwater diatom (*Navicula pelliculosa*); blue-green cyanobacteria (*Anabeana flow-aquae*); and marine diatom (*Skeletonema costatum*). Other outstanding non-target aquatic plant toxicity tests are: floating freshwater aquatic macrophyte duckweed (*Lemna gibba*) – 850.4400 and rooted freshwater macrophyte rice (*Oryza sativa*) – 850.4225 and 850.4250 (2 tests on seedling emergence and vegetative vigor).

A summary of the submitted acute ecological toxicity data; avian sub-acute oral toxicity data; and aquatic plant toxicity data for the naphthenate salts are provided in Table 19.

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Table 19. Ecological Toxicity of the Naphthenate Salts

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Comments	Reference (MRID No.)
Acute Avian Toxicity					
Bobwhite quail (*Colinus virginianus*)	Copper Naphthenate 9.55%	LD_{50} = >2250 NOAEL = <292	Relatively nontoxic	- 14-day test duration - 19 weeks of age	423486-01
Bobwhite quail (*Colinus virginianus*)	Zinc Naphthenate 14.33%	LD_{50} = >2250 NOAEL = <175	Relatively nontoxic	Supplemental - 14-day test duration - 19 weeks of age - data not provided to support the NOEL	423486-04
Subacute Avian Toxicity					
Bobwhite quail (*Colinus virginianus)*	Zinc Naphthenate 14.33%	LC_{50} (diet) = >5620 NOAEC = 5620	Relatively nontoxic	- 8-day test duration - 10 days of age	423486-05
Mallard duck (*Anas platyrhynchos)*	Zinc Naphthenate 14.33%	LC_{50} (diet) = >5620 NOAEC = 5620	Relatively nontoxic	- 8-day test duration - 10 days of age	423486-06
Bobwhite quail (*Colinus virginianus)*	Copper Naphthenate 9.55%	LC_{50} (diet) = >5620 NOAEC = 1780	Relatively nontoxic	- 8-day test duration - 10 days of age	423486-02
Mallard duck (*Anas platyrhynchos)*	Copper Naphthenate 9.55%	LC_{50} (diet) = >5620 NOAEC = 5620	Relatively nontoxic	- 8-day test duration - 10 days of age	423486-03
Acute Freshwater Fish Toxicity					
Bluegill Sunfish (*Lepomis macrochirus)*	Copper naphthenate 98.9%	LC_{50} = 3.1	Moderately toxic	- 96-hr test duration - static renewal test system	424891-01
Rainbow Trout (*Oncorhynchus mykiss*)	Zinc naphthenate 98.9%	LC_{50} = 1.1 NOAEC = 0.39	Moderately toxic	- 96-hr test duration - static test system	424891-02
Acute Freshwater Invertebrates Toxicity					
Waterflea (*Daphnia magna)*	Copper Naphthenate 95.6%	EC_{50} = 0.34 NOAEC = 0.12	Highly toxic	- 48-hr test duration - static test system	424891-03

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b. Ecological Exposure and Risk

For the ecological exposure and risk assessment, the Agency has only evaluated the naphthenate salts wood preservative use scenarios. Wood preservative uses are considered to be "outdoor uses," which are considered during reregistration.

The EPA performed an environmental risk assessment using estimated environmental concentrations (EECs) for the naphthenate salts, which were developed by modeling the release of the naphthenate salts 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 the naphthenate salts wood preservative use scenarios. The highest EEC of 1.67 mg copper naphthenate per liter of water was calculated for the smallest body of water (1 acre foot). For a 6 foot deep water body, the EEC was calculated as 0.278 mg copper naphthenate per liter of water. The risk estimates represent a higher risk to aquatic organisms in the smallest body of water (1acre foot). 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. Risk estimates for the larger water body (6 feet deep) indicate no acute or chronic concerns for aquatic organisms, and a slight exceedance for aquatic endangered species. This assessment is a conservative, screening level evaluation of the risks to aquatic organisms, including endangered species. Additional data, such as a wood leaching study, could further refine the risk assessment. However, the risks to aquatic organisms from use of the naphthenate salts are likely to be low.

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 slightly exceeded for freshwater fish (RQ of 0.54). The acute LOCs were exceeded for freshwater aquatic invertebrates (RQ of 4.91) in small bodies of water (1 acre foot). However, in bodies of water 6 acre feet in size or greater, the acute LOCs (0.5) were not exceeded for freshwater fish (RQ of 0.09). The acute LOCs were indicate a slight exceedance for freshwater aquatic invertebrates (RQ of 0.82). However, risks to endangered freshwater fish and aquatic invertebrates (RQ is 0.09 and 0.82, respectively**)** were of concern in larger bodies of water. 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 the naphthenate salts is likely to be low.

There were no acceptable acute toxicity studies for estuarine/marine fish (OPPTS 850.1075, estuarine marine shrimp (OPPTS 850.1035 and mollusks (OPPTS 850.1025). Therefore, the acute aquatic estuarine/marine species assessment is incomplete due to lack of toxicity data.

Estuarine/marine toxicity studies are needed to fulfill guideline requirements. Therefore, the aquatic toxicity assessment for estuarine/marine species could not be assessed due to lack of data.

Plants

No aquatic or terrestrial plant toxicity studies are available for the naphthenate salts. Therefore, the risks to aquatic or terrestrial plants could not be conducted. As noted previously, data are needed to evaluate the potential risks.

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, label language must be added to prohibit use of wood that is treated with the naphthenate salts in the construction of beehives.

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).

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Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination.

Using a screening-level model to assess potential exposure from wood preservative uses, potential risks to Listed Species appear to be relatively low. The model is only intended to provide a screening-level assessment, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations. Further refinement of the model is recommended before any regulatory action is taken regarding the wood preservative uses of the naphthenate salts. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors (see General Risk Mitigation, below). Due to these circumstances, the Agency defers making a determination for the wood preservative uses of the naphthenate salts until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the naphthenate salts will be revised, and the risks to Listed Species will be reconsidered. 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 for the naphthenate salts are such that the Agency defers making 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.

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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 naphthenate salts as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing naphthenate salts.

The Agency has completed its assessment of the occupational, residential, and ecological risks associated with the use of pesticide products containing the active ingredients napthenate salts. Based on a review of these data and on public comments on the Agency's assessments for the active ingredients naphthenate salts, the Agency has sufficient information on the human health and ecological effects of naphthenate salts 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 naphthenate salts-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of naphthenate salts 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 napthenate salts and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of naphthenate salts, the Agency has determined that napthenate salts 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 naphthenate salts. If all changes outlined in this document are incorporated into the product labels, then all current risks for napthenate salts will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, the EPA worked with stakeholders and the public to reach the regulatory decision for naphthenate salts. The EPA released its preliminary risk assessment for naphthenate salts for public comment on July 23, 2007. The Agency received comments from registrants and wood treaters during the 60-day public comment period on the naphthenate salts risk assessment and supporting science documents, which closed on September 24, 2007.

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C. Regulatory Position

The EPA assessed the risks associated with naphthenate salts use. 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 naphthenate salts 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 naphthenate salts from all possible sources.

a. Determination of Safety to U.S. Population

The Agency has determined that the naphthenate salts, 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 naphthenate salts. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of the naphthenate salts.

A dietary risk assessment was not conducted for naphthenate salts because the use patterns are not expected to result in dietary exposure. Therefore, naphthenate salts do not pose a dietary risk. Similarly, the Agency does not anticipate significant contamination of drinking water as a result of the registered uses of naphthenate salts and did not conduct a drinking water assessment.

The Agency did consider the potential pathways of non-dietary exposure to residents in determining the need to conduct an aggregate assessment. Scenarios considered for the aggregate assessment include: short-term inhalation exposure by adult handlers and short-term dermal and incidental oral post-application exposure by children from contact with treated lumber. Because the endpoints for the short-term dermal and incidental oral routes of exposure were based on route-specific studies resulting in different effects, separate route-specific aggregate assessment are appropriate. However, only one exposure scenario was identified for each route of exposure. Therefore, the Agency did not conduct an aggregate assessment for the naphthenate salts. Based on the risk assessment and mitigation measures contained in this document residential exposures do not pose a risk of concern.

b. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of naphthenate salts, 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 naphthenate salts residues in this population subgroup.

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The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water or residential exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of the napthenate salts as active ingredients. Therefore, an FQPA hazard analysis is not necessary at this time.

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

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D. Regulatory Rationale

The Agency has determined that the napthenate salts are 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 napthenate salts. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

A dietary risk assessment was not conducted for napthenate salts because the use patterns are not expected to result in residues on food and, thus, dietary exposure. Therefore, napthenate salts do not pose as a dietary risk and no mitigation measures are needed at this time.

b. Drinking Water Risk Mitigation

The napthenate salts are 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. Napthenate salts are not used for potable water treatment and effluents containing this chemical are not expected to significantly contaminate 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 napthenate salts as wood preservative coatings and water repellents (applied via brush, roller and low pressure coarse spray). Inhalation risks were not of concern. Short-term (ST) dermal risks of concern were identified for zinc napthenate for applicators using a brush or roller and low pressure sprayers at the maximum application rate (ST dermal MOEs of 17 and 25, target MOE of 30).

No dermal risks of concern were identified for applicators using copper napthenate products. The difference between zinc napthenate and copper napthenate is based on the fact that there were toxicological endpoints identified for dermal exposures to zinc napthenate based on the available data but there were no toxicological endpoints for dermal exposure identified for copper napthenate using available data.

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To mitigate the dermal risks the maximum application rate for residential zinc napthenate products (i.e., 1 gallon containers of diluted product sold to consumers) must be reduced to 16% active ingredient by weight. This will result in acceptable MOEs.

ii. Post-Application Risk Mitigation

For the residential post-application assessment, representative scenarios were assessed for contact with surface residues from wood treated with naphthenate salts (dermal and incidental oral exposure to children). No risks of concern were identified for wood preservatives uses. 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 MOE of 10 with a 100% transfer factor) for zinc naphthenate. Copper naphthenate products do not pose risks of concern. The Agency believes that actual residues available for exposures will be substantially less that this worst-case assessment. The Agency also assessed exposures assuming a transfer rate of 5% which the Agency believes is more representative of actual levels of potential exposure. Using the 5% transfer assumption, the risks were well above the target MOE of 30 (MOE = 200) and, therefore, not of concern. To confirm that the 5% assumption is not an underestimate of potential exposure, a leaching study using treated textiles is required as well.

The Agency also assessed potential incidental oral exposures to children mouthing treated tenting. The short-term oral MOE for this scenario are of concern (MOE = 10, Target MOE = 100). However, the technical registrants of napthenate salts have indicated that as a textile preservative, napthenate salts are to be used only in military/industrial settings. To address the oral 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 incidental oral risks of concern.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

As mentioned above, there is a difference between zinc napthenate and copper napthenate in terms of dermal exposures and risks. This difference is based on the fact that there were toxicological endpoints identified for dermal exposures to zinc napthenate (irritation in the ST and systemic effects in the IT) based on the available data but there were no toxicological endpoints for dermal exposure identified for copper napthenate using available data. Therefore a dermal assessment for occupational handlers was not conducted for copper napthenate.

It should be noted that for the dermal route, only intermediate-term (IT) dermal exposure is assessed for occupational handler scenarios since the IT toxicity endpoint selected is based on systemic effects. Short-term (ST) dermal exposures were not evaluated because the ST toxicity endpoint is based on dermal irritation. Dermal irritation exposures and risks will be mitigated using label-specified personal protective equipment (PPE) or default PPE requirements based on

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the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products that result in classification of category I, II, or III for skin irritation potential will be a long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron.

Occupational handler dermal risks (IT) of concern were identified for zinc napthenate for several use scenarios (Target MOE = 100). These include the preservation of textiles using a brush/ roller (MOE = 33) or liquid pour method of application (MOE=50); treatment of exterior wood structures using a brush/roller (MOE = 25) or an airless sprayer (MOE = 5); remedial treatment of utility poles (MOE = 33); blender/spray operators (MOEs = 70 to 90); and pressure treatment operators (MOE = 25).

To mitigate the dermal risks of concern for zinc napthenate the following steps must be taken:

- Limit application for preservation of outdoor-use textiles for zinc naphthenate products to low-pressure sprayer and liquid pump applications. Application to outdoor-use textiles using a brush/roller or liquid pour is prohibited;
- Remove pressure treatment and remedial treatment of utility poles from all zinc napthenate labels;
- Limit application for general preservation of wood for zinc naphthenate products to low-pressure sprayer applications. Application for general preservation of wood using a brush/roller or airless sprayer is prohibited;
- Reduce maximum application rate for use in wood preservative applications by blender spray operators to 15% a.i. by weight. Applicators must wear long sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and chemical resistant apron;
- Reduce maximum application rate for use in dip tanks operations to 25 % a.i.; and
- Require chemical resistant gloves to be used on all zinc napthenate products.

Short- and intermediate-term (ST/IT) inhalation risks of concern were identified for both copper and zinc napthenate for one occupational handler use scenarios; treatment of exterior wood structures using an airless sprayer (MOE = 23). For this assessment, the Agency assumed that a commercial applicator would handle 50 gallons of dilute product per day. Based on comments received during the public comment period, the Agency believes that it is more likely that an applicator will handle a maximum of 10 gallons of dilute product which corresponds to the amount needed to treat two entire roofs. A typical work day would not be expected to exceed two roofs. Based on this assumption, the MOEs for inhalation exposure for both copper and zinc napthenate are not of concern. Additionally, it is not likely that an applicator would be using an airless sprayer for an operation such as this.

Confirmatory inhalation toxicity data are needed to refine the occupational inhalation risks. A target inhalation MOE of 1,000 was selected to determine the need for additional inhalation data because the inhalation endpoint was based on an oral NOAEL. For inhalation MOEs below the target of 1,000, it is Agency policy to request confirmatory inhalation toxicity data to further refine potential risks because the endpoint is based on an oral NOAEL.

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ii. Post-Application Risk Mitigation

Occupational post-application dermal risks (IT) of concern were identified for zinc napthenate (Target MOE = 100) for workers in pressure treatment facilities. In order to mitigate these risks the pressure treatment use as a wood preservative must be removed from all zinc napthenate product labels.

2. Environmental Risk Management

For the wood preservative uses of the naphthenate salts, the Agency used a Tier I screening model to estimate exposures that could result from this use. Levels of concern (LOCs) for aquatic organisms ranged from 0.54 to 4.91 for small water bodies and 0.09 to 0.82 for large water bodies. The Agency believes that the large water body scenario is more representative of actual exposure potential because 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. Further, based on the conservative nature of the models, the Agency does not anticipate significant exposures to non-target aquatic organisms. Therefore, the risks to aquatic organisms from naphthenate salts appear to be low.

It should be noted that the Tier I model used for the ecological hazard and risk assessment has inherent assumptions and uncertainties that may result in over or under estimation of exposure levels. Additional information, including wood leaching data and non-target organism data 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:

> 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 naphthenate salts antisapstain wood preservative product labels to incorporate the required label language, which will help mitigate ecological risks of concern. The following statement must be placed on all antisapstain products to decrease leaching risks:

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"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/zinc napthenate 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 naphthenate salts. 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

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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.

Using a screening-level model to assess potential exposure from wood preservative uses, potential risks to Listed Species appear to be relatively low. The model is only intended to provide a screening-level assessment, and, as such, has inherent uncertainties and limitations which may result in inaccurate exposure estimations. Further refinement of the model is recommended before any regulatory action is taken regarding the wood preservative uses of the naphthenate salts. Additionally, impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and runoff when wood is stored outdoors (see General Risk Mitigation, below). Due to these circumstances, the Agency defers making a determination for the wood preservative uses of the naphthenate salts until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the naphthenate salts will be revised, and the risks to Listed Species will be reconsidered.

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 for the napthenate salts are such that the Agency defers making 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

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

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V. What Registrants Need to Do

The Agency has determined that the naphthenate salts are 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 24). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

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

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

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

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

Within the time limit specified in the generic DCI:

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

Please contact Diane Isbell at (703) 308-8154 with questions regarding generic reregistration.

By US mail:

Document Processing Desk
Diane Isbell
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
Diane Isbell
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

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For end-use products containing the naphthenate salts as an active ingredient, the registrant needs to submit the following items for each product.

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

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

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

Within eight months from the receipt of the PDCI:

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

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

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

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

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

By US mail:

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

By express or courier service:

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

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A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of the naphthenate salts have 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.

Toxicity Data:

- Inhalation toxicity study (90-day) (870.3465) (zinc and copper naphthenate)

Occupational and Residential Exposure Data:

- Dermal Outdoor Exposure and Dermal Indoor Exposure (875.1100 and 875.1200);
- Inhalation Outdoor Exposure and Inhalation Indoor Exposure (875.1300 and 875.1400);
- Product Use Information (875.1700 and 875.2700); and
- Description of Human Activity (875.2800).

Ecological Data:

- Acute aquatic invertebrate study (850.1010) (zinc naphthenate);
- Estuarine/marine fish acute study (850.1075) (both copper and zinc naphthenate);
- Estuarine/marine shrimp acute study (850.1035) (both copper and zinc naphthenate);
- Estuarine/marine mollusk acute study (850.1025) (both copper and zinc naphthenate);
- Freshwater green alga (850.5400) (both copper and zinc naphthenate);
- Freshwater diatom (850.5400) (both copper and zinc naphthenate);
- Blue-green cyanobacteria (850.5400) (both copper and zinc naphthenate);
- Marine diatom (850.5400) (both copper and zinc naphthenate);
- Freshwater floating macrophyte duckweed (850.4400) (both copper and zinc naphthenate);
- Freshwater rooted macrophyte rice seedling emergence (850.4225) (both copper and zinc naphthenate);
- Freshwater rooted macrophyte rice vegetative vigor (850.4250) (both copper and zinc naphthenate); and
- Wood leaching study (AWPA E11-06) (both copper and zinc naphthenate).

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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 25, 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 25, 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 naphthenate salts RED. The following table describes how language on the labels should be amended.

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Table 20. 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 pesticide is toxic to aquatic invertebrates, shrimp, and oysters/clams. 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 Residential Use		
Applications preservative to textiles and wood products	"The application rate for zinc naphthenate applied to textiles or wood products using the low pressure sprayer or a brush/roller shall be limited to 16%."	
End Use Products Intended for Occupational Use		
PPE Requirements	"Applicators must wear chemical resistant gloves while handling or applying naphthenate salts." "Applicators must wear organic vapor respirators while applying naphthenate salts with an airless sprayer." "Blender/spray operators must wear organic vapor respirators while applying naphthenate salts to non-pressure treated wood."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
For all antisapstain end-use products	"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
For all wood preservative uses	"Wood treated with copper or zinc naphthenate shall not be used in the construction of beehives."	This language is to be included in the Environmental Hazards section of the label

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For all diptank wood preservative uses	"The application rate for wood treated with copper or zinc naphthenate in a diptank shall not exceed 25%."	
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 naphthenate salts, are to be used only in military or industrial settings. Treated textiles are for non-residential/military use only."	

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VI. APPENDICES

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Appendix A: Use patterns Eligible for Reregistration
Napthenate Salts

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials preservatives				
Rope, burlap, canvas including, nets(not including fishing nets), seines, tents, awnings, tarpaulins Textiles	Ready to use Reg: 1022-409 Reg: 1719-43 Reg: 43437-4 Reg: 71992-5 Reg:71992-3 Reg: 71992-1 Reg: 71992-4 Reg: 1719-39 Reg: 1719-44* Reg: 1719-38*	Brush , dip, roller or spray	Materials should be dipped or sprayed until wet	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the labeling
Particle board, insulation board, and other wood base fiber and particle materials	Ready to use Reg: 1022-522	Brush, dip, roller, or spray	Mix with furnish resin or binding agent at 1 to 3% based on dry weight of wood	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the labeling

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Wood preservatives				
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members, railroad ties	Ready to use (paste) Reg: 1022-579 Reg: 1022-536 Reg: 71653-1 Reg: 75341-5 Reg: 75341-13	Brush ,trowel, caulking gun, or roller, Bandage, Wrap	Apply to form a 1/16 inch thick layer on the surface to be treated, or by application to "Pol nu Paper" to create a bandage Bandages may be used to cover ground line areas of structures in bands typically 18 to 22 inches in height For railroad ties apply a 1/8 inch thick layer and cover the area with a tie plate the same size as the treated area leaving no -exposed preservative	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the labeling
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members, all exterior wood exposed to moisture or weather Wooden boat hulls, piers	Ready to use Reg: 1022-49 Reg: 43437-1 Reg: 1022-518 Reg;1022-522 Reg: 1022-571 Reg: 7424-9 Reg:7424-1 Reg: 1022-523	Brush, dip, roller , or spray	Dip treatment is the most effective. A three minute immersion is adequate for most applications. 12 to 48 hours immersion time is required for wood placed in contact with the soil or used in construction of boats piers and other large wooden structures Brush, roller or, spray treatments are satisfactory	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the labeling

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(Con) (Exterior use only) Lumber, timber's, posts, poles, and other wooden members, all exterior wood exposed to moisture or weather Wooden boat hulls, piers	Reg: 577-545 Reg: 577-541 Reg: 1022-507 Reg: 10465-34 Reg: 66591-1 Reg: 71992-5 Reg: 71992-4 Reg: 71992-2 Reg: 75340-4 Reg: 60061-16 Reg: 60061-19 Reg:1719-38* Reg: 66591-3* Reg: 60061-9*		for above ground applications, but should be used for ground contact applications only when dipping is not possible. In such cases, apply at least 2 coats by brush, roller, or spray treatments allowing at least 1 hour between each coat.	
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members, wooden boat hulls, piers	Soluble Concentrate Reg: 1719-43 Reg: 75341-	Brush, dip, roller , spray, or pressure treatment	Mix 1 gallon of emulsion with 1 to 3 gallons of water. May be applied by brushing freely , spraying	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	11 Reg: 75341-12 Reg: 1022-528 Reg: 9630-12 Reg: 9630-31 Reg: 9630-11 Reg: 71992-3 Reg: 43437-3* Reg: 9630-10* Reg: 9630-21*		or dipping in a tank, most effective when wood is unpainted dry and clean Mix to a 17% to 33%by weight solution, a 17% solution is 4.9 to 6.7 parts solvent per part of product, and a 33% solution is two to three parts of solvent per part of product. Dip treatment is the most effective. A three minute immersion is adequate for most applications. 12 to 48 hours immersion time is required for wood placed in contact with the soil or used in construction of boats piers and other large wooden structures Brush, roller or, spray treatments are satisfactory for above ground applications, but should be used for ground contact applications only when dipping is not possible.In such cases, apply at least 2	labeling

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			coats by brush, roller, or spray treatments allowing at least 1 hour between each coat. Dilute with 3 volumes of water to obtain 2% copper metal or 7 volumes of water to obtain 1% copper metal Above ground contact: For wood used above ground in critical (structural) applications or under more severe exposure conditions where it is subject to extended periods of wetting, extended soaking or pressure treatment in accordance with AWPA Standards* with a solution containing 0.5 to 1.0 percent by weight copper metal to a retention in the wood of 0.4 to 1.0 pounds copper metal per cubic foot is recommended Ground contact: For wood uses in ground contact, extended soaking or pressure treatment in	

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			accordance with AWPA Standards* with a solution containing .75 to 1.0 percent by weight copper metal to a retention in the wood of .04 to 1.0 pounds copper metal per cubic foot is recommended	
	Formulation Reg: 1022-568 Reg: 9630-8 Reg: 9630-5 Reg: 9630-4 Reg:9630-6* Reg: 9630-7*	Brush, dip, roller , or spray Pressure treatment	Dilute with 3 volumes of water to obtain 2% copper metal or 7 volumes of water to obtain 1% copper metal Above ground contact: For wood used above ground in critical (structural) applications or under more severe exposure conditions where it is subject to extended periods of wetting, extended soaking or pressure treatment in accordance with AWPA Standards* with a solution containing 0.5 to 1.0 percent by weight copper metal to a retention in the wood of 0.4 to 1.0 pounds copper metal per cubic foot	For exterior use only, treated wood should not come in contact with food, feed, or potable water. It is a violation of federal law to use this product in a manner inconsistent with the labeling

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Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			is recommended Ground contact: For wood uses in ground contact, extended soaking or pressure treatment in accordance with AWPA Standards* with a solution containing .75 to 1.0 percent by weight copper metal to a retention in the wood of .04 to 1.0 pounds copper metal per cubic foot is recommended	

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APPENDIX B: Naphthenate Salts (3099)

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

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

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

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

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

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

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) PRPDICT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		40996503 41708001 40317001 40996501
830.1600 830.1620 830.1650	61-2 A	Starting Materials and Manufacturing Process		40996503 41708001 40317001 40996501
830.1670	61-2 B	Formation of Impurities		40996503 41708001
830.1670	61-3	Discussion of Formation of Impurities		40996503 40317001 40698401 40996501
830.1700	62-1	Preliminary Analysis		40996503 42125201 40317001 40698401
830.1750	62-2	Certification of Limits		40996503 42125201 40317001 40698401
830.1800	62-3	Analytical Method		40996503 42125201
830.6302	63-2	Color		40996503 42118901 41704302
830.6303	63-3	Physical State		40996503 42118901 41704302

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.6304	63-4	Odor		40996503 42118901 41704302
830.7200	63-5	Melting Point		40996503 42118901
830.7220	63-6	Boiling Point		40996503 42118901 41704302
830.7300	63-7	Density		40996503 42118901 41704302
830.7840 830.7860	63-8	Solubility		40996503 42118901 41704302
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		40996503 41032503
830.7000	63-12	pH		40996503 41704302
830.6313	63-13	Stability		40996503 42118901
830.6314	63-14	Oxidizing/Reducing Action		40996503 Data Gap
830.6315	63-15	Flammability		40996503 44677202
830.6316	63-16	Explodability		40996503 Data Gap
830.6317	63-17	Storage Stability		40996503 40317001
830.6318	63-18	Viscosity		40996503 44677202

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.6319	63-19	Miscibility		40996503 44677202
830.6320	63-20	Corrosion Characteristics		40996503 42049602 42688702
830.6321	63-21	Dielectric Breakdown Voltage		40996503 Data Gap
ECOLOGICAL EFFECTS				
850.2100	71-1 A	Avian Acute Oral Toxicity Test - Quail/Duck		42348601 42348604
850.2200	71-2	Avian Acute Dietary		42348602 42348603 42348605 42348606 42489101 42489102
850.1075	72-1 A	Fish Acute Toxicity - Bluegill		42489102
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout		Data Gap
850.1010	72-2 A	Acute Aquatic Invertebrate Toxicity		42489103 Data Gap (zinc naphthenate)
850.1025	72-3 A	Estuarine/Marine Toxicity Mollusk		Data Gap
850.1035	72-3 B	Estuarine/Marine Toxicity Shrimp		Data Gap
850.1045	72-3 C	Estuarine/Marine Toxicity Shrimp		Data Gap
850.1400	72-4 A	Early Life Stage Fish, Freshwater		Data Gap (reserved)
850.1350	None	Mysid Chronic Toxicity Test		Data Gap (reserved)

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.1300	72-4 B	Life Cycle Invertebrate		Data Gap (reserved)
850.1730	72-6 165-4	Fish Bioconcentration Study		Data Gap (reserved)
850.1735	None	Whole Sediment Acute Toxicity Invertebrates, Freshwater		Data Gap (reserved)
850.1740	None	Whole Sediment Acute Toxicity Invertebrates, Estaurine		Data Gap (reserved)
850.3030	141-2	Honey Bee Residue on Foliage		Data Gap
850.4225	123-1	Seeding Emergence		Data Gap
850.4250	123-1	Vegetative Vigor		Data Gap
850.4400	122-2 123-2	Aquatic Plant Toxicity Test Using Lemna spp. Tiers I and II		Data Gap
850.5400	122-2 123-2	Algal Toxicity Tiers I and II		Data Gap
AWPA E11-06	None	Wood Leaching Study		Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity		244277 (acc#) 266172 (acc#)
870.1200	81-2	Acute Dermal Toxicity – Rat Acute Dermal Toxicity - Rabbit		244277 (acc#) 41140710
870.1300	81-3	Acute Inhalation Toxicity - Rat		244277 (acc#) 41486301
870.2400	81-4	Acute Eye Irritation		244277 (acc#) 260891 (acc#)

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.2500	81-5	Acute Dermal Irritation		41400704 244277 (acc#) 260891 (acc#)
870.2600	81-6	Skin Sensitization		41444401 244277 (acc#)
870.3250	82-3	90 Day Dermal-Rodent		41615001 41676101
870.3465		Inhalation Toxicity Study - Rat		Data Gap
870.3700	83-3 A	Prenatal Developmental Toxicity - Rat		41615002 41615101
870.5100	84-2	Mutation		41400701 41400702 41400703 41402502 41402503 41402504
ENVIRONMENTAL FATE				
None	None	Special Leaching Study		43851101 44095101
OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.1100	230	Dermal Exposure - Outdoor		Data Gap
875.1200	231	Dermal Exposure – Indoor		Data Gap
875.1300	232	Inhalation Exposure - Outdoor		455021101
875.1400	234	Inhalation Exposure - Indoor		455021101

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DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
875.1700 875.2700		Product Use Information		Data Gap
875.2400	133-3	Dermal Exposure		45524304
875.2500	133-4	Inhalation Exposure		45524304
875.2800		Description of Human Activity		Data Gap

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Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 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 docket initially contained the July 12, 2007 draft 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 www.regulations.gov

These documents include:

- Napthenate Salts Draft Risk Assessment; Notice of Availability, June 25, 2007.

Risk Assessments and Supporting Documents:

- Naphthenate Salts: Draft Risk Assessment Document. PC Codes: 023102, 088301, 863508, 900436 and 025101, Case #3099. Antimicrobials Division, September 25, 2007, Timothy F. McMahon, Ph.D., Najm Shamim, Ph.D., Siroos Mostaghimi, Ph.D., Jonathan Chen, Ph.D., Genevieve Angle, Biologist.
- Dietary Exposure Assessment of Copper Napthenate as a wood preservative. Antimicrobials Division, February 20, 2007, A. Najm Shamim, Ph.D.
- Dietary Exposure Assessment of Zinc Napthenate as a wood preservative. Antimicrobials Division, February 20, 2007, A. Najm Shamim, Ph.D.
- Ecological Hazard and Environmental Risk Assessment Chapter for Naphthenate Salts, Antimicrobials Division, July 17, 2007, Genevieve Angle, Biologist.
- Occupational and Residential Exposure Chapter for Copper and Zinc Naphthenates, (RED Case 3099), Antimicrobials Division, September 25, 2007, Doreen Aviado, Biologist.
- Naphthenate Salts Toxicity Chapter for PC Codes: 023102, 088301, 863508, 900436, 025101. Antimicrobials Division, September 25, 2007, Timothy F. McMahon, Ph.D.
- Environmental Fate Risk Assessment of Copper Naphthenate, (RED Case 3099), Antimicrobials Division, February 13, 2007, A. Najm Shamim, Ph.D.
- Environmental Fate Risk Assessment of Zinc Naphthenate, (RED Case 3099), Antimicrobials Division, February 20, 2007, A. Najm Shamim, Ph.D.
- Incident Report Associated with Copper and/or Zinc Naphthenate, (RED Case 3099), Antimicrobials Division, May 3, 2007, Jonathan Chen, Ph.D.

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

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00244277	Bioresearch, Inc. (1980): Acute Inhalation Toxicity Study. Project #:80- 2171A.
00244277	Bioresearch, Inc. (1980): Acute Oral Toxicity Study. Project #:80-2171A.
00244277	Bioresearch, Inc. (1980): Dermal Irritation Study. Project #:80-2171A.
00244277	Bioresearch, Inc. (1980): Dermal Sensitization Study. Project #:80-2171A.
00244277	Bioresearch, Inc. (1980): Eye Irritation Study. Project #:80-2171A.
00260891	Applied Biological Sciences Laboratory, (1975): Study # 2778.
00266172	Cannon Laboratories, Inc. (1980): Acute Oral Toxicity. Project #: OF- 7374.
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40996503	West, M. (1989). Product Chemistry for Chapco Z Nap 8-0. Unpublished study prepared by Chapman Chemical Co. 4 p
41140710	Angerhofer, R.A. and L.W. Metger: Phase 3 Preliminary Assessment of the Relative Toxicity of Copper Naphthenate. Acute Studies: Acute Oral and Dermal Toxicity Studies.
41140710	Angerhofer, R.A. and L.W. Metger: Phase 3 Preliminary Assessment of the Relative Toxicity of Copper Naphthenate. Acute Studies: Primary Skin Irritation and Dermal Sensitization Studies.

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41400702 Putnam, D.L. and Morris. M.J. (1990): Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells. Test Article Zinc Naphthenate. Microbiological Associates, Inc, Rockville, MD. Study No. T9036.337.

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41402502 Harbell, J.W. (1990): L5178Y TK Mouse Lymphoma Mutagenesis Assay with Confirmation. Test Article Copper Naphthenate. Microbiological Associates, Inc, Rockville, MD. Study No. T9037.701.

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Appendix E. Generic Data Call-In

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

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Appendix F. Product Specific Data Call-In

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

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

The Agency will complete the batching for Naphthenate Salts at a later date.

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

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

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

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

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

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

    b. 84-1 Clarification of Label Improvement Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

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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.

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