Docket Number: EPA-HQ-OPP-2010-0455
www.regulations.gov

United States
Environmental Protection
Agency

Chemical Safety
and Pollution Prevention
(7510P)

September 2010

Naphthenate Salts (copper naphthenate and zinc naphthenate) Summary Document: Registration Review

Naphthenate Salts (copper naphthenate and zinc naphthenate)
Summary Document
Registration Review: Initial Docket
September 2010

Case # 3099

Approved By:

Joan Harrigan-Farrelly
Director, Antimicrobials Division

Date:

9/10/10

TABLE OF CONTENTS

Naphthenate Salts (copper naphthenate and zinc naphthenate)
Registration Review Team

Human Health & Environmental Effects
Nathan Mottl
Srinivas Gowda

Risk Management
Monisha Harris
Lance Wormell

Office of General Counsel
Philip Ross

I. PRELIMINARY WORK PLAN – Naphthenate Salts (copper naphthenate and zinc naphthenate)

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (USEPA, EPA, or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of naphthenate salts (copper naphthenate and zinc naphthenate).

There are two active ingredients in the naphthenate salts case 3099: copper naphthenate (PC Code 023102) and zinc naphthenate (PC Code 088301). Although the case name groups these chemicals using the term "naphthenate salts," throughout this document and the supporting documents for this case the compounds will be named individually as "copper naphthenate" and "zinc naphthenate" to avoid potential confusion. Copper and zinc naphthenate are both fatty acid salts also known as metal soaps or copper and zinc soaps, which are practically insoluble in water, soluble in organic solvents, and have no measurable vapor pressures.

Copper naphthenate was first registered with the Agency in 1951. There are 30 registered copper naphthenate products. These are registered for use as a material preservative (rope, burlap, canvas products including, nets (except fish nets), seines, tents, awnings, textiles, particle board, insulation board, and other wood base fiber and particle materials tarpaulins) and as a wood preservative (lumber, timbers, posts, poles, and other wooden members, all exterior wood exposed to moisture or weather, wooden boat hulls, piers).

Zinc naphthenate was first registered with the Agency in 1975. There are 10 registered zinc naphthenate products. Zinc naphthenate products are registered for use as a wood preservative (foundations, boats, construction posts, docks & piers, door frames, doors, fence posts, fences, fencing, end cuts, foundation timbers greenhouse wood and stakes, house siding, landscape logs lawn furniture, millwork, planking, planter boxes, plywood, poles, porches, posts, pressure treated wood end cut protection, roofs, shakes, shingles, sidings, sills, stairs, structural logs, structural lumber; structural timber, subflooring, windows and frames) and a material preservative (non-apparel fabrics, ropes, fishnets, twine, canvas, burlap and other non-apparel fabric material).

A Reregistration Eligibility Decision (RED) for copper and zinc naphthenate salts was issued by EPA in September 2007. The RED can be located at http://www.epa.gov/pesticides/reregistration/status.htm.

Risk Assessment Status & Anticipated Data Needs

Human Health Risk Assessment Status and Anticipated Data Needs

The Agency has reviewed all the available information on toxicology and human exposure regarding copper and zinc naphthenate and does not anticipate that additional data will be needed for this registration review case.

Further human health information is available in the document titled "Human Health Effects Data for the Copper and Zinc Naphthenate Registration Review Decision," dated July 19, 2010.

Dietary and Drinking Water Assessment

Dietary Exposure

EPA does not anticipate conducting dietary (food) risk assessments because there are no registered food use tolerances for the active ingredients, no registered food uses, and no indirect food uses. However, a drinking water assessment is expected.

Drinking Water Exposure

Copper and zinc naphthenate products are registered for use in treated wood used to construct structures that may result in drinking water (e.g., docks and piers). The Agency will model environmental concentrations of the wood preservative uses of copper and zinc naphthenate in surface water during the registration review risk assessment process and will conduct a drinking water assessment.

Tolerances

There are no tolerances or exemptions from tolerances for the copper and zinc naphthenate active ingredients and no registered food uses. There are inert exemptions from tolerances for copper naphthenate. However, inert exemptions from tolerances are not addressed in this registration review.

Aggregate and Cumulative Exposure

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, as well as non-occupational pesticide exposures. Food exposures of concern are not anticipated based on the fact that copper or zinc naphthenate are not expected to be introduced into food, there are no food use tolerances for the active ingredient, no registered food uses, and no indirect food uses. The Agency will conduct surface water modeling and a drinking water assessment. The Agency expects to conduct a residential assessment to examine hand-to-mouth and dermal exposures to children from playsets and decks. The Agency will conduct an aggregate assessment that includes both residential and drinking water exposure.

Section 40(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not yet determined whether copper and zinc naphthenate has a common mechanism with other compounds; consequently a cumulative assessment will not be performed at this time.

Occupational and Residential Assessment

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. Based on the available use information, the Agency believes there is potential exposure for occupational handlers (i.e., from applications of wood preservatives and textiles) and residential handlers (e.g., homeowner wood treatment applications). In addition, the Agency expects there also will be exposure from occupational post-application exposures (i.e., workers exposed to wood treatment facilities) and residential post-application exposure concerns for children (i.e., contact with treated wood playsets and decks). Depending on the outcome of the review of the new data from the copper and zinc naphthenate RED DCI, the Agency anticipates the need to conduct new handler and post-application assessments for registration review. The EPA also anticipates that occupational, residential, and aggregate assessments will be needed to ensure that copper and zinc naphthenate registration review case meets the safety standards established by FFDCA, as amended by FQPA.

Hander Exposure

Occupational Handlers

The Agency identified potential occupational handler exposures for copper and zinc naphthenate previously in the RED. No other new uses were identified during the registration review process. The potential occupational handler risk assessments (both short-term (1-30 days) and intermediate-term (>30 days)) by scenario that the Agency expects to conduct during registration review include:

- Incorporation into Textiles During Industrial Manufacturing;
- Handler Exposure to Workers at Non-pressure Treatment Facilities (i.e., diptank operator, blender/spray operator, and chemical operator);
- Handler Exposure to Workers at Pressure Treatment Facilities (i.e., treatment operator and treatment assistant);
- Handler Exposure to Workers at Commercial Wood/Lumber Facilities; and
- Application to In-service Utility Poles, Pilings, Posts, and Other Standing Timbers.

The methods of direct application include liquid pour and liquid pump, low pressure spray, brush/roller, non-pressure treatment, pressure treatment, brush, trowel or grease gun, and pre-manufactured bandage.

Residential Handlers

Residential handler exposure can occur through the application of copper and zinc naphthenate preservative coatings via paintbrush or sprayer application. The Agency expects to conduct residential handler risk assessments for these scenarios and the Agency is likely to conduct a risk assessment only of short-term duration. The short term duration was chosen to be assessed because the different scenarios (i.e. methods of application) are assumed to be episodic, not daily over the course of a year and would not typically exceed 30 days per year.

Postapplication Exposure

Occupational

The Agency identified potential occupational postapplication exposures for copper and zinc naphthenate previously in the RED. No other new uses were identified during the registration review process. The potential occupational scenarios include:

- Post-application Exposure to Workers at Sawmills/Planer Mills (e.g., grader, trim saw operator, millwright, and clean-up); and,
- Post-application Exposure to Workers at Pressure Treatment Facilities (e.g., tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman).

Residential

The Agency expects that it will need to conduct a residential assessment to examine hand-to-mouth and dermal exposures to children from playsets and decks.

Product Chemistry Status and Anticipated Data Needs

All product chemistry data requirements have been fulfilled for the active ingredient naphthenate salts. Therefore, it is anticipated that no additional product chemistry data will be needed for copper and zinc naphthenate salts.

For further information please refer to the Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Copper Naphthenate and Zinc Naphthenate Salts *Registration Review Decision Document, dated July 26, 2010.*

Environmental Fate and Ecological Risk Assessment Status and Anticipated Data Needs

The Agency does not expect to require additional data through the registration review process. The data requested as a result of the September 2007 RED for naphthenate salts (copper naphthenate and zinc naphthenate), required through a DCI issued on June 9, 2010 will be evaluated and used to support the registration review risk assessments.

For further information please refer to the Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Copper Naphthenate and Zinc Naphthenate Salts Registration Review Decision Document, dated July 26, 2010.

Endangered Species

The Agency has not conducted a risk assessment that supports a complete endangered species determination for naphthenate salts (copper naphthenate and zinc naphthenate). The ecological risk assessment planned during registration review will allow the Agency to determine whether use of naphthenate salts has “no effect” or “may affect” federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide’s use “may affect” a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

Incidents:

Ecological

There are no reported incidents in the Agency’s Ecological Incident Information System (EIIS) involving copper naphthenate or zinc naphthenate. The absence of documented incidents does not necessarily mean that incidents did not occur.

Human Health

EPA consulted the following sources of information for human poisoning incidents related to copper and zinc naphthenate 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.

The Agency reviewed available sources of human incident data for incidents relevant to copper and zinc naphthenate as part of the 2007 RED. No new incidents have been reported to the Agency since the completion of the RED. 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. For incidents involving copper or zinc naphthenate in conjunction with other chemicals, the most common symptoms reported for cases of ocular exposure were eye irritation/burning. Eye pain and swelling of eyes also have been reported in some cases. No incidents of oral exposure have been reported.

Timeline:

EPA has created the following estimated timeline for the completion of the naphthenate salts (copper naphthenate and zinc naphthenate) registration review:

Anticipated Schedule

Activities	Estimated Month/Year
Phase 1: Opening the docket	
Open Public Comment Period for Naphthenate Salts Docket	September 2010
Close Public Comment Period	November 2010
Phase 2: Case Development	
Develop Final Work Plan (FWP)	February 2011
Open Public Comment Period for Preliminary Risk Assessments	June 2013
Close Public Comment Period	August 2013
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	October 2014
Close Public Comment Period	January 2015
Final Decision and Begin Post-Decision Follow-up	2015
Total (years)	5

Guidance for Respondents:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the naphthenate salts registration review case.

Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality

Naphthenate salts is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for naphthenate salts, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm) in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to naphthenate salts compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Structure Activity Relationships

EPA must rely upon information of appropriate quality and reliability for each decision made by the Agency. In the Office of Pesticide Programs (OPP), the evaluation process for a pesticide chemical traditionally begins with the applicant's submission of a set of studies conducted with the specific pesticide chemical of interest. The use of the results of such testing (measured data) is a logical, scientifically rigorous process that

identifies the physical, chemical, and environmental fate properties of the pesticide, as well as the dose and endpoints at which an adverse effect can occur in various animal species.

Today, there is significant interest in alternative techniques, i.e., techniques other than data generation that could significantly inform the Agency's decision-making process. Recently, OPP has made increasing use of structure activity relationship (SAR) as part of its regulatory decision-making process. In the SAR process, a chemical's molecular structure is compared to that of other chemicals for which data are available. These structural similarities are then used to make predictive judgments about a chemical's physical, chemical, and biological properties. Thus, the chemical's physical, chemical, and biological properties are a function of (or directly related to) the chemical's molecular structure. Quantitative SAR is referred to as QSAR. To develop a QSAR, a selected set of measured data on a single physical, chemical, or biological property is used to derive a model (an equation) to predict the value of that property.

Since SAR assessments and QSAR modeling are another set of tools that are available to Agency scientists, OPP has begun a process shift that envisions shifting from the current study-by-study approach to an approach in which the use of predicted data, generated using validated models, is considered along with information from open literature and studies specifically generated under Part 161 requirements. All relevant information would be considered as part of a weight-of-the-evidence evaluation.

At this time, EPA believes that for certain endpoints, especially physical/chemical and fate properties, that SAR and QSAR might be effectively utilized to fulfill these data requirements for many antimicrobial pesticide chemicals. When considering biological properties, at this time, EPA believes that SAR and QSAR can be most effectively utilized in the evaluation of chemicals that exhibit lower toxicity for human health and/or ecotoxicity parameters. This is appropriate because the risk assessment for lower toxicity chemicals can be stream-lined, i.e., a screening-level assessment procedure rather than multiple tiers of assessments with progressively more data requirements.

If stakeholders believe that submission of predicted data can fulfill one of the data needs for naphthenate salts, then the Agency invites submission of this information. The submitter would be expected to supply a rationale describing the utility of the information and provide documentation on the scientific validity of the information. The determination that the predicted data fulfills the data requirement would be at the sole discretion of the Agency. Pre-submission consultation with the Agency is encouraged.

Endocrine Disruptor Screening Program

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making

the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Naphthenate salts is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Additional Information

Stakeholders are also specifically asked to provide available information and data that will assist the Agency in refining the risk assessments. The Agency is interested in receiving the following information.

1. Confirmation on the following label information:
    a. Sites of application
    b. Formulations
    c. Application methods and equipment
    d. Maximum application rates
    e. Frequency of application, application intervals and maximum number of applications
    f. Geographic limitations on use
2. Use or potential use distribution
3. Use history
4. Usage/use information for non-agricultural uses (e.g., materials preservation)
5. Typical application interval
6. State or local use restrictions

7. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
8. Monitoring data
9. Structure Activity Relationships

Next Steps:

After the 60-day comment period closes in November, 2010, the Agency will review and respond to any comments received in a timely manner, and then issue a Final Work Plan for Naphthenate Salts (copper naphthenate and zinc naphthenate).

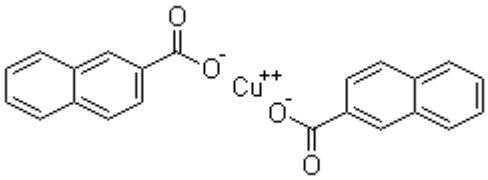
II. FACT SHEET

Background Information

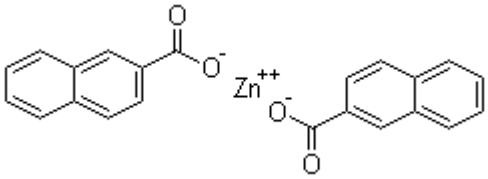
- Chemical Name: naphthenate Salts (copper naphthenate and zinc naphthenate)
- Common Names: copper salts and zinc salts
- Registration review case number: 3099
- PC Code: copper naphthenate 023102 and zinc naphthenate 088301
- CAS#: copper naphthenate 1338-02-9 and zinc naphthenate 12001-85-3
- Technical Registrants:
    - copper naphthenate - IBC Manufacturing Co, OMG Americas Inc, OMG Belleville Limited, Merichem Chemicals & Refinery Services LLC, and Osmose Utilities Services, Inc.
    - zinc naphthenate - OMG Americas Inc and OMG Belleville Limited
- First approved for use in a registered product: copper naphthenate October 29, 1951 and zinc naphthenate November 26, 1975
- There are 30 registered products that contain copper naphthenate and 10 registered products that contain zinc naphthenate.
- Antimicrobials Division Chemical Review Manager (CRM): Monisha Harris, harris.monisha@epa.gov
- Antimicrobials Division Product Manager (PM): Jacqueline Campbell-McFarlane, campbell-mcfarlane.jacqueline@epa.gov

Chemical Structure:

Copper naphthenate



Zinc naphthenate



Use & Usage Information

Type of Pesticide: Fungicide and Insecticide

Antimicrobial Use Sites:

Materials Preservatives
Rope, burlap, canvas products including, nets (except fish nets), seines, tents, awnings, textiles, particle board, insulation board, and other wood base fiber and particle materials tarpaulins.

Wood Preservatives
(Exterior use only) Lumber, timbers, posts, poles, and other wooden members, all exterior wood exposed to moisture or weather. Wooden boat hulls, piers.

Recent Regulatory Actions

As part of the RED process, the Agency issued a DCI for naphthenate salts (copper naphthenate and zinc naphthenate) on June 9, 2010. Also, the RED recommended label changes to minimize the dermal risk of concern from zinc naphthenate. The Agency expects to receive updated zinc naphthenate labels within 9 months of the DCI. The Agency intends to use information from the updated labels received in response to the RED to conduct the risk assessments for this registration review.

The RED for copper and zinc naphthenate salts was issued by EPA in September 2007. http://www.epa.gov/pesticides/reregistration/status.htm

Human Health Risk Assessment Status

The Agency does not anticipate requiring additional human health data for copper and zinc naphthenate for registration review. The toxicity and exposure data required recently by DCI as a result of the RED are presented in the RED.

Further human health information is available in the document titled "Human Health Effects Data for the Copper and Zinc Naphthenate Registration Review Decision," dated July 19, 2010.

Product Chemistry Database Status

The Agency has reviewed the product chemistry database for the naphthenate salts (copper naphthenate and zinc naphthenate) registration review case and anticipates that no additional product chemistry data will be needed for registration review because all product chemistry data requirements have been satisfied.

Further information is available in the "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Copper Naphthenate and Zinc Naphthenate Salts Registration Review Decision Document," dated July 26, 2010.

Environmental Fate & Ecological Risk Assessment Status

The Agency does not expect to require additional data through the registration review process. The data requested as a result of the September 2007 RED for naphthenate salts (copper naphthenate and zinc naphthenate), required through a DCI issued on June 9, 2010, will be evaluated and used to support the registration review risk assessments.

The Agency anticipates concluding that the registered uses of naphthenate salts (copper naphthenate and zinc naphthenate) will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS). EPA anticipates conducting no further analysis of potential risks to endangered or threatened species unless public comments provide additional information that would alter the Agency's current position that naphthenate salts will have "no effect" on such species or their designated critical habitat.

For further information please refer to the Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Copper Naphthenate and Zinc Naphthenate Salts Registration Review Decision Document, dated July 26, 2010.

Tolerances

There are no tolerances or exemptions from tolerances for the copper and zinc naphthenate active ingredients and no registered food uses. There are inert exemptions from tolerances for copper naphthenate. However, inert exemptions from tolerances are not addressed in this registration review.

Data Call-In Status

- In November of 1993, EPA issued a GDCI (generic data call-in) for copper naphthenate for product chemistry data, human toxicity data, ecological effects and environmental fate data. EPA also issued a GDCI for zinc naphthenate for ecological effects data and environmental fate data.

- In January of 1994, EPA issued a GDCI for copper naphthenate for product chemistry data, ecological effects data, and human toxicity data. EPA also issued a GDCI for zinc naphthenate for product chemistry data, ecological effects data, human toxicity data, human exposure data, and environmental fate data.
- In May of 1994, EPA issued a GDCI for copper naphthenate for product chemistry data, ecological effects data, human toxicity data, and environmental fate data.
- In March of 1997, EPA issued a GDCI for zinc naphthenate for product chemistry data, ecological effects data, human toxicity data, and environmental fate data.
- In June of 2010, EPA issued a GDCI for copper naphthenate for ecological effects data, human toxicity data, and human exposure data. EPA also issued a GDCI for zinc naphthenate for ecological effects data, human toxicity data, and human exposure data.
- In June of 2010, EPA issued a PDCI (product data call-in) for copper naphthenate for product chemistry data and human toxicity data. EPA also issued a PDCI for zinc naphthenate for product chemistry data and human toxicity data. The 90-day due date is scheduled for October 2010.

Labels

There are 30 registered products that contain copper naphthenate and 10 registered products that contain zinc naphthenate. The EPA registration numbers are provided in Table 1 and 2 below. For future reference, during registration review a list of product registration numbers will be included in the docket. Product registration labels may be obtained from the Pesticide Product Label System (PPLS) website at: http://oaspub.epa.gov/pestlabl/ppls.home.

Table 1. Registered Active Products of Copper Naphthenate

Registration #	Registration Name	Company Name	Formulation type	% of Active Ingredient
577-541	Cuprinol Wood Preservative	The Sherwin-Williams Co.	Ready-to-Use Solution	22.3
1022-409	Copper Naphthenate WR Wood Preservative Ready To Use	IBC Manufacturing Co.	Ready-to-Use Solution	25
1022-507	Copper Naphthenate 1%	IBC Manufacturing Co.	Ready-to-Use Solution	7.5
1022-518	Cunapsol-1	IBC Manufacturing Co.	Ready-to-Use Solution	9.08
1022-522	Cunapsol-5	IBC Manufacturing Co.	Soluble Concentrate	45.4
1022-523	Cunapsol-2	IBC Manufacturing Co.	Ready-to-Use Solution	18.16
1022-528	Copper Naphthenate Concentration 8%	IBC Manufacturing Co.	Soluble Concentrate	68
1022-536	POL-NU CURAP 20	IBC Manufacturing Co.	Ready-to-Use Solution	18.16
1022-568	CHAPCO CU-NAP 800 EC	IBC Manufacturing Co.	Emulsifiable Concentrate	80
1022-571	CHAPCO CU-NAP 400	IBC Manufacturing Co.	Soluble Concentrate	40
1022-579	CURAP 20 PAK	IBC Manufacturing Co.	Ready-to-Use Solution	18.16
1719-43	COP-R-TOX Wood Preservative	Mobile Paint Manufacturing Company Inc.	Ready-to-Use Solution	22.59
9630-4	6% Copper Nap-All	OMG Americas Inc.	Formulation Intermediate	**67**
9630-5	M-GARD S120	OMG Americas Inc.	Formulation Intermediate	**77**
9630-12	M-GARD S520	OMG Americas Inc.	Soluble Concentrate	80
43437-4	8% Copper Naphthenate	OMG Belleville Limited	Soluble Concentrate	89
60061-16	No. 00 Ready To Use Copper Treat	Kop-Coat, Inc.	Ready-to-Use Solution	21.6
60061-19	Copper Treat 120	Kop-Coat, Inc.	Ready-to-Use	21.6

Registration #	Registration Name	Company Name	Formulation type	% of Active Ingredient
	Ready-To-Use		Solution	
66591-1	Copper Green Wood Preservative	Green Products Co.	Ready-to-Use Solution	10
71653-1	Cobra Wrap	Genics Inc.	Ready-to-Use Solution	17.8
71992-1	CUNAP-8 Wood Preservative	Merichem Chemicals & Refinery Services LLC	Soluble Concentrate	68
71992-2	CUNAP-2	Merichem Chemicals & Refinery Services LLC	Soluble Concentrate	18
71992-3	CU NAP-5W Wood Preservative	Merichem Chemicals & Refinery Services LLC	Soluble Concentrate	42
75340-3	COP-R-NAP RTU Solution	Osmose Railroad Services, Inc.	Ready-to-Use Solution	19.25
75340-4	Osmose CU-89-RTU II	Osmose Railroad Services, Inc.	Ready-to-Use Solution	17
75341-5	COP-R-Plastic Wood Preserving Compound	Osmose Utilities Services, Inc.	Ready-to-Use Solution	20
75341-8	Osmose COP-R-NAP	Osmose Utilities Services, Inc.	Soluble Concentrate	77
75341-11	COP-R-NAP	Osmose Utilities Services, Inc.	Soluble Concentrate	68
75341-12	Hollow Heart CF	Osmose Utilities Services, Inc.	Soluble Concentrate	41.27
75341-13	COP-R-Plastic II Wood Preserving Compound	Osmose Utilities Services, Inc.	Ready-to-Use Solution	17.68

Table 2. Registered Active Products of Zinc Naphthenate

Registration #	Registration Name	Company Name	Formulation Type	% of Active Ingredient
577-545	Clear Cuprinol Brand Wood Preservative No. 20	The Sherwin-Williams Co	Ready-to-Use Solution	13.5
1719-44	Zin-Tox Wood Preservative	Mobile Paint Manufacturing Company Inc.	Ready-to-Use Solution	16.00
7424-9	Jasco Termin-8 H2O Clear	Jasco Chemical	Ready-to-Use	15.75

Registration #	Registration Name	Company Name	Formulation Type	% of Active Ingredient
	Wood Preservative	Corporation	Solution	
9630-6	8% Zinc Nap-All M-GARD S150 Wood Preservative	OMG Americas Inc.	Formulation Intermediate	63.0
9630-7	Zinc Hydro-Nap M-GARD W152 Wood Preservative	OMGAmericas Inc.	Formulation Intermediate	63.0
9630-10	M-GARD W550 wood Preservative	OMG Americas Inc.	Emulsifiable Concentrate End use Product	63.0
9630-21	M-GARD S550 wood Preservative	OMG Americas Inc.	Soluble Concentrate	63.0
43437-3	8% Zinc Naphthenate	OMG Belleville Limited	Soluble Concentrate	69.0
60061-9	Wolman Wood Preservative With Water Repellent Clear	Kop-Coat, Inc.	Ready-to-Use Solution	7.5
66591-3	Green's Clear Wood Preservative	Green Products Co	Ready-to-Use Solution	23.6

III. GLOSSARY of TERMS & ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
ASTM	American Society for Testing and Materials
AWPA	American Wood Preserver's Association
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAIRA	Pure Active Ingredient Radiolabelled
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program

PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TEP	Typical End-Use Product
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

IV. APPENDIX A

Use Patterns for Naphthenate Salts (copper naphthenate and zinc naphthenate)

Copper Naphthenate

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 1022-409 1719-43 43437-4 71992-3 71992-1	Brush , dip, roller or spray	Dip or spray until wet.	For exterior use only, treated wood should not come in contact with food, feed or potable water.
Particle board, insulation board, and other wood base fiber and particle materials	Ready to use 1022-522	Brush, dip, roller, or spray	Mix with furnish resin or binding agent at 1-3% based on dry weight of wood.	For exterior use only, treated wood should not come in contact with food, feed or potable water.
Wood preservatives				
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members, railroad ties	Ready to use (paste) 1022-579 1022-536 71653-1 75341-5	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.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(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 1022-518 1022-522 1022-571 7424-1 1022-523 577-541 1022-507 66591-1 71992-2 75340-4 60061-16 60061-19	Brush, dip, roller , or spray	1 minute immersion is adequate for most applications. 12-48 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 coats by brush, roller, or spray treatments allowing at least 1 hour between each coat.	For exterior use only, treated wood should not come in contact with food, feed or potable water. Dip treatment is the most effective.
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members, wooden boat hulls, piers	Soluble Concentrate 1719-43 75341-11 75341-12 1022-528 9630-12 9630-11 71992-3	Brush, dip, roller , spray, or pressure treatment	Mix 1 gallon of emulsion with 1 to 3 gallons of water. Apply by brushing freely, spraying or dipping in a tank. Is most effective when wood is unpainted, dry and clean Mix to a 17% to 33% by weight solution (17% solution is 4.9 - 6.7 parts solvent per part of product; 33% solution is 2 - 3 parts of solvent per part of product.) Dip treatment is the most	For exterior use only, treated wood should not come in contact with food, feed or potable water.

			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. For such, apply at least 2 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 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 1022-568 9630-5 9630-4	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 is recommended Ground contact: For wood uses in ground contact, extended soaking or	For exterior use only, treated wood should not come in contact with food, feed, or potable water.

			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	

Zinc Naphthenate

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 1719-44 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.
Wood preservatives				
(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 7424-9 577-545 1719-38 66591-3 60061-9	Brush, dip, roller , or spray	Dip treatment is the most effective. 3 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	For exterior use only. Treated wood should not come in contact with food, feed, or potable water.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			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 43437-3 9630-10 9630-21	Brush, dip, roller , spray, or pressure treatment	Mix 1 gallon of emulsion with 1 to 3 gallons of water. Apply by brushing freely , spraying or dipping in a tank; is most effective when wood is unpainted dry and clean Mix to a 17% to 33% by weight solution (17% solution is 4.9 - 6.7 parts solvent per part of product, 33% solution is 2.0 – 3.0 parts of solvent per part of product). Dip treatment is the most effective. 3 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 coats by brush, roller, or spray treatments allowing at	For exterior use only. Treated wood should not come in contact with food, feed, or potable water.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			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 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	Brush, dip, roller ,	Dilute with 3 volumes of water	For exterior use only. Treated wood should not come in

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	9630-6 9630-7	or spray Pressure treatment	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 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.	contact with food, feed, or potable water.