United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-07-010
December 2007

Reregistration Eligibility Decision for Sodium Fluoride

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 draft risk assessments for the antimicrobial sodium fluoride. The enclosed Reregistration Eligibility Decision (RED) document was approved on December 20, 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 sodium fluoride and the 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 sodium fluoride are available to the public in EPA's Pesticide Docket EPA-HQ-2007-0833 at: http://www.regulations.gov.

The sodium fluoride RED was developed through EPA's public participation process, published in the Federal Register on October 10, 2007, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision-making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the sodium fluoride risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, residential, occupational and ecological risks posed by exposure to sodium fluoride 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 sodium fluoride will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, SanYvette Williams-Foy, (703) 305-7702. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Adam Heyward at (703) 308-6422 or heyward.adam@epa.gov.

Sincerely,

Betty Shackleford for

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY
DECISION
for
Sodium fluoride
List C
Case 3132

Approved by:

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division

12/20/07

Date

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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
NTP	National Toxicology Program
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RAC	Raw Agricultural Commodity
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 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

ABSTRACT

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

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reregistration assessments of chemicals registered prior to 1984. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for sodium fluoride.

Sodium fluoride is used for commercial use only as a wood preservative for utility poles and railroad ties. Sodium fluoride products are used as supplemental wood treatments and are not intended for primary wood preservative or pressure treated wood preservation.

The Agency has concluded that no special hazard-based safety factor under the Food Quality Protection Act (FQPA) of 1996 is needed for sodium fluoride based on its current registered use patterns.

Risks summarized in this document are those that result only from the use of the active ingredients sodium fluoride. The FFDCA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike the pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not yet initiated a review to determine if there were any other chemicals that have a mechanism of toxicity common with that of sodium fluoride. Risks summarized in this document are those that result only from the use of sodium fluoride. Therefore, the Agency did not perform a cumulative risk assessment as part of this RED for sodium

fluoride. For purposes of this RED, the Agency has assumed that sodium fluoride does not have a common mechanism of toxicity with other substances. If the Agency identifies other substances that share a common mechanism of toxicity with sodium fluoride, the Agency will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment. Upon the Agency's request and according to a schedule determined by the Agency, the Registrant must submit such information as needed in order to evaluate issues related to whether sodium fluoride shares a common mechanism of toxicity with any other substance. 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 sodium fluoride. 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 sodium fluoride 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 www.regulations.gov (Docket # EPA-HQ-2007-0833).

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 sodium fluoride and its regulatory history. Section III, Summary of sodium fluoride Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

Sodium fluoride products were initially registered in 1964. Sodium fluoride was originally sold to the U.S. telecommunications company in the 1930s as a wood preservative for utility poles lumber, timbers, posts, poles, ties, pilings, and all exterior wood exposed to moisture or weather. There are six registered products. There are no inert uses or tolerances for this chemical.

B. Chemical Identification

Figure 1. Molecular Structure of Sodium Fluoride

Common Name: Chemifluoro, Dentafluoro, Villiaumite

Chemical Name: Sodium fluoride

Other Name(s): Floridine, Florocid

CAS Registry Number: 7681-49-4

OPP Chemical Code: 075202

Case Number: 3132

Empirical Formula: NaF

Molecular Weight: 42.00

Basic Manufacturer: Osmose Inc.

Chemical Properties: Sodium fluoride (TGAI) is a yellow powder with a weak musty odor and melting point of 993 ^{o} C. The boiling point for sodium fluoride is 1704 ^{o} C. Sodium fluoride (TGAI) has an estimated log K_{ow} of -0.77 [1] and a vapor pressure of 5.43 x 10^{-26} mm Hg (25 ^{o} C)[1*]. Sodium fluoride (TGAI) is soluble in water at .4.10 g/100 ml; at 15°C and 4.3 g/100 ml at 25 ^{o} C. Sodium fluoride (TGAI) is readily soluble in many organic solvents and has a density of 2.55 g/cm^3.

The pH for sodium fluoride is slightly alkaline and stable under normal storage conditions. The Henry Law Constant (air/water partition constant) is 5.04×10^{-33} atm m^3/mole[1]

C. Use Profile

The following is information on the currently registered uses of sodium fluoride, including an overview of use sites and application methods. A detailed table of the uses of sodium fluoride eligible for reregistration is available in Appendix A.

Type of Pesticide: Fungicide

Target Pests: Fungi

Formulation Types: Powder (Technical Grade Active Ingredients (TGAI)); Soluble Concentrate (Manufacturing Use Products (MP)); Soluble Concentrate, Ready-to-use Solution, Pelleted/tablet (End Use Products (EP))

Use Sites: Wood Preservative- (Exterior use only) Lumber, Timber, Posts, Poles, Ties, Pilings, and Other Wood Products.

Methods and Rates of Application:

Wood Preservative: For control of internal decay, fill decay pockets and voids using a grease gun or other pressurized applicator. Plug application holes with secure-fitting dowels

Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening.

Typical pole application is from 3 inches above to 18 inches below the ground line and lower where deeper decay is suspected. Application on poles to be restored should extend the length of wrap around type repair systems. Wrap the treatment area with water proof bandage.

III. Summary of Sodium fluoride Fluoride (NaF) 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 Sodium Fluoride (NaF). While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0833, 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 NaF 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 Sodium Fluoride

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 NaF can be found in the document titled "Toxicology Chapter for Sodium Fluoride RED," dated July 23, 2007. These documents are available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0833).

The Agency has reviewed all toxicity studies submitted for sodium fluoride and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. The acute toxicity data for sodium fluoride is summarized below in Table 1.

Table 1. Acute Toxicity Data for Sodium Fluoride

Guideline Number	Study Type/Test substance (% a.i.)	MRID Number / Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral – Rat Purity 95.6% - Sodium Fluoride	43778501	LD_{50} (combined) = 105 (93-119 CL) Male LD_{50} = 120 mg/kg Female LD_{50} = 89 mg/kg	II
870.1200 (§81-2)	Acute Dermal – Rat Purity 95.6% - Sodium Fluoride	43778502	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute Inhalation - Rat Purity 95.6% - Sodium Fluoride	43778503	LC_{50} = 1.00 mg/L	III
870.2400 (§81-4)	Primary Eye Irritation - Rabbit Purity 95.6% - Sodium Fluoride	43778504	Severely irritating to unwashed eyes	II
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit purity 95.6% – Sodium Fluoride	43778505	Slightly Irritating	IV
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity 95.6 % - Sodium Fluoride	43778506	Buehler: Not a skin sensitizer	No
870.2600 (§81-6)	Dermal Sensitization - Guinea pig purity not reported	40866801	Not a dermal sensitizer	No

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

General Toxicity Observations

Acute Toxicity

For the technical grade active ingredient, sodium fluoride has a high order of toxicity via the oral route of exposure (Toxicity Category II) and a moderate order of toxicity via the dermal and inhalation routes of exposure (Toxicity Category III). Primary eye irritation studies classify sodium fluoride as corrosive (Toxicity Category I) whereas dermal irritation studies classify sodium fluoride as a mild or slight irritant (Toxicity Category IV). Sodium fluoride is not a dermal sensitizer.

Acute and Chronic Reference Dose (RfDs)

Dietary exposure to NaF is not expected. Therefore, acute and chronic dietary endpoints were not selected.

Incidental Oral Exposure

Incidental oral exposure to NaF is not expected, based on registered use patterns. Therefore, incidental oral endpoints were not selected.

Dermal Exposure

For short-term dermal exposures, a LOAEL of 20 mg/kg/day was selected from a oral subchronic toxicity study in rats based on significant reductions in body weight gain and suppressed spontaneous motor activity. The target MOE is 300 for the short-term (ST) dermal exposures, based on 10x for inter-species extrapolation, 10x for intra-species variation, and 3x for use of a LOAEL. For intermediate-term dermal exposures, a NOAEL of 1.5 mg/kg/day was selected from a six month National Toxicology Program (NTP) oral toxicity study in the mouse based on histopathology observed in bone with degeneration in tibias and femurs of animals. The target MOE is 100, based on 10x inter-species extrapolation and 10x for intra-species variation. For long-term dermal exposures, a LOAEL of 1.3 mg/kg/day was selected from a 2 year NTP chronic toxicity/carcinogenicity study in rats, based on dentine dysplasia in males and females, and ameloblast degeneration in males. The target MOE is 300 for the short-term (LT) dermal exposures, based on 10x for inter-species extrapolation, 10x for intra-species variation, and 3x for use of a LOAEL. Dermal absorption is assumed to be 100% in the absence of actual dermal absorption data. Sodium fluoride is not a dermal sensitizer.

Inhalation Exposure

For short-term inhalation exposures, a LOAEL of 20 mg/kg/day was selected from an oral subchronic toxicity study in rats. Effects observed at the LOAEL of 20 mg/kg/day included significant reductions in body weight gain and suppressed spontaneous motor activity. The target MOE is 300 for occupational exposures (10X for interspecies extrapolation, 10X for intraspecies variability, and 3x for use of a LOAEL). For intermediate-term inhalation exposures, a NOAEL of 1.5 mg/kg/day was selected from a six month National Toxicology Program (NTP) oral toxicity study in the mouse based on histopathology observed in bone with degeneration in tibias and femurs of animals. The target MOE is 100, based on 10x inter-species extrapolation, and 10x for intra-species variation. For long-term inhalation exposures, a LOAEL of 1.3 mg/kg/day was selected from a 2 year NTP chronic toxicity/carcinogenicity study in rats, based on dentine dysplasia in males and females, and ameloblast degeneration in males. The target MOE is 300 for the long-term (LT) inhalation exposures, based on 10x for inter-species extrapolation, 10x for intra-species variation, and 3x for use of a LOAEL.

Carcinogenicity

Based on the available data, sodium fluoride has been classified as a "Group D" (inadequate evidence of carcinogenicity). This conclusion is consistent with the recent report by the National Academy of Sciences which concluded that "the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed."

Mutagenicity Potential

Positive mutagenicity results have been reported in mouse lymphoma assays, in chromosome aberration assays, in unscheduled DNA synthesis assays, and in *in vitro* sister chromatid exchange assays.

Endocrine Disruption Potential

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

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

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10xX), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. Sodium fluoride is not used in food and therefore, the toxicological database is considered to be complete with respect to assessing the increased susceptibility to infants and children as required by FQPA. There are no food tolerances for NaF and the use patterns considered for the reregistration eligibility decision (RED) document do no involve dietary exposure. As a result, an FQPA safety finding is not applicable.

3. Dietary Exposure Assumptions & Dietary Risk Assessment

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

a. Dietary Risk from Drinking Water

The antimicrobial uses of sodium fluoride are not expected to pose a hazard to groundwater or surface water. Therefore, a drinking water exposure and risk assessment has not been performed.

4. Residential Risk Assessment

Based on registered uses, negligible residential exposures to NaF are anticipated. No residential assessment has been conducted. Although remedial wood treatment for poles and beams on bridges do not occur in high traffic areas for bystanders, distribution utility poles are numerous and often located in people's front yards. The vapor pressure of sodium fluoride is negligible (i.e., 5.43×10^{-26} mmHg at 25 C), and therefore, no vapor will be released in the vicinity of treated poles. Additionally, label directions to cap treated holes after application will minimize any potential for dermal contact. Likewise, groundline treatments are also covered (i.e., brush-on and wrap treatments are below the groundline and then covered with dirt) and will minimize potential dermal contact to children playing in areas of treated poles.

5. 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 there are no dietary, residential or other non-occupational sources of exposure to NaF, an aggregate exposure assessment was not performed.

6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Sodium fluoride is used as an antimicrobial pesticide as a remedial wood treatment for the protection against decay producing fungi. Potential occupational exposure can occur in various use sites, which include treatment of railroad ties and groundline treatment around utility poles. Additional information can be found in the document titled, "Revised Occupational and Residential/Bystander Assessment of the Antimicrobial Use (Remedial Wood Treatment) of Sodium Fluoride for the Reregistration Eligibility Decision (RED) Document. Case Number 3132. PC Code 075202," dated October 1, 2007.

a. Occupational Toxicity

The doses and toxicological endpoints used in the occupational handler assessment of NaF scenarios are summarized in Table 2 below.

Table 2. Sodium Fluoride for Use in Human Risk Assessment

Exposure Scenario	Dose (mg/kg/day) used in risk assessment UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (general population and females 13-49)	No appropriate endpoints were identified that represent a single dose effect. Therefore, this risk assessment is not required.		
Chronic Dietary	No appropriate endpoints were identified that represent a chronic dose effect. Therefore, this risk assessment is not required.		
Non-Dietary Risk Assessments			
Short -Term Dermal (1 - 30 Days)	LOAEL = 20 mg/kg/day	**Target MOE**=300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of LOAEL)	Oral Subchronic Toxicity – Rat (Sodium Fluoride) LOAEL = 20 mg/kg/day, based on significant reductions in body weight gain and suppressed spontaneous motor activity.
Intermediate -Term Dermal (30 Days- 6 months)	NOAEL = 1.5 mg/kg/day	**Target MOE**=100 (10x inter-species extrapolation, 10x intra-species variation)	6-month NTP oral toxicity study-mouse LOAEL = 7.5 mg/kg/day based on histopathology observed in bone with degeneration in tibias and femurs of animals
Long-Term Dermal (> 6 months)	LOAEL = 1.3 g/kg/day	**TARGET MOE =** 300 (10x inter-species extrapolation, 10x intra-species variation and 3x for use of LOAEL)	2-year NTP chronic toxicity/carcinogenicity study in rats LOAEL = 1.3 mg/kg/day, based on dentine dysplasia in males and females, and ameloblast degeneration in males
Short-term Inhalation (1-30 days)	LOAEL = 20 mg/kg/day	**Target MOE**=300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of LOAEL) *Note:* 10x route extrapolation for confirmatory inhalation study.	Oral Subchronic Toxicity – Rat (Sodium Fluoride) LOAEL = 20 mg/kg/day, based on significant reductions in body weight gain and suppressed spontaneous motor activity.

Exposure Scenario	Dose (mg/kg/day) used in risk assessment UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-term Inhalation	NOAEL = 1.5 mg/kg/day	**Target MOE**=100 (10x inter-species extrapolation, 10x intra-species variation) Note: 10x route extrapolation for confirmatory inhalation study.	6-month NTP oral toxicity study-mouse LOAEL = 7.5 mg/kg/day based on histopathology observed in bone with degeneration in tibias and femurs of animals
Long-term Inhalation	LOAEL = 1.3 mg/kg/day	**TARGET MOE =**300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of LOAEL) Note: 10x route extrapolation for confirmatory inhalation study.	2-year NTP chronic toxicity/carcinogenicity study in rats LOAEL = 1.3 mg/kg/day, based on dentine dysplasia in males and females, and ameloblast degeneration in males
Cancer	Sodium fluoride has been classified as a "Group D" (not classifiable as to carcinogenicity). This conclusion is consistent with the recent report by the National Academy of Sciences which concluded that 'the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed.'		

Notes: UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level.

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.

Potential occupational handler exposures can occur when sodium fluoride is used as a remedial wood treatment for the protection against decay producing fungi. The Agency evaluated representative occupational handler scenarios to assess and determine dermal and inhalation exposures. For sodium fluoride, handler scenarios were assessed by using unit exposure data to estimate occupational exposures. Unit exposures are estimates of the amount of exposure to an active ingredient a handler receives while performing various handler tasks and are expressed in terms of micrograms or milligrams of active ingredient per pounds of active ingredient handled. A series of unit exposures have been developed that are unique for each scenario typically considered in assessments (i.e., there are different unit exposures for different types of application equipment, job functions, and level of protection).

Application techniques include a product-specific dispenser, grease/caulking guns, pressurized sprayers, preservative cartridges, brush-on and/or trowel-on applications. The personal protective equipment (PPE) listed on the label range from a minimum protection of goggles to a maximum protection of goggles, gloves, and respirators.

Chemical-specific exposure data were not submitted to support the remedial wood applications. Therefore, the Agency developed a screening-level assessment using surrogate data to determine the potential risks associated with remedial wood treatment. Based on the label review listed in Table 3 below, there are two basic remedial applications: (1) applying product into pre-drilled holes; and (2) applying product around the circumference of poles at or below the groundline. The brush on treatment represents the high-end exposures for the trowel on and impregnated wraps. Each remedial application can be applied using various techniques and PPE. Surrogate exposure data are not available for all application techniques specified on the label. Representative exposure scenarios (i.e., application techniques) are used to represent the potential worker short-, intermediate, and in some cases long-term durations of inhalation and dermal exposures. Inhalation exposure is expected to be minimal for the groundline treatments because of the viscosity of the product as well as its low vapor pressure. Table 3 presents a summary of sodium fluoride labels.

Table 3. Summary of Sodium Fluoride Labels

EPA Reg No.	% ai	Signal Word	PPE	Label Directions (e.g., application techniques, rates, etc.)
3008-58	97.5	Danger	Respirator, goggles	Includes a non pesticide statement
75340-2	54.92	Warning	Gloves	TIE-GARD dispenser; grease gun; pressurized applicator; Apply to drilled holes to “fill” and cap; Used on rail road ties and structural timbers such as bridge pilings and posts.
75341-6	92.6	Danger	Gloves	FLURODS (i.e., preservative cartridges, solid sticks) placed into drilled holes and capped. For treating poles, posts, timbers, crossties, etc. Rate: 39.2 grams/cubic foot wood.
75341-4	70.6	Danger	Gloves, goggles	PoleWrap. Groundline treatment. Dig 20 inches around pole, wrap down to 18 inches below groundline to 2 inches above groundline and cover with dirt.
75341-5	44.4	Danger	Goggles	Used in combination with copper naphthenate. Brush-on, trowel-on, grease gun. 1/16th of an inch rate 18 inches below and 3 inches above groundline and covered with a wrap. Also used in drilled holes applied by a grease gun and capped (paste density 12 lbs/gallon).
75341-12	8.39	Danger	Gloves, goggles, respirator, and	Used in combination with copper naphthenate. Mix 1 gallon of product

			respirator when spraying for continued or prolonged use or frequent use	with 1.5 gallons of water. Apply using air or mechanical pressure pump into prepared opening (assume pre-drilled). Rate: 1 gallon of treatment solution per cubic foot of wood.
75341-13	44.42	Warning	Goggles, face shield or safety glasses, protective clothing, and chemical resistant-gloves	Used in combination with copper naphthenate. Brush-on, trowel-on, grease gun. 1/16th of an inch rate 18 inches below and 3 inches above groundline and covered with a wrap. Also used in drilled holes applied by a grease gun and capped.

i. Sodium Fluoride Application Methods

TIE-GARD and FLUROD Applications

TIE-GARD and FLURODS are sodium fluoride products that are inserted into pre-drilled holes and capped and are expected to result in minimal inhalation and dermal handler exposure because the products are engineered to be closed systems. The FLURODS are solid sticks that are placed in the pre-drilled holes. TIE-GARD is a gel product containing sodium fluoride. The automated rail tie use is packaged in 30 gallon PVC closed head drums. It is applied from high capacity rubber track machinery that rides on railroads and automatically injects the gel product into rail ties. Applicator exposure from these uses is expected to be negligible. Any potential for exposure from leaks/spills from these products (i.e., TIE GARD and FLURODS) is believed to be best mitigated by the label requirement for the availability of PPE such as chemical resistant gloves, goggles, long pants, and long sleeved-shirts in the event of a spill. Therefore, the handler risks to pre-packaged products are assumed to be minimal and are not quantified.

Spray/Injection Applications

Although EPA does not have a specific surrogate exposure scenario for injection of pesticides into wooden poles, similar exposure data for hand-held application equipment exist. The spray application is believed to represent the high end of exposure to the grease gun. The exposure data for hand-held applications that are available to EPA include data from the Pesticide Handlers Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF). The data available from these sources are for garden hose-end sprayers, low pressure hand-wands, backpack sprayers, high pressure handwands, and rod shank termiticide applications. The most representative data available for an injection-type hand-held devise is the rod shank termiticide application from PHED. Other equipment types are not believed to be as representative because each one involves a spray and the injection into the pole will minimize spray.

The rod shank termiticide injection data in PHED are used to develop a screening-level assessment for the pole use. The dermal unit exposure (UE) for combined liquid pour and termiticide injection is based on 17 replicates with the test subjects wearing a single layer of clothing and chemical resistant gloves with AB grades (i.e., guideline

recommendations for analytical quality). The dermal UE is 0.36 mg/lb ai. The inhalation UE is based on the same 17 replicates and the grades are also AB. The inhalation UE is 0.0022 mg/lb ai. Although not all of the labels currently specify the use of chemical resistant gloves (e.g., EPA Reg. No. 75341-5), the "gloved" clothing scenario is the only one available to assess risks.

Groundline Treatments

Groundline treatments consist of brush and trowel-on applications as well as impregnated wraps around poles. Once applied, the pole treatment is covered with dirt. The most representative surrogate exposure data available to assess the high-end of the exposure potential are for painting with a paint brush. The product is expected to have a much higher viscosity then paint. Because of the high viscosity and low vapor pressure, inhalation exposure is expected to be minimal. Dermal unit exposure values for paint brush applications from PHED were used (single layer of clothing). The dermal unit exposure is 24 mg/lb a.i. for the painting scenario for a test subject wearing long pants, long-sleeved shirt, and chemical resistant gloves.

ii. Application Rates and Amounts Handled

Label directions indicate that sodium fluoride is applied into poles, timbers, etc, via four different formulations; paste, bandage or wrap, liquid and solid rods. The application for these formulations is very different from each other due to the physical properties and percentage of sodium fluoride present in each formulation. Typically paste formulations are applied by brush-on application around the groundline area of pole and then wrapped with a protective barrier before being backfilled with soil. The dry impregnated wrap is applied around the groundline portion of the pole. Liquid formulations are normally applied to internal voids through means of pressurized injection and rods are applied by drilling application holes, inserting the rods into the holes and then plugging them.

Labeled application rates for pastes are to apply by brush to a thickness of 1/16th inch. The dry wrap is applied by cutting the wrap to match the circumference of the pole. Liquid application instructions include filling application holes to refusal and more specific instructions such as 1 gallon of diluted solution per cubic foot of wood. However, label directions are not provided to determine neither the number of holes per pole nor the number of cubic feet per pole to be treated with sodium fluoride. Therefore, for this assessment 1 cubic foot of wood per pole is assumed to be treated for the spray/injection application.

Specific amounts of sodium fluoride applied by workers daily are not available. Therefore, in addition to the number of cubic feet treated per pole, the number of poles treated per day (i.e., pre-drilled treatments, not groundline applications) with sodium fluoride was also estimated.

The amount of paste applied to each pole for groundline treatments is estimated to be 0.167 gallons/pole for distribution poles and 0.255 gallons per transmission pole (i.e., 21 inch wide treatment x up to 34 inch circumference for distribution poles and 50 inches for transmission poles x 1/16 inch thickness of product treatment).

- Distribution Poles - the smaller diameter wooden distribution poles (~140 million distribution poles in service) are treated at a high end rate of ~24 per day (for short-term duration). Workers treat these types of poles as their main work function, treating 5 days per week, on a yearly basis (i.e., 250 days/year). This scenario is represented by the short-, intermediate- and long-term exposure durations.

- Transmission Poles - the larger wooden transmission poles are treated at a rate of 30 per day. Workers treat these types of poles as their main work function, treating 5 days per week, on a yearly basis (i.e., 250 days/year). This scenario is represented by the short-, intermediate- and long-term exposure durations.

c. Occupational Handler Risk Summary

Table 4 presents the representative exposure scenarios used to assess the labeled remedial wood treatment uses.

Table 4. Occupational Handler Exposure Scenarios

Remedial Applications	High-end Exposure Scenarios	Application Techniques Represented by the High-end Exposure Scenario
Pre-drilled holes	Closed systems	TIE GARD dispenser for rail ties; FLURODS (solid sticks)
	Sprays	Grease/caulking gun; air or mechanical pressure pump
Groundline	Brush-on	Brush; Trowel; PoleWrap (dry wrap)

Evaluation of the spray applications into pre-drilled holes, indicates no dermal risks of concern for the short-term duration for the distribution pole. Dermal risks, however, are triggered for the intermediate- and long-term durations. The intermediate- and log-term dermal MOEs are 26 and 22, respectively, with a target MOE of 300. No inhalation risks are triggered for the distribution poles at any timeframe.

For the spray applications into pre-drilled holes for the transmission poles, the inhalation (all durations) and short-term dermal risks are not of concern. However, the short-, intermediate- and long-term dermal risks for the transmission poles are of concern. The short-, intermediate- and long-term dermal MOEs are 280, 21 and 18, respectively, with a target MOE of 300 for short-term and long-term and 100 for intermediate-term.

All of the dermal MOEs are below the target MOE of 300 for short-term and long-term and 100 for intermediate-term for the groundline brush-on treatments (MOEs less then or equal to 1). The brush-on treatment also represents the high-end exposures for the trowel-on and impregnated wraps. Inhalation exposure is expected to be minimal

for the groundline treatments because of the viscosity of the product as well as its low vapor pressure.

The exposure and risks to handlers of the TIE-GARD product used in the automated rail tie treatment system and the solid stick FLURODS are expected to be minimal and are not quantified. Table 5 presents the potential dermal and inhalation short-, intermediate-, and long-term inhalation and dermal exposures and risks for the remedial pole treatment uses of sodium fluoride.

Table 5. Dermal and Inhalation Exposure and Risks for Remedial Applications of Sodium Fluoride to Poles.

Application	Dermal UE (mg/lb a.i)	Inhalation UE (mg/lb a.i)	Rate (gal/pole)	Rate (lb a.i/gal)	# poles	Dermal dose (mg/kg/day)	Inhalation dose (mg/kg/day)	Dermal MOEs			Inhalation MOEs		
								ST (300)	IT (100)	LT (300)	ST (300)	IT (100)	LT (300)
Spray (Distribution Poles)	0.36	0.0022	1	0.47	24	0.058	0.00035	350	26	22	56,000	4200	3700
Spray (Transmission Poles)	0.36	0.0022	1	0.47	30	0.073	0.00044	280	21	18	45,000	3400	2900
Brush-on (Distribution Poles)	24	NA	0.225	5.33	24	9.87	NA	2	<1	<1	NA		
Brush-on (Transmission Poles)	24	NA	0.368	5.33	30	20.2	NA	1	NA	NA	NA		

NA = Not applicable (e.g., short-term (ST) MOEs are only applicable for the high treatment frequency of poles).
ST = short-term; IT = intermediate-term; LT = long-term.

UE are from PHED for termiticide MLAP, liquid pour, rod shank injection
Dermal UE is single layer of clothing and chemical resistant gloves.
Treatment solution for spray from EPA Reg. No. 75341-12 (i.e., 1 gal product x 8.34 lb/gal x 8.39% a.i / 1.5 gallons water = 0.47 lb a.i/gal treatment solution)
Brush-on rate EPA Reg No 75341-5 is 44.4% a.i; density of 12lb/gal = 5.33lb a.i./gallon
poles = registrant estimate during the reregistration phase 1 error comment period (Distribution is 24 poles per day and transmission is 30 poles per day
Dermal (mkd) = Dermal UE x rate x # poles x 1/70kg
Inhalation dose (mkd) = Inhalation UE x rate x #poles x 1/70kg
MOE ST Dermal & inhalation = LOAEL 20 mkd / dose; UF = 300
MOE IT Dermal & Inhalation = NOAEL 1.5 mkd / dose; UF = 100
MOE LT Dermal & Inhalation = LOAEL 1.3 mkd / dose; UF = 300

d. Occupational Post-application Risk Summary

Occupational post-application exposure is not anticipated for the antimicrobial uses of sodium fluoride. The vapor pressure of sodium fluoride is negligible (i.e., 5.43×10^{-26} mmHg at 25 °C), and therefore, no vapor will be released in the vicinity of treated poles. Additionally, label directions to cap treated holes after application will minimize any potential for dermal contact. Likewise, groundline treatments are also covered (i.e., brush-on and wrap treatments are below the groundline and then covered with soil).

7. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to sodium fluoride. 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.

There are only limited acute incidents associated with sodium fluoride used in wood preservatives. All the symptoms are classified as either minor or moderate. Historically, there have been some fatal incidents associated with oral exposure to sodium fluoride. These fatalities occurred when sodium fluoride was ingested at a much higher concentration than is used in antimicrobial wood treatment.

The potential bystander inhalation exposure to sodium fluoride is minimized by the extremely low vapor pressure. The potential for dermal exposure to bystanders (i.e., children, capping of pre-drilled holes and groundline applications covered with soil).

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. Sodium fluoride use as a wood preservative could result in environmental exposures. The following risk characterization is intended to describe the magnitude of the estimated environmental risks associated with sodium fluoride use and any potential uncertainties.

For a detailed discussion of all aspects of the environmental risk assessment, refer to the Environmental Risk Assessment (Section 8) in the "Sodium Fluoride Draft Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 075202 (active). Case No. 3132," dated August 14, 2007; the "Ecological Hazard and Environmental Risk Assessment

Chapter for Sodium Fluoride RED," dated July 23, 2007; and the "Environmental Fate Science Chapter for Sodium Fluoride RED," dated August, 2007.

1. Environmental Fate and Transport

The Agency evaluated the environmental fate of this chemical, using a search of published literature. The results of the literature search are provided below. Additional information can be found in the document titled, "Environmental Fate Risk Assessment Science Chapter for the Sodium Fluoride RED," dated July 26, 2007.

Sodium fluoride is an organic substance which does not undergo hydrolysis but is water soluble and dissociates in water to sodium and fluoride ions. Fluoride ions undergo hydrolysis to form hydrogen fluoride acid and hydroxide ions which can shift the pH to alkaline. Sodium fluoride does not adversely affect soil biomass, microflora and macro invertebrates, and is not expected to be bio-accumulative. A field monitoring study of sodium fluoride treated poles found that sodium fluoride ions occasionally exceed background levels and do not migrate outward from treated poles more than 10 cm or for more than 50 cm deep. Elevated levels returned to background by the end of the 18 month study. Sodium fluoride is not expected to pose a hazard to groundwater or surface waters.

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 summary of acute ecological toxicity is provided in Table 6 below.

a. Environmental Toxicity

Toxicity to Birds

Available data indicate that sodium fluoride is moderately toxic to birds on an acute oral basis and practically 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, sodium fluoride exhibits high toxicity via the oral route; moderate dermal, and inhalation toxicity (toxicity category III). For primary eye irritation, sodium fluoride is corrosive (toxicity category I). Sodium fluoride is classified as a mild skin irritant (toxicity category IV) and is not classified as a dermal sensitizer.

Toxicity to Aquatic Animals

Freshwater acute toxicity tests indicate that sodium fluoride is practically nontoxic to fish on an acute basis. Based on available data, sodium fluoride is practically nontoxic to freshwater invertebrates.

Since sodium fluoride is not expected to reach the estuarine or marine environment from the currently registered use patterns, an evaluation of its impact on estuarine or marine species was not evaluated.

Because of the limited use pattern with low potential for chronic exposure to aquatic organisms, sodium fluoride is not expected to present a chronic aquatic toxicity.

Toxicity to Plants

Current sodium fluoride wood treatment use patterns are limited and are not expected to result in surface water residues of sufficiently large quantities to adversely affect terrestrial or aquatic plant species. Therefore, non-target plant toxicity studies are not required for the current wood treatment use patterns.

Non-target Insects

Honeybees should not be exposed to sodium fluoride wood treatments due to the requirement to wrap the treated area with a waterproof barrier or the requirement to inject sodium fluoride into the wood and then seal the bore hole. Beehives should not be constructed from wood treated with sodium fluoride. The product label(s) must state: "Sodium fluoride must not be used to treat wood intended for construction or maintenance of beehives." Otherwise, the following bee toxicity and honey residue studies are needed: 850.3020, 850.3030 and 860.1500.

A summary of the submitted acute ecological toxicity data, avian sub-acute dietary toxicity data, chronic freshwater fish toxicity data, data for sodium fluoride are provided in Table 6.

Table 6. Ecological Toxicity of the Sodium Fluoride

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint	Toxicity Category	Comments	Reference (MRID No.)
Acute Avian Toxicity					
Bobwhite quail (*Colinus virginianus*)	Sodium Fluoride 95%	LD_{50} = >387 mg/kg NOAEL = 45 mg/kg	Moderately toxic		436115-01
Subacute Avian Toxicity					
Bobwhite quail (*Colinus virginianus)*	Sodium Fluoride 95%	LC_{50} (diet) = >5620 ppm NOAEC = 1000 ppm	Practically nontoxic	- 8-day test duration	435931-02
Mallard duck (*Anas platyrhynchos)*	Sodium Fluoride 95%	LC_{50} (diet) = >5620 ppm NOAEC = 5620 ppm	Practically nontoxic	- 8-day test duration	435931-01
Acute Freshwater Fish Toxicity					
Bluegill Sunfish (*Lepomis macrochirus)*	Sodium Fluoride 95%	LC_{50} = 830 mg/L NOAEC = 350 mg/L	Practically nontoxic	- 96-hr test duration - static renewal test system	43648201
Rainbow Trout (*Oncorhynchus mykiss*)	Sodium Fluoride 95%	LC_{50} = 317 mg/L NOAEC <26 mg/L	Practically nontoxic	- 96-hr test duration - static test system	43648202
Acute Freshwater Invertebrates Toxicity					
Waterflea (*Daphnia magna)*	Sodium Fluoride 95%	EC_{50} >120 mg/L NOAEC = 120 mg/L	Practically nontoxic	- 48-hr test duration - static test system	43648203

b. Ecological Exposure and Risk

Because of the limited use patterns for sodium fluoride, environmental exposure is expected to be low. In addition, product labels require applicators to follow certain precautions, such as waterproof wraps and sealed injections into utility poles, to prevent release into the terrestrial or aquatic environment. Some exposure to woodpeckers and wood boring insects may occur, however, sodium fluoride is practically nontoxic to avian and aquatic species tested. Any incidental exposure is not expected to be toxic to non-target species. Therefore, an environmental risk assessment was not conducted for the sodium fluoride wood treatment uses.

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.

This preliminary analysis indicates that current sodium fluoride wood treatment uses are not likely to enter the environment in sufficient quantities to adversely affect terrestrial or aquatic species; however, an endangered species effects determination will not be made at this time.

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 sodium fluoride 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 sodium flouride.

The Agency has completed its assessment of the occupational, residential, and ecological risks associated with the use of pesticide products containing the active ingredient sodium fluoride. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient sodium fluoride, the Agency has sufficient information on the human health and ecological effects of sodium fluoride 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 sodium fluoride-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 sodium fluoride 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 sodium fluoride 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 sodium fluoride, the Agency has determined that sodium fluoride 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 sodium fluoride. If all changes outlined in this document are incorporated into the product labels, then all current risks for sodium fluoride 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 sodium fluoride. The EPA released its preliminary risk assessment for sodium fluoride for a 60-day public comment on October 10, 2007. The Agency received one comment on the sodium fluoride risk assessments noting that the product should not be manufactured or sold because of the availability for safer alternatives., The agency has considered this comment in making its registration determination.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

There are no registered uses of sodium fluoride that are expected to result in dietary or residential exposure. There are no tolerances. As a result, the only risks assessed for sodium fluoride are those associated with occupational exposures. Therefore a "risk cup" determination is not warranted

b. Determination of Safety to U.S. Population

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

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

The Agency considered the potential pathways of non-dietary exposure to residents in determining the need to conduct an aggregate assessment. The Agency does not anticipate residential exposure as a result of the registered uses of sodium fluoride and did not conduct a residential risk assessment or an aggregate risk assessment.

c. Determination of Safety to Infants and Children

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

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 sodium fluoride as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

d. 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, sodium fluoride may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of sodium fluoride. 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 forsodium fluoride. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

D. Regulatory Rationale

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

The following is a summary of the rationale for managing risks associated with the uses of sodium fluoride. 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 sodium fluoride because the use patterns are not expected to result in residues on food and, thus, dietary exposure. Therefore, sodium fluoride does not pose as a dietary risk and no mitigation measures are needed at this time.

b. Drinking Water Risk Mitigation

Sodium fluoride is not expected to come into contact with or be exposed to drinking water and, therefore, the Agency did not conduct a drinking water exposure assessment. Sodium fluoride is 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

Based on registered uses, negligible residential exposures to sodium flouride are anticipated. No residential assessment has been conducted. Although remedial wood treatment for poles and beams on bridges do not occur in high traffic areas for bystanders, distribution utility poles are numerous and often located in residential front yards. The vapor pressure of sodium fluoride is negligible (i.e., 5.43×10^{-26} mmHg at 25 C), and therefore, no vapor will be released in the vicinity of treated poles. Additionally, label directions to cap treated holes after application will minimize any potential for dermal contact. Likewise, groundline treatments are also covered (i.e., brush-on and wrap treatments are below the groundline and then covered with dirt) and will minimize potential dermal contact to children playing in areas of treated poles. Moreover, the results of a field monitoring study of sodium fluoride treated poles found that outward migration did not exceed 10 cm (i.e., <4 inches) further indicating little to no likelihood of residential exposure.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

Occupational handler dermal risks (IT and LT) of concern were identified for the remedial wood treatment applications of sodium fluoride for several use scenarios (Target MOE = 100 and 300 respectively). These include the application as a spray (MOEs range from 18 to 26) and as a brush-on treatment (MOEs <1). The dermal risk assessment is considered to be very conservative because a default dermal absorption assumption of 100% was used to estimate exposures. The Agency does not expect actual dermal absorption to be significant based on the chemical attributes of sodium fluoride. To confirm that dermal absorption is significantly lower than 100% a 90-day dermal toxicity study will be required.

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

- All labels will need to include increased levels of PPE including elongated elbow-length chemical-resistant coverings, face shield and chemical-resistant aprons.
- Equipment for the brush-on applications will be limited to only brushes that have handles several feet in length to reduce the potential for exposure.
- To confirm the effectiveness of the mitigation measures a dermal exposure study will need to be conducted.
- Require all labels to include training and passage of company-developed competency examinations prior to workers handling sodium fluoride products. These programs are already in place but have not previously been included on labels;

No inhalation risks of concern were identified in the risk assessment.

The Agency also considered the potential benefits of the use of sodium fluoride in making its determination. There are limited alternatives available for the remedial treatment of existing transmission and distribution poles. There are economic benefits associated with the use of remedial treatments in that they increase the service life of the treated poles thus deferring or avoiding replacement costs. Additionally, a benefit of remedial treatments is the reduction in the use of heavy-duty wood preservatives which would be needed to treat replacement poles.

ii. Post-Application Risk Mitigation

Occupational post-application exposure is not anticipated for the antimicrobial uses of sodium fluoride. The vapor pressure of sodium fluoride is negligible (i.e., 5.43×10^{-26} mmHg at 25 °C), and therefore, no vapor will be released in the vicinity of treated poles. Additionally, label directions to cap treated holes after application will minimize any potential for dermal contact. Likewise, groundline treatments are also covered (i.e., brush-on and wrap treatments are below the groundline and then covered with soil)

2. Environmental Risk Management

Because of the use patterns for sodium fluoride, environmental exposure is expected to be low. In addition, product labels require applicators to follow certain precautions, such as waterproof wraps and sealed injections into utility poles, to prevent release into the terrestrial or aquatic environment. Some exposure to woodpeckers and wood boring insects may occur, however, sodium fluoride is practically nontoxic to avian and aquatic species tested. Any incidental exposure is not expected to be toxic to non-target species. Therefore, an environmental risk assessment was not conducted for the sodium fluoride wood treatment uses.

3. Other Labeling Requirements

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

4. Listed Species Considerations

a. The Endangered Species Act

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

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

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.

This preliminary analysis indicates that current sodium fluoride wood treatment uses are not likely to enter the environment in sufficient quantities to adversely affect terrestrial or aquatic species; however, an endangered species effects determination will not be made at this time.

b. General Risk Mitigation

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

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

V. What Registrants Need to Do

The Agency has determined that sodium fluoride is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. To implement the risk mitigation measures, 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 7). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For the sodium fluoride 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

For end-use products containing sodium fluoride 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

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of sodium fluoride has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements and will be included in the generic data call in (DCI) for this RED.

- Dermal toxicity study (90-day) (870.3250)
- Dermal exposure outdoor (875.1100, 875.1600)

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 7, 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 7, 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 sodium fluoride RED. The following table describes how language on the labels should be amended.

Table 7. 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	"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
PPE Requirements	"Applicators must wear chemical resistant gloves and a face shield while handling or applying sodium fluoride." "Applicators must wear elongated chemical-resistent sleeves while handling or applying sodium fluoride."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
For all brush-on application products	"Equipment for the brush-on applications is limited to only brushes that have handles that are several feet in length."	**Directions for Use**
Training	"All users must be trained and pass a company-developed competency examination prior to handling sodium fluoride products"	**Directions for Use**

VI. APPENDICES

Appendix A

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Wood preservatives				
(Exterior use only) Lumber, timber's, posts, poles, ties, pilings, and other wooden members, all exterior wood exposed to moisture or weather	Impregnated materials Reg: 75341-4	Staples or tacks	Dig around the ground line of the pole to be treated to a depth of approximately 20 inches. Remove hardened creosote and rotted wood. Inspect pole as to remaining serviceability. Clean the surface of the pole to be treated. Measure the circumference of the pole. Cut from the roll of impregnated material the length needed. Apply to the pole to the depth of approximately 18 inches below ground line, and 2 inches above ground line. Attach to pole by means of staples or tacks. Be sure bandage is pulled tight to be in close contact with the wood pole. Back fill and tamp the earth around the pole to 2 inches above original ground line.	Proper use includes the covering of any exposed product above the groundline in areas where children or livestock may come in contact with it.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(Exterior use only) Lumber, timber's, posts, poles, ties, pilings, and other wooden members, all exterior wood exposed to moisture or weather	Ready to use Reg: 75340-2	Approved dispenser/ pressurized applicator	RAILROAD TIES: Product is to be placed in the adzed portion of the railroad tie by approved dispenser/applicator. Treated areas should be completely covered by tie plate. STRUCTURAL TIMBERS: For control of internal decay, fill decay pockets and voids using a grease- gun or other pressurized applicator. Fill to refusal. Plug application holes with secure-fitting dowels.	
(Exterior use only) Lumber, timber's, posts, poles, ties, pilings, and other wooden members, all exterior wood exposed to moisture or weather	Ready to use Reg: 75341-5	Brush or trowel	EXTERNAL TREATMENT: Excavate the soil from the groundline of the pole for a depth of 18", or deeper where specified. Remove rotted wood. Clean the surface of the pole to be treated. Apply by brush or	Application of this product may produce a strong, lingering unpleasant odor.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			trowel to a thickness of 1/16”on poles and timber. Typical application is from 3” above to 18” below groundline and lower where deeper decay is suspected. Application on poles to be restored should extend the length of wrap-around type repair systems. Wrap the treated area with water-proof bandage**.** INTERNAL TREATMENT: For control of internal decay in poles and other timbers, holes may be drilled in areas of the poles or timber where protection Is required. Fill drilled holes, decay pockets, and voids using a caulking/grease gun. Plug application holes with secure-fitting dowels.	
(Exterior use only) Lumber, timber’s, posts, poles, ties, pilings, and	Pellets/tablets Reg: 75341-6	Insertion	Specific number of preservative cartridges is dependent on the	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
other wooden members, all exterior wood exposed to moisture or weather			volume of wood to be treated. The recommended minimum dosage is 39.2 grams per cubic foot of to be protected. Drill a hole or holes that will accommodate the number of preservative cartridges needed. After insertion of the preservative cartridges, cap with a wood or plastic plug, or seal with a filler such as putty.	
(Exterior use only) Lumber, timber's, posts, poles, ties, pilings, and other wooden members, all exterior wood exposed to moisture or weather	Soluble Concentrate Reg: 75341-12	Air or Mechanical pressure pump	Stir before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. Shake or stir well. Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu.ft of wood) or to refusal.	Application of this product may produce a strong, lingering unpleasant odor.

APPENDIX B: Sodium fluoride (case 3132)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of sodium fluoride. These requirements apply to sodium fluoride in all products, including data requirements for which a technical grade active ingredient is the test substance.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		43563101
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		43563101
830.1670	61-2b	Formation of Impurities		43563101
830.1700	62-1	Preliminary Analysis		43563101
830.1750	62-2	Certification of Limits		43563101
830.1800	62-3	Analytical Method		43563101
830.6302	63-2	Color		43563101
830.6303	63-3	Physical State		43563101
830.6304	63-4	Odor		43563101
830.7200	63-5	Melting Point		43563101
830.7300	63-7	Density		43563101

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7840 830.7860	63-8	Solubility		43563101
830.7000	63-12	pH		43563101
835-2120	161-1	Hydrolysis		Open Literature
850.1010	72-2	Acute Aquatic Invertebrate Toxicity		43648203
850.1075	72-1a	Fish Acute Toxicity – Freshwater (Bluegill)		43648201
850.1075	72-1b	Fish Acute Toxicity – Freshwater (Rainbow Trout)		43648202
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail)		43611501
850.2200	72-1	Avian Dietary Toxicity-quail		43593102
850.2200	72-1	Avian Dietary Toxicity-duck		43593101
850.3020	141-1	Honey Bee acute contact toxicity		Reserved
850-3030	141-2	Honey Bee toxicity of residues on foliage		Reserved
RESIDUE CHEMISTRY				
860.1500	171-4k	Crop Field Trails		Reserved
TOXICOLOGY*				
870.1100	81-1	Acute Oral - Rat		162945, 40928201,40932003, 43778501

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.1200	81-2	Acute Dermal - Rabbit		162946,40928202,40932002,43778502
870.1300	81-3	Acute Inhalation - Rat		43778503
870.2400	81-4	Primary Eye Irritation - Rabbit		162948,40928204,40932001,41204001,43778504
870.2500	81-5	Primary Dermal Irritation - Rabbit		162947,40928203,40932004,43778505
870.2600	81-6	Dermal Sensitization		40866801,40866901,43778506
870.3100	82-1a	90-Day Feeding-Rodent		NTP study
870.3250	82-3	90-Day Dermal Toxicity-Rodent		Data Gap
870.3700	83-3a	Developmental Toxicity -Rat		Open Literature
870.3700	83-3b	Developmental Toxicity –Non rodent		Open Literature
870.3800	83-4	Reproduction and fertility effects		Open Literature
870.4100	83-1a	Chronic Toxicity-Rat		Open Literature
870.4200	83-2a	Carcinogenicity-Rat		Open Literature
870.4200	83-2b	Carcinogenicity-Mouse		NTP study
870.4300	83-5	Combined chronic toxicity/ Carcinogenicity		NTP study
870.5100	84-2	Bacterial Reverse Mutation Assay		NTP study
870.5300	84-2	Detection of gene mutations in somatic cells		NTP study

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.5375	84-2	In Vitro mammalian chromosome aberration test		NTP study
870.5380	84-2	Mammalian spermatogonial chromosome aberration test		Open Literature
870.5385	84-2	Mammalian bone marrow chromosome aberration test		Open Literature
870.5395	84-2	Mammalian erythrocyte micronucleus test		Open Literature
870.5500	84-2	Bacterial DNA damage or repair test		Open Literature
870.5550	84-2	Unscheduled DNA synthesis in mammalian cell culture		Open Literature
870.5900	84-2	In Vitro sister chromatid exchange assay		NTP study
870.5915	84-2	In Vitro sister chromatid exchange assay		Open Literature
870.7485	85-1	General metabolism and pharmokinetics		Open Literature

Appendix C. Technical Support Documents for Sodium Fluoride

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 10/10/2007 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at www.regulations.gov

These documents include:

- Sodium fluoride Preliminary Risk Assessment; Notice of Availability, 10/10/2007.

Preliminary Risk Assessment and Supporting Science Documents:

- Sodium Fluoride Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 075202 (active). Case No. 3132, September 30, 2007.

- Revised Occupational and Residential/Bystander Assessment of the Antimicrobial Use (Remedial Wood Treatment) of Sodium Fluoride for the Reregistration Eligibility Decision (RED) Document. Case Number 3132. PC Code 075202. October 1, 2007. Timothy Leighton, Ph.D.

- Environmental Fate Science Chapter on Sodium Fluoride for RED Process. Case Number 3132. PC Code 075202. September 25, 2007. A. Najm Shamim, Ph.D.

- Sodium Fluoride Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document. PC Code: 075202. Case No. 3132. September 30, 2007. Timothy F. McMahon, Ph.D.

- Product Chemistry Science Chapter For: Sodium Fluoride Reregistration Eligibility Decision (RED). Case Number 3132. PC Code 075202. September 25, 2007. A. Najm Shamim, Ph.D.

- Ecological Hazard and Environmental Risk Assessment Chapter for Sodium

Fluoride. Case Number 3132. PC Code 075202. September 25, 2007. Richard Petrie, Agronomist.

- Sodium Fluoride – Incident Report Summary. Case Number 3132. PC Code 075202. Jonathan Chen, Ph.D. August 3, 2007

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

1. MRID Studies

MRID #	Citation
162945	Wingard, B. (1984) Acute Oral LD50 Study in Rats Using NG-84: Study No. 410-1844. Unpublished study prepared by Toxigenics, Inc. 26 p.
162946	Kreuger, J. (1984). Acute Dermal Toxicity Study in Rabbits Using NG-84at a Dose Level of 2 Grams per Kilogram of Body Weight: Study No. 410-1845. Unpublished study prepared by Toxigenics, Inc. 14p.
162947	Mellon, K. (1984). Primary Dermal Irritation Study in Rabbits Using NG-84: Study No. 410-1846. Unpublished study prepared by Toxigenics, Inc. 14 p.
162948	Doyle, G. (1984). Primary Eye Irritation Study in Rabbits Using NG-84: Study No. 410-1847. Unpublished study prepared by Toxigenics, Inc. 16 p.
40866801	Siglin, J. (1988). Delayed Contact Hypersensitivity Study in Guinea Pigs with Patox-Lite: Final Report: SLS Study No. 3191.8. Unpublished study prepared by Springborn Life Sciences, Inc. 24 p.
40866901	Siglin, J. (1988). Delayed Contact Hypersensitivity Study in Guinea Pigs with Adz-Pad (EPA): Final Report: SLS Study No. 3191.9. Unpublished study prepared by Springborn Life Sciences, Inc. 23 p.
40928201	Naas, D. (1988). Acute Oral Toxicity (LD50) Study in Albino Rats with Copper Naphthenate/Sodium Fluoride Grease: Final Report: Project No. WIL-127001. Unpublished study prepared by WIL Research Laboratories, Inc. 21 p.
40928202	Naas, D. (1988). Acute Dermal Toxicity (LD50) Study in Albino Rabbits with Copper Naphthenate/Sodium Fluoride Grease: Final Report: Project ID WIL-127002. Unpublished study prepared by WIL research Laboratories, Inc. 29p
40928203	Naas, D. (1988). Primary Dermal Irritation Study in Albino Rabbits with Copper Naphthenate/ Sodium Fluoride Grease: Final

Report: Project IN WIL 127003. Unpublished study prepared by WIL Research Laboratories, Inc. 17 p.

40928204 Naas, D. (1988). Primary Irritation Study in Albino Rats with Copper Naphthenate/Sodium Fluoride Grease: Final Report: project ID WIL-127004. Unpublished study prepared by Bioassay Systems Corp. 19 p.

40932001 Goodband , J. (1982). Primary Eye Irritation Test Performed on Osmoplastic: Project No. 11005. Unpublished study prepared by Bioassay Laboratories, Inc. 21 p.

40932002 Goodband, J. (1982). Acute 14-Day Dermal Range Finding Determination Performed on Osmoplastic, Batch No. C059: Project No. 11005. Unpublished study prepared by Bioassay Systems Corp. 10p.

40932003 Goodband, J. (1982). Acute Oral LD_{50} Determination Performed on Osmoplastic: Project No. 11005. Unpublished study prepared by Bioassay Systems Corp. 19p.

40932004 Goodband, J. (1982). Primary Dermal Irritation Test Performed on Osmoplastic: Project No. 11005. Unpublished study prepared by Bioassay Systems Cor. 12 p.

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43563101 Muchow, T. (1994). Product Chemistry Data: Sodium Fluoride. Unpublished study prepared by Osmose Wood Preserving, Inc. 27 p.

43593101 Campbell, S.; Beavers, J. (1995) Osmose Sodium Fluoride: A Dietary LC50 Study with the Mallard: Lab Project Number: 391-102. Unpublished study prepared by Wildlife International Ltd. 29 p.

43593102 Campbell, S.; Beavers, J. (1995) Osmose Sodium Fluoride: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 391-101. Unpublished study prepared by Wildlife International Ltd. 31 p.

43611501 Campbell, S. and J. Beavers. 1995. “Osmose Sodium Fluoride: An Acute Oral Toxicity Study with the Northern Bobwhite”: Lab Project Number: 391/103. Unpublished study prepared by Wildlife International Ltd. 31p.

43648201 Collins, M. 1995. "Osmose Sodium Fluoride CTM—Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static-Renewal Conditions": Final Report: Lab Project Number: 94/9/5477: 1325/0594/6102/100. Unpublished study prepared by Springborn Labs, Inc. 65p.

43648201 Collins, M. 1995. "Osmose Sodium Fluoride CTM—Acute Toxicity to Bluegill sunfish (*Lepomis macrochirus*) Under Static-Renewal Conditions": Final Report: Lab Project Number: 94/9/5477: 1325/0594/6102/100. Unpublished study prepared by Springborn Labs, Inc. 65p.

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43648203 Collins, M. (1995) Osmose Sodium Fluoride CTM--Acute Toxicity to Daphnids (Daphnia magna) Under Static Conditions: Final Report: Lab Project Number: 94/9/5480: 1325/0594/6103/110. Unpublished study prepared by Springborn Labs, Inc. 64 p.

43778501 Wnorowski G. (1995). Acute Oral Toxicity Defined LD50 (in Rats): Composite NaF: Lab Project Number: 3719:P320. Unpublished study prepared by Product Safety Labs. 28 p.

43778502 Wnorowski G. (1995). Acute Dermal Toxicity Limit test (in Rats): Composite NaF: Lab Project Number: 3722:P322. Unpublished study prepared by Product Safety Labs. 15 p.

43778503 Wnorowski, G. (1995). Acute Inhalation Toxicity Defined LC50 (in Rats): Composite NaF: Lab project Number: 3724:P330. Unpublished study prepared by Product Safety Labs. 42p.

43778504 Wnorowski, G. (1995). Primary Eye Irritation (in Rabbits): Composite NaF: Lab project Number: 3720:P324. Unpublished study prepared by product Safety Labs. 26 p.

43778505 Wnorowski, G. (1995). Primary Skin Irritation (in Rabbits): Composite NaF: Lab Project Number: 3721: P326. Unpublished study prepared by Product Safety Labs. 16 p.

43778506 Wnorowski, G. (1995). Dermal Sensitization Test-Buehler Method (in Guinea Pigs): Composite NaF: Lab Project Number: 3723: P328. Unpublished study prepared by Product Safety Labs. 24 p.

Open Literature

Citation

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Abukurah AR, Moser AM Jr, Baird CL, et al. 1972. Acute sodium fluoride poisoning. JAMA 222:816- 817.

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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 sodium fluoride RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

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

Appendix G. Batching of sodium fluoride Products for Meeting Acute Toxicity Data Requirements for Reregistration.

The Agency intends to add at a later date.

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

The Agency intends to add at a later date.

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

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

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

Instructions

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

   b. 84-1 Clarification of Label Improvement Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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