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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 1, 2007

MEMORANDUM

SUBJECT: 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.

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This document is a review of the occupational applicator and residential bystander assessment for the antimicrobial remedial wood treatment use of sodium fluoride to support the Reregistration Eligibility Decision (RED) document. It has been revised to include comments from the Phase 1 "*error comment*" period.

EXECUTIVE SUMMARY

The Antimicrobials Division (AD) assessed the occupational and potential bystander risks to the remedial wood treatment uses of sodium fluoride. The remedial wood treatment is used to treat poles, crossties, structural timbers such as bridge pilings and posts, etc., against decay producing fungi. Based on label directions, two distinct application types were assessed including predrilled hole treatments as well as groundline treatments. The pre-drilled hole treatments that are applied using an automated rail tie application technique as well as the solid stick product are expected to result in minimal exposure that can be mitigated with personal protective equipment (PPE) are not assessed quantitatively. PPE should be required for these products to mitigate potential exposure for leaks, etc. The inhalation risks for the pre-drilled hole spray applications using the mechanical pressure pumps are not of concern. However, dermal risks are triggered for this application scenario for the treatment of distribution and transmission poles. Additionally, all of the dermal MOEs are below the target MOE 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 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 playing in the vicinity of treated poles) is minimized by the enclosure of the application site (i.e., capping of pre-drilled holes and groundline applications covered with dirt).

1.0 Introduction

1.1 Purpose

In this document, the Antimicrobials Division (AD) presents the results of its review of the potential human health effects of occupational and residential exposure to sodium fluoride. This information is for use in EPA's development of the sodium fluoride Reregistration Eligibility Decision (RED) document.

1.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For sodium fluoride, both criteria are met. Toxicological endpoints were selected for short-, intermediate-, and long-term dermal and inhalation exposures to sodium fluoride. There is the potential for occupational exposure to some of the application methods used in the remedial wood treatment (e.g., brush-on, pressurized sprays, etc). Therefore, risk assessments are required for occupational uses.

In this document, 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 levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the USEPA and international organizations such as Health Canada and OECD (Organization for Economic Cooperation and Development). Using surrogate unit exposure data, maximum application rates from labels, and EPA estimates of daily amount handled, exposures and risks to handlers were assessed.

1.3 Physical/Chemical Properties

Table 1.2 shows physical/chemical characteristics that have been reported for sodium fluoride.

Table 1.2. Physical/Chemical Properties of Sodium Fluoride

Parameter	Sodium Fluoride
Molecular Weight	42
Density	2.55 g/cm^3
Boiling Point	1704 °C

Table 1.2. Physical/Chemical Properties of Sodium Fluoride	
Parameter	Sodium Fluoride
Water Solubility	4.1 g/100 ml at 15 °C
Vapor Pressure	5.43 x 10^{-26} mmHg at 25 °C (EPI Suite)

2.0 USE INFORMATION

2.1 Formulation Types and Percent Active Ingredient

The products containing sodium fluoride as the active ingredient (a.i) are formulated as liquid ready-to-use, soluble concentrate, wraps, and rods. Concentrations of sodium fluoride range from 8.39% to 97.5%.

2.2 Summary of Use Pattern

The Agency determines potential exposures to handlers of the product by identifying exposure scenarios from the various application methods that are plausible, given the label uses. Based on a review of product labels, sodium fluoride is the active ingredient in remedial wood treatments. Specific application techniques are presented in Section 4 below.

3.0 Toxicological Endpoints of Concern

Table 3.1 presents the acute toxicity categories (USEPA 2007).

Table 3.1. Acute Toxicity Categories for Sodium Fluoride	
Study Type	Toxicity Category
Acute Oral Toxicity	II
Acute Dermal Toxicity	III
Acute Inhalation Toxicity	III
Primary Eye Irritation	II
Primary Dermal Irritation	IV
Dermal Sensitization	negative

Table 3.2 summarizes the toxicological endpoints for sodium fluoride (USEPA 2007).

Table 3.2. Summary of Sodium Fluoride Toxicological Endpoint Selection.			
Exposure Scenario	Dose (mg/kg/day)	Level of Concern	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. 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 mg/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, and 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.

Table 3.2. Summary of Sodium Fluoride Toxicological Endpoint Selection.			
Exposure Scenario	Dose (mg/kg/day)	Level of Concern	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, and 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" (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.'		

4.0 Remedial Wood Treatment

4.1 Exposure Scenarios

Sodium fluoride is used as a remedial wood treatment for the protection against decay producing fungi. Table 4.1 summarizes the various sodium fluoride label parameters used in this assessment including EPA Reg. No., percent active ingredient, signal word, personal protective equipment, and use directions/application methods. 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. Label PPE should be reviewed for accuracy and consistency.

Table 4.1. 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 respirator when spraying for continued or prolonged use or frequent use	Used in combination with copper naphthenate. Mix 1 gallon of product 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.

Chemical-specific exposure data were not submitted to support the remedial wood applications. Therefore, AD 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 4.1 above, 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. Each remedial application can be applied using various techniques. 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. Table 4.2 presents the representative exposure scenarios used to assess the labeled remedial wood treatment uses.

Table 4.2. Respresentative Exposure Scenarios for Remedial Wood Treatments.

Remedial Applications	High-end Exposure Scenarios	Application Techniques Represented by the High-end Exposure Scenario
Pre-drilled holes	Closed systems (PPE mitigation)	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)

4.1.1 Pre-Drilled Hole Treatments

TIE-GARD and FLURODS:

TIE-GARD and FLURODS are sodium fluoride products that are inserted into pre-drilled holes and capped 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. 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 of PPE such as chemical resistant gloves, goggles, long pants, and long sleeved-shirts. Therefore, the handler risks to pre-packaged products 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.

4.1.2 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.

4.2 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 dirt. 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 rate of ~24 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.

- 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.

4.3 Exposure and Risk Estimates

Table 4.3 presents the potential dermal and inhalation short-, intermediate-, and long-term exposures and risks for the remedial pole treatment uses of sodium fluoride. 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.

The spray applications into pre-drilled holes indicate no dermal risks of concern for the short-term duration for the distribution poles. Dermal risks, however, are triggered fro the intermediate- and long-term durations. The intermediate- and long-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 100 for intermediate-term.

All of the dermal MOEs are below the target MOE 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.

Table 4.3. Dermal and Inhalation Exposure and Risks for Remedial Applications of Sodium Fluoride to Poles.

Application	Dermal UE (mg/lb ai)	Inhalation UE (mg/lb ai)	Rate (gal/pole)	Rate (lb ai/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	4,200	3,700
Spray (Transmission Poles)	0.36	0.0022	1	0.47	30	0.073	0.00044	280	21	18	45,000	3,400	2,900
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 unit exposure represents workers wearing 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% ai / 1.5 gallons water = 0.47 lb ai/gal treatment solution)

Brush-on rate EPA Reg No 75341-5 is 44.4% ai; density of 12 lb/gal = 5.33 lb ai/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

5.0 Bystander/Residential Exposure and Risks

In general, remedial wood treatment for poles and beams on bridges do not occur in high traffic areas for bystanders. However, distribution 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.

6.0 Conclusions

Applications of sodium fluoride include pre-drilled hole treatments and groundline treatments. The pre-drilled hole treatments are applied with pre-packaged insert products and also mechanical pressure pumps. Exposure to the automated TIE-GARD and solid stick FLURODS are expected to be negligible and is not assessed quantitatively. PPE should be required for these products to mitigate potential exposure for leaks, etc. The inhalation (all durations) and short-term dermal risks for the pre-drilled hole spray applications for the distribution poles using the mechanical pressure pumps are not of concern. However, the dermal risks for the intermediate- and long-term dermal risk for the distribution poles are of concern (i.e., MOEs are 26 and 22, respectively, with a target MOE of 100 and 300, respectively). For the transmission poles, no inhalation risks were identified for any duration. However, the dermal risks for the short-, intermediate- and long-term durations for the transmission poles are of concern (i.e., MOEs are 280, 21, and 18, respectively, with a target MOE of 300, 100, and 300, respectively). All of the dermal MOEs are below the target MOE 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.

EPA has used the best available surrogate exposure data from PHED and CMA to develop a screening-level assessment for the handlers of sodium fluoride. The following uncertainties should be considered by the regulatory risk managers during the decision making process:

- Unit exposures are not available for the scenarios that are prescribed for remedial pole injection. Nonetheless, the data from PHED for combined mixing/loading/injecting a liquid termiticide is a reasonable surrogate for the pole treatment as the label for the remedial wood treatment indicates to apply a spray into predrilled holes with an air or mechanical pressure pump. The PHED termiticide scenario is considered to be of "high confidence" (i.e., 17 replicates of Grade AB data – indicating the analytical portion of the study meets EPA exposure test guidelines).

- Sodium fluoride is used to treat both poles and timbers. The assessment for the remedial wood treatments is based on applications to distribution and transmission poles as representative of all the remedial treatments. Although it is unknown how many timbers

in a bridge or other structure are treated, the pole use is believed to be representative of the high end use.

· The use information for the remedial pole treatments is based on the registrant's response during the error comment period. The individuals contacted have experience in these operations and their estimates are believed to be the best available without undertaking a statistical survey of the uses.

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 playing in the vicinity of treated poles) is minimized by the enclosure of the application site (i.e., capping of pre-drilled holes and groundline applications covered with dirt).

7.0 Reference

USEPA. 2007. Toxicological endpoint selection memorandum.