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SUBJECT: **Revised** Ecological Hazard and Environmental Risk Assessment Chapter for Sodium Fluoride RED – Error Corrections
Antimicrobial Division
Case Number: 3132
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Attached please find the Ecological Hazard and Environmental Risk Assessment Chapter for the Sodium Fluoride RED with error corrections.

ECOLOGICAL HAZARD AND ENVIRONMENTAL RISK ASSESSMENT CHAPTER
Sodium Fluoride

PC Codes 075202

CASE No.: 3132

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Ecological Hazard and Environment Risk Assessment For Sodium Fluoride

Executive Summary:

Sodium fluoride is registered 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.

Sodium fluoride can be rolled or brushed onto an external wood surface typically 3 inches above and 18 inches below the ground surface. The application is then wrapped with a water proof bandage. Another method of application is by drilling holes into the timber and inserting sodium fluoride rods that contain pellets or tablets into the drilled holes. The holes are then sealed with a plug or putty filler. Sodium fluoride is also injected as a gel to a portion of a railroad tie that is completely covered by the metal tie plate. The sodium fluoride gel slowly migrates into the railroad tie from the point of injection (spike hole)to protect the wood against fungal rot.

Sodium fluoride is an inorganic 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.

Sodium fluoride use as a wood preservative is not expected to pose an adverse risk to terrestrial or aquatic animals or plants based on current use patterns unless a spill were to occur. The use of water proof wraps and sealed injections should serve to greatly reduce environmental exposure.

Label Hazard Statements/Use Recommendations:

"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 required: 850.3030, 860.1500

I. Ecological Toxicity Data

The toxicity endpoints presented below are based on the results of ecotoxicity studies submitted to EPA to meet the Agency's data requirements for the uses of sodium fluoride.

A. Toxicity to Terrestrial Animals

(1) Birds, Acute

In order to establish the toxicity of sodium fluoride to avian species, the Agency requires an acute oral toxicity study using the technical grade active ingredient (TGAI). The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland game bird). The result of an acceptable acute oral toxicity study submitted for sodium fluoride is provided in the following table (Table 1).

Table 1. Acute Oral Toxicity of Sodium Fluoride to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Bobwhite quail (*Colinus virginianus*)	Sodium Fluoride 95%	LD_{50} = > 387 NOAEL = 45	Moderately toxic	Yes (core)	43611501

An acceptable acute oral toxicity study on the bobwhite quail indicate that sodium fluoride is moderately toxic on an acute oral basis. The guideline requirement OPPTS 850.2100 is satisfied.

(2) Birds, Subacute

A subacute dietary study using the TGAI may be required on a case-by-case basis depending on the results of lower-tier ecological studies and pertinent environmental fate characteristics in order to establish the toxicity of a chemical to avian species. The preferred-test species are the mallard duck and bobwhite quail. The results of subacute dietary toxicity studies for sodium fluoride are provided in the following table (Table 2).

Table 2. Subacute Oral Toxicity of Sodium Fluoride to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (ppm)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Bobwhite quail (*Colinus virginianus*)	Sodium Fluoride 95%	LC_{50} (diet) = >5620 NOAEC = 1000	Practically nontoxic	Yes (core) - 8-day test duration	43593102
Mallard duck (*Anas platyrhynchos*)	Sodium Fluoride 95%	LC_{50} (diet) = >5620 NOAEC = 5620	Practically nontoxic	Yes (core) - 8-day test duration	43593101

Sodium fluoride is practically nontoxic to avian species through subacute dietary exposure. These studies fulfill guideline requirements OPPTS 850.2200 (Bobwhite quail and Mallard duck).

(3) Mammals, Acute and Chronic Toxicity

Wild mammal testing is not required by the Agency. In most cases, rat toxicity values obtained from studies conducted to support data requirements for human health risk assessments substitute for wild mammal testing. Refer to the human toxicology chapter for mammalian toxicity data.

(4) 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 or 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 required: 850.3020, 850.3030, 860.1500

B. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

In order to establish the acute toxicity of sodium fluoride to freshwater fish, the Agency requires a freshwater fish toxicity studies using the TGAI. Preferred test species are rainbow trout (a cold water fish) and bluegill sunfish (a warm water fish). The results of two freshwater fish acute studies submitted for sodium fluoride are presented in Table 3.

Table 3. Acute Toxicity of Sodium Fluoride to Freshwater Fish

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Bluegill Sunfish (*Lepomis macrochirus)*	Sodium fluoride 95%	LC_{50} = 830 NOAEC = 350	Practically nontoxic	Yes (core) - 96-hr test duration - static renewal test system	43648201
Rainbow Trout (*Oncorhynchus mykiss*)	Sodium fluoride 95%	LC_{50} = 317 NOAEC = < 26	Practically nontoxic	Yes (core) - 96-hr test duration - static test system	43648202

Freshwater acute toxicity tests indicate that sodium fluoride is practically nontoxic to fish on an acute basis. Study 43648201 fulfills the guideline requirement for the warm water species and study 43648202 fulfills the guideline requirement for the cold water fish species under OPPTS 850.1075.

(2) Freshwater Invertebrates, Acute

The Agency requires a freshwater aquatic invertebrate study using the TGAI to establish the acute toxicity to freshwater invertebrates. The preferred test species is *Daphnia magna*. The result of one study submitted for sodium fluoride is provided in the following table (Table 4).

Table 4. Acute Toxicity of Sodium Fluoride to Freshwater Invertebrates

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Waterflea (*Daphnia magna*)	Sodium Fluoride 95%	EC_{50} = > 120 NOAEC = 120	Practically nontoxic	Yes (core) - 48-hr test duration - static test system	43648203

The results of 43648203 indicate that sodium fluoride is practically nontoxic to freshwater invertebrates. This study fulfills guideline requirement OPPTS 850.1010.

(3) Estuarine and Marine Organisms, Acute

Acute toxicity testing with estuarine and marine organisms using the TGAI is required when the end-use product is intended for direct application to the marine/estuarine environment or effluent containing the active ingredient is expected to reach this environment. The preferred fish test species is the sheepshead minnow. The preferred invertebrate test species are mysid shrimp and eastern oysters. Sodium fluoride is not expected to reach the estuarine or marine environment, therefore, studies OPPTS 850.1075, OPPTS 850.1035, and OPPTS 850.1025 are not required for the current wood treatment use patterns.

(4) Aquatic Organisms, Chronic

Chronic toxicity tests (fish early life stage and aquatic invertebrate life cycle) are required for pesticides when certain conditions of use and environmental fate apply. The preferred freshwater fish test species is the fathead minnow. The preferred freshwater invertebrate is *Daphnia magna*. Sodium fluoride is not expected to present a chronic aquatic toxicity concern, therefore, studies OPPTS 850.1300 and OPPTS 850.1400 are not required for the current wood treatment use patterns.

C. Toxicity to Plants

Non-target plant phytotoxicity tests are required for pesticides when certain conditions of use and environmental fate apply. Tests are conducted with one species of aquatic vascular plant (*Lemna gibba*) and four species of algae: (1) freshwater green alga, *Selenastrum capricornutum,* (2) marine diatom, *Skeletonema costatum,* (3) freshwater diatom, *Navicula pelliculosa,* and (4) bluegreen cyanobacteria, *Anabaena flos-aquae.* The rooted aquatic macrophyte rice (*Oryza sativa*) is also tested in seedling emergence and vegetative vigor tests.

Current sodium fluoride wood treatment use patterns are not expected to result in surface water or spray drift residues of sufficiently large quantities to adversely affect terrestrial or aquatic plant species. Therefore, non-target plant toxicity studies 850.4225, 850.4400, and 850.5400 are not required for the current wood treatment use patterns.

II. Risk Assessment and Characterization

A. Environmental Fate Assessment Summary

Sodium fluoride is an inorganic 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. (Refer to the Environmental Fate Science Chapter for greater detail.)

B. Exposure and Risk to Nontarget Terrestrial and Aquatic Organisms

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are used by OPP to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute** -- potential for acute risk to non-target organisms which may warrant regulatory action in addition to restricted use classification, (2) **acute restricted use** -- the potential for acute risk to non-target organisms, but may be mitigated through restricted use classification, (3) **acute endangered species** - endangered species may be adversely affected by use, (4) **chronic risk** - the potential for chronic risk may warrant regulatory action, endangered species may potentially be affected through chronic exposure, (5) **non-endangered plant risk** – potential for effects in non-target plants, and (6) **endangered plant risk** – potential for effects in endangered plants. Currently, OPP does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds), (2) LD_{50} (birds and mammals), (3) EC_{50} (aquatic plants and aquatic invertebrates) and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEC (birds, fish, and aquatic invertebrates), and (2) NOAEC (birds, fish and aquatic invertebrates). For birds and mammals, the NOAEC generally is used as the ecotoxicity test value in assessing chronic effects, although other values may be used when justified. However, the NOAEC is used if the measurement endpoint is production of offspring or survival.

Risk presumptions and the corresponding RQs and LOCs are tabulated below.

Table 5. Risk Presumption Categories

Risk Presumption for Terrestrial Animals	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.2
Acute Endangered Species: endangered species may be adversely affected by use	>0.1
Chronic Risk: potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Aquatic Organisms	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.1
Acute Endangered Species: endangered species may be adversely affected by use	>0.05
Chronic Risk: potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Terrestrial and Aquatic Plants	**LOC**
Potential for risk for all non-endangered and endangered plants	>1

An environmental risk assessment was not conducted for sodium fluoride wood treatment uses because precautions are taken 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.

C. Endangered Species Considerations

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.

III. Label Hazard Statements for Terrestrial and Aquatic Organisms and Use Recommendations

"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 required: 850.3030, 860.1500.

IV. REFERENCES

MRID 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.

MRID 43648202 – Collins, M. 1995. "Osmose Sodium Fluoride CTM—Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static-Renewal Conditions": Final Report: Lab Project Number: 94/10/5489: 1325/0594/6101/103. Unpublished study prepared by Springborn Labs, Inc. 64p

MRID 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.

MRID 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.

MRID 43648202 – Collins, M. 1995. "Osmose Sodium Fluoride CTM—Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static-Renewal Conditions": Final Report: Lab Project Number: 94/9/5477: 1325/0594/6102/100. Unpublished study prepared by Springborn Labs, Inc. 65p