



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

**OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

SUBJECT: Sodium Fluoride – Incident Report Summary

PC Code: 075202

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Attached is RASSB's incident reports summary associated with sodium fluoride.

INCIDENT REPORTS ASSOCIATED WITH

Sodium Fluoride

(PC CODE: 075202)

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0.0 INTRODUCTION

The purpose of this chapter is to review the evidence of health effects in humans resulting from exposure to sodium Fluoride.

Two approaches are used in this section:

1. The potential health effects of sodium fluoride in humans, reported as incident reports from different sources, are summarized.
2. A literature search of chronic health effects associated with sodium fluoride exposure, including results of epidemiological studies, is summarized.

1.0 INCIDENT REPORT DATA ASSOCIATED WITH HEALTH EFFECTS

The following databases have been consulted for incident data:

OPP Incident Data System (IDS) - The Incident Data System of The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) 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. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

Poison Control Centers - as the result of a data purchase by EPA, OPP received Poison Control Center data covering the years 1993 through 2003 for all pesticides. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings involving drugs, household products, pesticides, etc.

California Department of Pesticide Regulation - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive, has been prepared. The total number of calls was tabulated for the categories of human incidents, animal incidents, calls for information, and others.

1.1 OPP's Incident Data System (IDS)

There is no incident has been reported in the OPP incident data system is specific associated with sodium fluoride exposure.

1.2 Poison Control Center (1993 – 2003)

There are 5 incidents been reported in the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) between 1993-2003.

Between 1993-1998, two cases involved oral exposure are reported. The patients exhibited symptoms as a result of the exposure which are consider have moderate effects and were not life-threatening and the patients have returned to a pre-exposure state of well-being with no residual disability or disfigurement. The reported symptoms including blurred visions, and chest and abdominal pain.

Between 1999-2003, three cases (two involved oral exposure and one involved aerosol inhalation exposure) are reported. All the three cases are classified as minor effects as the result of the exposure and the symptoms resolve rapidly and returned to a pre-exposure state of well being and have no residual disability or disfigurement. For oral exposure, vomiting is the primary reported symptom. For inhalation exposure, nausea and headache are the primary reported symptoms.

1.3 California Data - 1982 through 2003

There is one sodium fluoride involved incident reported. A worker applies a wood preservative to the base of a telephone pole and got some on his cheek. While wiping it off with his sleeve, he rubbed it into his left eye. He flushed the eye with a portable kit. The reported symptoms include pain, burning sensation, and marked conjunctival infection in the left eye. However, creosote and potassium dichromate may also be involved in this incident.

1.4 National Pesticide Telecommunications Network (NPTN)

There is no incident reported in the NPTN database related to sodium fluoride exposure.

1.5 Incident Reports / Epidemiological Studies Published in Scientific Literature

There are some concerns associated with sodium fluoride exposure reported in the public literature.

1.5.1 Acute Effects

Direct contact with fluoride can result in tissue damage. At high concentrations, fluoride can cause irritation and damage to the respiratory tract, stomach, and skin following inhalation, oral, and dermal exposure, respectively (ATSDR, 2003). Dermal irritation and contact urticaria have been reported from dermal contact of sodium fluoride (Camarasa et al., 1993).

There are incidences associated with sodium fluoride through acute oral ingestion (Abukurah et al. 1972; Hayes, 1975; Eichler et al., 1982). As summarized by Dreisbach (1987), through oral exposure, soluble fluoride salts may cause salivation, nausea and vomiting, diarrhea, and abdominal pain. Later, weakness, tremors, shallow respiration, carpopedal spasm, and convulsions occur. Death is by respiratory paralysis. If death does not occur immediately, jaundice and oliguria may appear. Experience with oral fluoride supplements used to prevent tooth decay has been reassuring; no adverse effects occur unless enormous amounts are ingested. A variety of metabolic disorders may occur, including hypocalcemia, hypomagnesemia, metabolic and/or respiratory acidosis and sometimes hyperkalemia, may also occur in acute fluoride poisoning (Gosselin, et al., 1984).

Cardiac effects have been reported associated with acute sodium fluoride through oral, dermal, and/or inhalation exposure routes. Approximately 2 hours after ingestion of 120 g of roach powder (97% sodium fluoride) in an unsuccessful suicide attempt, a 25-year-old male had severe toxic reactions that included tetany, multiple episodes of ventricular fibrillation, and esophageal stricture (Abukurah et al. 1972). Within 14 hours following exposure, the patient experienced 63 episodes of ventricular fibrillation. For example, a plasma fluoride level of 2,000 µg/L was reported in a case of severe oral poisoning with 53 g fluoride as sodium fluoride (Abukurah et al. 1972). The noticed cardiac symptoms may be associated with the metabolic disorder resulted from acute fluoride exposure.

1.5.2 Chronic Effects

Fluoride intake has been shown to decrease the prevalence of dental caries. However, the primary concerns associated with chronic exposure to high level of fluoride, especially through oral route, can cause dental fluorosis and can result in an increased prevalence of bone fractures in the elderly or skeletal fluorosis (ATSDR, 2003).

Numerous epidemiological studies have examined the issue of a connection between fluoridated water with heart disease. There are studies show there were no significant differences between areas with different fluoride levels in mortality due to coronary disease, angina, and other heart disease (Leone et al. 1954; Heasman and Martin 1962). Although there is a study show a positive relationship between heart disease and water fluoridation (Hagan et al. 1954), this study was criticized for the sampling population was not properly age adjusted (Jansen and Thomson, 1974). There are other studies have suggested fluoridation can decrease the incidence of cardiovascular disease (Bernstein et al. 1966; Luoma 1980; and Taves, 1978).

Numerous epidemiological studies have examined the issue of a connection between fluoridated water and cancer. Most studies have not found significant increases in cancer mortality (Erickson 1978; Hoover et al. 1976; Rogot et al. 1978; Taves 1977) or site-specific cancer incidence (Freni and Gaylor 1992; Gelberg et al. 1995; Hoover et al. 1976; Mahoney et al. 1991; McGuire et al. 1991). However, a couple of studies have reported significant fluoridation-related increases in cancer mortality. In order to address the cancer concern, the National Toxicology Program (NTP) conducted two chronic oral bioassays of fluoride administered as sodium fluoride (0, 25, 100, or 175 ppm) in drinking water for 103 weeks, using F344/N rats and B6C3F1 mice (NTP, 1990). The estimated total fluoride intake (including fluoride in both water and diet) of control, low-, medium-, and high-dose male rats as 0.2, 0.8, 2.5, and 4.1 mg/kg/day, respectively. Similarly, the high doses for female rats, male mice, and female mice were 4.5, 8.1, and 9.1 mg/kg/day, respectively. The study found osteosarcomas in the bone of 1/50 male rats in the mid-dose group and 3/80 of the high dose male rats. An additional high-dose male had an extra skeletal osteosarcoma in subcutaneous tissue. Osteosarcomas were observed in one low-dose male mouse, one low-dose female mouse, and one control female mouse. There was also one osteoma in a control female mouse. No osteosarcomas were observed at mid- or high-dose levels in female rats or male or female mice.

In 1996, the EPA's Office of Prevention, Pesticides, and Toxic Substances classified sodium aluminofluoride (cryolite) as a "Group D" carcinogen (not classifiable as to carcinogenicity), citing the National Toxicology Program's carcinogenicity study of sodium fluoride (NTP, 1990). More recently, the National Academy of Sciences (NAS, 2006) at the request of the EPA, conducted a review of the toxicologic, epidemiologic, and clinical data on fluoride since the 1993 NAS report. With respect to carcinogenicity, the 2006 NAS report concluded that "on the basis of the committee's collective consideration of data from humans, genotoxicity assays, and studies of mechanism of action in cell systems...the evidence on the potential of fluoride to initiate or promote cancers, particularly of the bone, is tentative and mixed." This recent conclusion is consistent with the past conclusion of OPPTS regarding carcinogenic potential of fluoride.

2.0 CONCLUSIONS

There are only limited acute incidences associated with sodium fluoride used in wood preservatives. All the symptoms are classified as either minor or moderate. Historically, there are some fatal incidences associated with oral exposure to sodium fluoride, it happened at much higher concentration.

For chronic exposure, fluoride intake has been shown to decrease the prevalence of dental caries. At high level of fluoride, especially through oral route, can cause dental fluorosis and can result in an increased prevalence of bone fractures in the elderly or skeletal fluorosis (ATSDR, 2003). In 1996, the EPA's Office of Prevention, Pesticides, and Toxic Substances classified sodium aluminofluoride (cryolite) as a "Group D" carcinogen (not classifiable as to carcinogenicity).

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