

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 9 September 2011
Document Number: 130108
Date Revised: 24 September 2014
Revision Number: 3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):

NUPRO Aerosol Fluoride Foams

Part/Item Number:

130110, 130113, 130114, 130115

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:

Topical fluoride treatment for teeth.

Restrictions on Use:

For Professional Use Only. Do not use this product on patients with known allergies to any of the components.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:

DENTSPLY Professional

Manufacturer/Supplier Address:

1301 Smile Way
York, PA 17404

Manufacturer/Supplier Telephone Number:

800-989-8826 or 717-767-8502 (Product Information)

Email address:

ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Acute Toxicity Category 4 (H302) Eye Damage Category 1 (H318)	Not Hazardous	Flammable Aerosol Category 1 (H222) Gas Under Pressure: Compressed Gas (H280)

EU Classification: Extremely Flammable (F+), Irritant (Xi), Harmful (Xn) R12, R22, R36

2.2 Label Elements:



Signal Word: Danger

Contains: Sodium Fluoride, Phosphate Ester, Cetyl Phosphate

Hazard Phrases	Precautionary Phrases
H222 Extremely flammable aerosol. H280 Contains gas under pressure; may explode if heated. H302 Harmful if swallowed. H318 Causes serious eye damage.	P210 Keep away from heat, sparks, open flames, and hot surfaces. No smoking. P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use. P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear eye protection, and face protection P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. P410 + P403 + P412 Protect from sunlight. Store in a well-ventilated place. Do not expose to temperatures exceeding 50°C/122°F. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-Hazardous Ingredients	Mixture	Mixture	Not Applicable	65-75
Heptafluoropropane	431-89-0	207-079-2	Press. Gas (H280)	5-15
Ethyl Alcohol (Ethanol)	64-17-5	200-578-6	F, R11 Flam. Liq. 2 (H225), Eye Irrit. 2 (H319)	<5
Sodium Fluoride	7681-49-4	231-667-8	T, Xi R25, R32, R36/38 Acute Tox. 3 (H301), Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), EUH032	<3
Phosphate Ester	39464-69-2	Not listed	Xi R38, R41 Skin Irrit. 2 (H315), Eye Dam. 1 (H318)	<3
Polyethylene Glycol	25322-68-3	500-038-2	Xi R37 STOT SE 3 (H335)	<3
Cetyl Phosphate	3539-43-3	Not listed	Xi R38, R41 Skin Irrit. 2 (H315), Eye Dam. 1 (H318)	<2
Ethanesulfonic acid, 2-(methylamino)-, N-coco acyl derivs., sodium salts	61791-42-2	263-174-9	Xi R36 Eye Irrit. 2 (H319)	<2

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Immediately flush eyes with large quantities of water for at least 20 minutes, while holding the eyelids apart. Get immediate medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. If irritation or if symptoms occurs, get medical attention. Launder clothing before re-use. Treat for frostbite if necessary.
Inhalation	Immediately remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Ingestion is an unlikely route of exposure for aerosol products. Get immediate medical attention, if concentrate is swallowed. Immediately call poison control center or go to a hospital emergency room. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

This product is an aerosol product. Spraying into the eyes may cause severe eye irritation or injury. May cause skin irritation. May cause frostbite by skin contact. If inhaled may cause dizziness, drowsiness, loss of consciousness, irregular heartbeat, and death. Harmful if swallowed. Chronic overexposure may cause weight loss, brittle bones, anemia, weakness and stiff joints.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is required for eye contact, if inhaled or if swallowed.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use water spray or fog, carbon dioxide, foam or dry chemical. Do not use water jet.





5.2 Special Hazards Arising from the Substance or Mixture:

This product is an extremely flammable aerosol. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back. Contents under pressure. Keep away from ignition sources and open flames. Containers may rupture or explode under fire conditions. Decomposition may release oxides of carbon, fluorides, and smoke.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Use water to cool exposed containers and structures.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection. Use shielding to protect from bursting cans. Do not allow run-off from firefighting to enter drains or water courses.

Recommended Protective Equipment for Fire Fighters:


EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Eliminate all sources of ignition and ventilate area. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Leaking cans should be placed in a plastic bag or open pail until the pressure has dissipated. Contain and collect liquid with an inert absorbent and place in a container for disposal. Clean spill area thoroughly.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Avoid breathing vapors or aerosols. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas.

Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, well-ventilated area at temperatures below 50°C (122°F). Store away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials. Protect against electrostatic charges.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Non-Hazardous Ingredients	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Heptafluoropropane	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Ethyl Alcohol (Ethanol)	United States	1000 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL
	Germany	500 ppm TWA, 1000 ppm STEL DFG MAK
	United Kingdom	1000 ppm TWA UK WEL
	European Union	None Established
Sodium Fluoride (as Fluorides, F)	United States	2.5 mg/m ³ TWA ACGIH TLV 2.5 mg/m ³ TWA OSHA PEL
	Germany	1 mg/m ³ TWA, 4 mg/m ³ STEL DFG MAK (Inhalable, skin)
	United Kingdom	2.5 mg/m ³ TWA UK OEL
	European Union	2.5 mg/m ³ TWA EU OEL
Phosphate Ester	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Polyethylene Glycol	United States	10 mg/m ³ TWA AIHA WEEL
	Germany	1000 mg/m ³ TWA, 8000 mg/m ³ STEL DFG MAK (due to possible mist formation, exposure should be minimized).
	United Kingdom	None Established
	European Union	None Established
Cetyl Phosphate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Ethanesulfonic acid, 2-(methylamino)-, N-coco acyl derivs., sodium salts	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits:

Sodium Fluoride (as Fluorides) – Fluoride in urine, Prior to shift, 2 mg/L; Fluoride in urine, End of shift, 3 mg/L.

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with general or adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):


Specific Eye/face Protection: Chemical splash goggles are recommended to avoid eye contact.

Specific Skin Protection: Wear impervious gloves are recommended to prevent prolonged skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the exposure levels are excessive, an approved respirator with dust/mist cartridges or supplied air respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on Basic Physical and Chemical Properties:**

Appearance:	Aerosol can. Liquid under pressure, and white foam at normal pressure.	Explosive limits:	LEL: 3.3% (Ethanol) UEL: 19% (Ethanol)
Odor:	Characteristic odor	Vapor pressure (mmHg):	40-65 mmHg
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	3-4.5 (APF)	Relative density:	0.95 g/m3
Melting/freezing point:	Not applicable	Solubility(ies):	90% in water
Initial boiling point and boiling range:	Not determined	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	13°C (55°F) (Ethanol)	Auto-ignition temperature:	Not determined
Evaporation rate:	Not determined	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	Not determined

Explosive Properties:	Not determined	Oxidizing Properties:	Not an oxidizer
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9.2 Other Information: None known.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: Reaction with acids will release hydrogen fluoride gas.

10.4 Conditions to Avoid: Keep away from heat, sparks and all ignition sources. Dropping containers may cause bursting.

10.5 Incompatible materials: Oxidizing agents and strong acids.

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon, fluorides, and smoke.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with liquid may cause severe irritation or burns with possible eye damage.

Skin: Contact with liquid may cause skin irritation and frostbite.

Ingestion: Harmful if swallowed. Ingestion can cause gastrointestinal irritation, nausea, and diarrhea. Large doses of fluorides can bind with serum calcium resulting in hypocalcemia with toxic effects, including cardiac effects, due to electrolyte imbalance.

Inhalation: Inhalation of high concentrations may cause temporary central nervous system depression with anesthetic effects such as dizziness, headache, incoordination, and loss of consciousness. Prolonged exposure to high concentrations may cause irregular heartbeat, cardiac arrest, and death.

Chronic Health Effects: Prolonged overexposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Irritation: Sodium fluoride is not irritating to rabbit eyes or skin. Ethanol: Not irritating to rabbit skin, Irritating to rabbit eyes.

Corrosivity: No data available. Phosphate Ester is classified as a skin and eye corrosive material.

Sensitisation: Sodium fluoride was not sensitizing in a Buehler test with guinea pigs.

Carcinogenicity: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. Ethanol: Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo. This product is not expected to cause mutagenic activity. Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing central nervous or cardiovascular system diseases may be at increased risk from exposure.

Acute Toxicity Data:

Non-Hazardous Ingredients: No toxicity data available

Heptafluoropropane: Inhalation rat LC50- 800,000 ppm/4 hr

Sodium Fluoride: Oral Rat LD50- 32 mg/kg

Phosphate Ester: No toxicity data available

Ethanol: Oral rat LD50-7060 mg/kg; Inhalation Rat LC50 – 117-125 mg/L/4 hr

Polyethylene Glycol: No toxicity data available

Cetyl Phosphate: No toxicity data available

Ethanesulfonic acid, 2-(methylamino)-, N-coco acyl derivs., sodium salts: Oral rat LD50->2000 mg/kg, Skin rat LD50->2000 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found. Ethanol: Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, resulting in fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioral disorders and small head size.

Specific Target Organ Toxicity (STOT):

Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day. Ethanol: Ethanol when consumed as a beverage has been found to cause damage to the liver, nervous system and reproductive system.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) -83.7 mg/L, 48 hr EC50 daphnia magna -98 mg/L.

Ethanol: LC50 rainbow trout 13000 mg/L/96 hr; LC50 daphnia magna 9268-14221 mg/L/48 hr; EC50 Chlorella pyrenoidosa (Green algae; growth inhibition) 9310 mg/L/48 hr

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Ethanol is readily biodegradable in screening tests.

12.3 Bio-accumulative Potential: Ethanol has an estimated BCF of 3.

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	UN1950	Aerosols, flammable	2.1	None	Not applicable
ADR/RID	UN1950	Aerosols, flammable	2.1	None	Not applicable
IMDG	UN1950	Aerosols, flammable	2.1	None	Not applicable
IATA/ICAO	UN1950	Aerosols, flammable	2.1	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has an RQ of 33,333 lbs (based on the RQ of Sodium fluoride of 1,000 lbs present at <3%). Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	Yes
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	Yes		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Class A (Compressed Gas), Class B (Flammable/Combustible Material), Class D Division 2B (Toxic material causing other toxic effects)

Canadian Environmental Protection Act: One or more components of this product are not listed on the Domestic Substances list (DSL).

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): One or more components of this product are not listed on the EINECS inventory.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 3 Flammability – 2 Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

F Highly Flammable

T Toxic

Xi Irritant

Xn Harmful

R11 Highly flammable

R22 Harmful if swallowed.

R25 Toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R36 Irritating to the eyes.

R36/38 Irritating to eyes and skin.

R37 Irritating to the respiratory system.

R38 Irritating to the skin.

R41 Risk of serious damage to eyes.

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritant Category 2

Flam. Liq. 2 Flammable Liquid Category 2

Flam. Aerosol 1 Flammable Aerosol Category 1

Press. Gas Gas Under Pressure
Skin Irrit. 2 Skin Irritant Category 2
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H222 Extremely flammable aerosol.
H225 Highly flammable liquid and vapor.
H280 Contains gas under pressure; may explode if heated.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
EUH032 Contact with acids liberates very toxic gas.

Supersedes: 9 September 2011

Date Revised: 25 September 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.