

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: December 2004
Document Number: 130046
Date Revised: 26 August 2014
Revision Number: 8

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

1.1 Product Identifier:

Trade Name (as labeled): NUPRO® Gel Topical Acidulated Phosphate Fluoride
Part/Item Number: 130070, 130072

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

Recommended Use: Oral fluoride treatment
Restrictions on Use: For Professional Use Only. Do not use on persons hypersensitive to fluoride or other formula ingredients.

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
Skin Irritant Category 2 Eye Irritant Category 2	Not Hazardous	Not Hazardous

EU Classification: Not classified

2.2 Label Elements:

Signal Word: Warning



Contains: Sodium Fluoride, Phosphoric Acid, Hydrofluoric Acid

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation H319 Causes severe eye irritation	P264 Wash thoroughly after handling. P280 Wear protective gloves, eye protection, and face protection. P302 + P352 IF ON SKIN: Wash with plenty of water P332 + P313 If skin irritation occurs: Get medical attention P362 + P362 Take off contaminated clothing and wash it before reuse. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Sodium Fluoride	7681-49-4	231-667-8	T, Xi, R25, R36/38, R32 Acute Tox Cat 3 (H301), Skin Irrit Cat 2 (H315), Eye Irrit Cat 2 (H319), EUH032	2-3%
Phosphoric Acid	7664-38-2	231-663-2	C, R34 Skin Corr. Cat 1B, (H314)	<1
Hydrofluoric Acid	7664-39-3	231-634-8	C, T R26/27/28, R35 Acute Tox 2 (H300), Acute Tox 1 (H310), Acute Tox 2 (H330), Skin Corr 1A (H314)	<0.15

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 victim's eyes with large quantities of water for at several minutes, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation occurs. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Keep at rest in a position comfortable for breathing. If breathing is difficult, provide artificial respiration.
Ingestion	Do not induce vomiting. If conscious, rinse mouth with a small amount of water and give one glass of water to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical

attention if you feel unwell.

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

May eye and skin irritation. May be harmful if swallowed. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

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

Immediate medical attention should not be required except in cases of high quantities of ingestion.

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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use appropriate media for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:




Decomposition may release oxides of carbon, phosphorous, fluorine, and sodium.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures: Use water to cool exposed containers and structures.

Precautions for Fire Fighters: Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. 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. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing. Avoid contact with skin, eyes or clothing.

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, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

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. Avoid prolonged contact with skin. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

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

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat and incompatible materials. Protect from physical damage.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

Sodium Fluoride (as Fluoride)	United States	2.5 mg/m ³ ACGIH TLV TWA 2.5 mg/m ³ OSHA PEL TWA
	Germany	1 mg/m ³ (Inhalable, skin) DFG MAK
	United Kingdom	None Established
	European Union	None Established
Phosphoric Acid	United States	1 mg/m ³ TWA, 3 mg/m ³ STEL ACGIH TLV 1 mg/m ³ TWA OSHA PEL
	Germany	2 mg/m ³ DFG MAK (Inhalable fraction)
	United Kingdom	1 mg/m ³ TWA UK WEL, 2 mg/m ³ STEL
	European Union	1 mg/m ³ TWA, 2 mg/m ³ STEL
Hydrofluoric Acid (As Fluoride)	United States	0.5 ppm TWA, 2 ppm STEL ACGIH TLV 3 ppm TWA OSHA PEL

Germany	1 ppm DFG MAK
United Kingdom	1.8 ppm TWA, 3 ppm STEL UK WEL
European Union	1.8 ppm TWA, 3 ppm STEL

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Use explosion-proof equipment where required.

Individual Protection Measures (PPE):
Specific Eye/face Protection: Chemical splash goggles or chemical safety glasses with side shields are recommended to avoid eye contact.
Specific Skin Protection: Wear impervious gloves such as neoprene or butyl rubber to avoid skin contact.
Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with 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:	Aqueous solution	Explosive limits:	LEL: Not available UEL: Not available
Odor:	Various colors and flavors	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not available
pH:	3.0-4.0	Relative density:	Not available
Melting/freezing point:	Not determined	Solubility(ies):	Soluble in water.
Initial boiling point and boiling range:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Not flammable	Auto-ignition temperature:	Not determined

Evaporation rate:	Not available	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	Not applicable
Explosive Properties:	Not an explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable at normal temperatures and conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4 Conditions to Avoid: None known

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Decomposition may produce oxides of carbon, fluoride, and sodium.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with eyes may cause moderate to severe irritation with redness and tearing.

Skin: May cause irritation. Prolonged exposure may cause irritation or dermatitis.

Ingestion: Swallowing small amounts may cause irritation of the mouth and throat, salivation, nausea, vomiting. Large amounts may cause abdominal pain, weakness, tremor, spasm, or convulsions. Death may occur from respiratory paralysis.

Inhalation: No adverse effects are expected under normal use conditions.

Chronic Health Effects: Prolonged overexposure may cause drying of the skin and irritation. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel. Sodium fluoride has been shown to cause reproductive effects and birth defects studies with in laboratory animals.

Irritation: None of the components are sensitizing to animals or humans.

Corrosivity: Phosphoric acid: Corrosive to rabbit skin and rabbit eyes. Hydrofluoric Acid: Corrosive to rabbit skin and rabbit eyes

Sensitisation: Sodium Fluoride: Not sensitizing in Buehler test.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the European Substance Directive.

Mutagenicity: Phosphoric acid was negative in an in vitro mammalian cell gene mutation assay, in an in vitro mammalian chromosome aberration test and AMES test. The surfactant was negative in an in vitro genetic study.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Fluoride Oral rabbit LD50 - 320 mg/kg
Phosphoric Acid Oral rat LD50 1530 mg/kg, Skin rabbit LD50 2740 mg/kg
Hydrofluoric Acid: Inhalation rat LC50 1278 ppm/1 hr

Product ATE
Oral: 9,900 mg/kg
Dermal: 250,000 mg/kg
Inhalation: 500,000 ppm

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. Inorganic borates have been reported to cause adverse reproductive and developmental effects in laboratory animals given high oral doses. Phosphoric Acid: In a one generational study with rats, the offspring of adult male and female rats dosed with phosphoric acid did not display any negative effects resulting from the treatment.

Specific Target Organ Toxicity (STOT):

Single Exposure: Hydrogen fluoride is highly corrosive to rabbit skin. An 8% solution in a rabbit eye will cause reversible eye damage lasting 40-65 days.

Repeated Exposure: Repeated inhalation of 17 ppm hydrogen fluoride resulted in damage to the lungs, liver, and kidneys of animals, but similar inhalation of 8.6 ppm failed to elicit significant pathologic change in these tissues.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sodium Fluoride: Rainbow Trout 96hr LC50: 317 ppm; Daphnia magna 48hr EC50:352 mg/kg
Phosphoric Acid: 96 hr LC50 Mosquitofish- 138 mg/L
Hydrofluoric acid: No data available

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride and hydrogen fluoride.

12.3 Bio-accumulative Potential: The biological half-life of hydrogen fluoride is 12-24 hours.

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB Assessment: Not applicable.

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 that 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	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	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 a Reportable Quantity (RQ) of 33,333 lbs. based on the RQ for Sodium Fluoride of 1,000 lbs. Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local 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:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

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

Components	C.A.S. #	WT %
Hydrogen Fluoride	7664-39-3	<0.15

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): Not a controlled product.

Canadian Environmental Protection Act: All of the components in this product are 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 of the components in this product are not listed on the EINECS inventory.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: All of the components in this product are listed on the AICS for Australia.

China Inventory of Existing Chemicals and Chemical Substances: All of the components in this product are listed on the IECSC for China.

Japanese Existing and New Chemical Substances: One or more of the components in this product are not listed on the Japanese ENCS list.

Korean Existing Chemicals List: All of the components in this product are listed on the KECL for Korea.

Philippine Inventory of Chemicals and Chemical Substances: All of the components in this product are listed on the PICCS.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 0 Physical Hazard – 0

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

C Corrosive

T Toxic

Xi Irritant

R25 Toxic if swallowed.

R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.

R32 Contact with acids liberates very toxic gas

R34 Causes burns.

R35 Causes severe burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin. Acute Tox 3 Acute Toxicity Category 3

Acute Tox Cat 1 Acute Toxicity Category 1

Acute Tox Cat 2 Acute Toxicity Category 2

Eye Irrit Cat 2 Eye Irritant Category 2

Skin Corr Cat 1A Skin Corrosive Category 1A

Skin Irrit Cat 2 Skin Irritant Category 2

H300 Fatal if swallowed

H310 Fatal in contact with skin

H330 Fatal if inhaled

H314 Corrosive to skin and eyes

H315 Causes skin irritation

H319 Causes serious eye irritation

EU032 Contact with acids liberates very toxic gas

Supersedes: 01 February 2013

Date Revised: 26 August 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.