

Safety Data Sheet

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

Date Issued: 25 July 2008
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Date Revised: 25 September 2017
Revision Number: 4

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

1.1 Product Identifier:

Trade Name (as labeled): NUPRO® Prophylaxis Paste with and without Fluoride

Part/Item Numbers: 638027, 638028, 801111, 801112, 801122, 801126, 801127, 801171, 801211, 801212, 801213, 801221, 801222, 801223, 801225, 801226, 801227, 801231, 801232, 801235, 801299, 801300, 801301, 801302, 801306, 801307, 801308, 801309, 801310, 801311, 801312, 801313, 801314, 801317, 801318, 801319, 801321, 801322, 801326, 801327, 801328, 801329, 801330, 801331, 801332, 801333, 801334, 801335, 801336

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

Recommended Use: For cleaning and polishing procedures as part of a professionally administered dental prophylaxis 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
Acute Toxicity Category 4 (H302)	Not Hazardous	Not Hazardous

EU Classification: Harmful (Xn) R22

2.2 Label Elements:



Signal Word: Warning

Contains Sodium Fluoride

Hazard Phrases	Precautionary Phrases
H302 Harmful if swallowed.	P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. 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 %
Pumice	1332-09-8	Not listed	Not Applicable	45-55
Glycerin	56-81-5	200-289-5	Not Applicable	30-40
Sodium Fluoride	7681-49-4	231-667-8	T, Xi R25, R32, R36/38 Acute Tox. Cat 3, H301 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315 EUH032	1-<5
Sodium Silicate	1344-09-8	215-687-4	Xi R36/37/38 Eye Irrit. Cat 2A, H319 Skin Irrit. Cat 2, H315 STOT SE Cat 3, H335	1-<5
Diatomaceous Earth, Natural (kieselguhr)	61790-53-2	231-545-4	Not Applicable	<5
Crystalline Silica (Quartz)	14808-60-7	238-878-4	Xn 48/20 STOT RE Cat 1, H372 Carc. Cat 1, H350	<1

Note: The Crystalline Silica in this product is not unbound or respirable. Therefore, no warning is required.

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	Flush victim's eyes with water. Seek medical attention if irritation occurs or persists.
Skin	Wash skin with soap and water. Remove and launder clothing before re-use.
Inhalation	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if symptoms of exposure persist.
Ingestion	Do not induce vomiting. If conscious, rinse mouth out and give copious amount of milk, or water if milk is not available, 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:

Direct contact may cause eye. Prolonged skin contact may cause irritation. Harmful if swallowed. Prolonged inhalation of dusts from dried product may cause lung damage. 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. Contains crystalline silica. Prolonged overexposure to respirable crystalline silica may cause lung disease (silicosis) and increase the risk of lung cancer. Risk of cancer depends on duration and level of exposure. The crystalline silica in this product is encapsulated in a viscous liquid. Under normal conditions of use, exposure is not expected to occur.

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

Immediate medical attention should not be required.

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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Use water to cool fire-exposed containers. Fight fire from safe distance or protected location.
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.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes and prolonged skin contact. Do not breathe dust, mist or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. 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, skin and clothing. Do not breathe dust, mist or vapors. 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.

Do not reuse containers. 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, direct sunlight and incompatible materials. Do not store above 25°C (77°F).

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Pumice	United States	None Established
	Germany	None Established
	United Kingdom	None Established

	European Union	None Established
Glycerin	United States	5 mg/m ³ (Respirable fraction), 15 mg/m ³ (Total Dust) TWA OSHA PEL (As mist)
	Germany	50 mg/m ³ TWA 100 mg/m ³ STEL DFG MAK (Inhalable)
	United Kingdom	10 mg/m ³ TWA UK WEL
	European Union	Belgium: 10 mg/m ³ TWA
Sodium Fluoride (As Flouride, 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
Sodium Silicate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Diatomaceous Earth, Natural (kieselguhr)	United States	80 mg/m ³ OSHA PEL (total dust) % SiO ₂
	Germany	4 mg/m ³ TWA DFG MAK (inhalable)
	United Kingdom	1.2 mg/m ³ TWA UK WEL (respirable)
	European Union	None Established
Crystalline Silica as Quartz	United States	10 mg/m ³ TWA OSHA PEL (Respirable fraction) % SiO ₂ + 2 30 mg/m ³ TWA OSHA PEL (Total dust) % SiO ₂ + 2 0.025 mg/m ³ TWA ACGIH TLV (Respirable)
	Germany	None Established
	United Kingdom	0.1 mg/m ³ TWA UK WEL (as Silica, respirable crystalline)
	European Union	Belgium: 0.1 mg/m ³ TWA

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: No special ventilation normally required. For bulk handling, use with adequate ventilation to maintain exposure levels below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Follow facility requirements for operation. Eye glasses are recommended for bulk handling.

Specific Skin Protection: None required during the normal use of this product. Wear impervious gloves such as natural rubber if needed to for bulk handling.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved respirator with particulate cartridges or supplied air 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Abrasive dispersion of pumice in a viscous solution in various colors and flavors	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Characteristic of flavor	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not determined
pH:	9-10	Relative density:	Not determined
Melting/freezing point:	Not determined	Solubility(ies):	Slightly soluble in water.
Initial boiling point and boiling range:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not determined	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: % Volatile by Volume: <10%

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur. Contact with acids liberated very toxic gases. Contact with acids may form hydrogen fluoride. Crystalline silica will dissolve in hydrofluoric acid and produce silicone tetrafluoride.

10.4 Conditions to Avoid: Avoid excessive heat and direct sunlight.

10.5 Incompatible materials: Avoid oxidizing agents and acids.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness and tearing. Injury may occur from mechanical irritation.

Skin: Prolonged skin contact may cause irritation.

Ingestion: Harmful if swallowed. May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

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

Chronic Health Effects: Repeated excessive exposures to glycerin may cause increased fat levels in the blood and damage to the kidney and liver. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel. Excessive inhalation of respirable crystalline silica may cause a progressive, disabling and sometimes fatal lung disease called silicosis. The crystalline silica in this product is encapsulated in a viscous liquid and under normal conditions of use; exposure is not expected to occur.

Irritation: Sodium Silicate: Corrosive to not irritating in rabbit skin. Highly irritating to not irritating in rabbit eyes. Sodium Fluoride: Highly irritating to not irritating in rabbit skin. Highly irritating to moderately irritating to rabbit eyes.

Corrosivity: This product is not a corrosive material.

Sensitization: No data available. This product is not expected to cause sensitization.

Carcinogenicity: Glycerin: No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg. Sodium Fluoride: 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. Crystalline silica is classified as a Group 1 carcinogen by IARC, and "Known to be a Human Carcinogen" by NTP. In this product, the crystalline silica is incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable crystalline silica dust in the normal use of this product. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis. 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.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Pumice: No toxicity data available

Glycerin: Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m³/1 hr

Sodium Fluoride: Oral Rat LD50- 32 mg/kg

Sodium Silicate: Oral rat LC50 – 1960 mg/kg; Skin rabbit LD50 - >4640 mg/kg

Diatomaceous Earth, Natural: No toxicity data available

Crystalline Silica: Oral rat LD50 - >22,500 mg/kg

Reproductive Toxicity Data: Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg. 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.

Specific Target Organ Toxicity (STOT):

Single Exposure: Glycerin: When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. 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: Glycerin: In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed. 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. Crystalline Silica: Repeated inhalation of crystalline silica may cause lung damage and silicosis.

12. ECOLOGICAL INFORMATION

- 12.1 Toxicity:**
 Glycerin: 24 hr LC50 Goldfish - >5000 mg/L; 48 hr EC50 Daphnia magna -10,000 mg/L
 Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L
 Sodium Silicate: 96 hr LC50 Zebra fish – 3185 mg/L; 96 hr EC50 Daphnia magna – 216 mg/L
 Crystalline Silica Quartz: 72 hr LC50 Carp - >10,000 mg/L.
- 12.2 Persistence and Degradability:** Glycerin is readily biodegradable (96% in 24 hours). Biodegradability does not apply to inorganic compounds.
- 12.3 Bio-accumulative Potential:** Glycerin is not expected to bioconcentrate in fish and aquatic organisms.
- 12.4 Mobility in Soil:** Glycerin: Very high mobility in soil.
- 12.5 Results of PBT and vPvB Assessment:** Not applicable.
- 12.6 Other Adverse Effects:** No adverse effects are expected.

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 20,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 1-<5%). Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

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 %
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 %
Crystalline Silica as Quartz	14808-60-7	<1%

Note: The Crystalline Silica in this product is not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

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): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 0 Physical Hazard – 0

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

T Toxic

Xi Irritant

Xn Harmful

R22 Harmful if swallowed.

R25 Toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

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

R36/38 Irritating to eyes and skin.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation

Acute Tox. Cat 3 Acute Toxicity Category 3

Acute Tox. Cat 4 Acute Toxicity Category 4

Carc Cat 1 Carcinogen Category 1

Eye Irrit. Cat 2A Eye Irritant Category 2A

Skin Irrit. Cat 2 Skin Irritant Category 2

STOT SE Cat 3 Specific Target Organ Toxicity Single Exposure Category 3

STOT RE Cat 1 Specific Target Organ Toxicity Repeated Exposure Category 1

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

EUH032 Contact with acids liberates very toxic gas.

Supersedes: December 27, 2011

Date Revised: 25 September 2014

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

Date revised: 25 September 2017

Revision Summary: Updated logo and removed PPE pictograms.

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