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Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2020/878, US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 25 July 2008
Document Number: 001035
Date Revised: 20 December 2023
Revision Number: 7

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, 801110, 801111, 801112, 801120, 801122, 801126, 801127, 801130, 801171, 801210, 801211, 801212, 801213, 801220, 801221, 801222, 801223, 801225, 801226, 801227, 801230, 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 Sirona
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

Emergency Contact Telephone Number: **800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

2.2 Label Elements: None required.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Glycerin	56-81-5	200-289-5	Not Classified	30-40
Sodium Fluoride	7681-49-4	231-667-8	Acute Tox. 3 (H301) LD50-148.5 mg/kg Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) EUH032	1-<5
Sodium Silicate	1344-09-8	215-687-4	Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) STOT SE 3 (H335)	1-<5
Diatomaceous Earth, Natural (kieselguhr)	61790-53-2	231-545-4	Not Classified	<5
Crystalline Silica (Quartz)*	14808-60-7	238-878-4	STOT RE 1 (H372) Carc. 1 (H350)	<1

*Component is in a non-respirable form. 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 Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Rinse thoroughly with water, while holding the eye lids open to be sure the material is washed out. Get medical attention if irritation occurs and persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting unless directed to do so by a medical professional. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if symptoms develop.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Direct contact may cause mild eye and skin irritation.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
Immediate medical attention should not be required.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:	
Thermal decomposition may release carbon oxides, acrolein, and hazardous fluorine compounds.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Use water to cool fire-exposed containers. 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 skin. Avoid breathing vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.
6.2 Environmental Precautions:
Avoid releases to the environment. Report releases as required by local 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 Handing:
Avoid contact with the eyes, skin and clothing. Avoid breathing 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.
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:	
Titanium Dioxide	10 mg/m^3 TWA ACGIH TLV 15 mg/m^3 TWA OSHA PEL (total dust) 10 mg/m^3 (Inhalable), 4 mg/m3 (respirable) TWA UK WEL

	10 mg/m^3 TWA Belgium OEL
Glycerin	5 mg/m^3 TWA OSHA PEL (Respirable fraction), 15 mg/m^3 TWA OSHA PEL (total dust) 10 mg/m^3 TWA Belgium OEL 200 mg/m^3 TWA, 400 mg/m^3 STEL DFG MAK (inhalable) 10 mg/m^3 TWA UK WEL
Sodium Fluoride (As Flouride, F)	2.5 mg/m^3 TWA ACGIH TLV 2.5 mg/m^3 TWA OSHA PEL 2.5 mg/m^3 TWA Belgium OEL 1 mg/m^3 TWA, 4 mg/m^3 STEL DFG MAK (inhalable) 2.5 mg/m^3 TWA UK WEL 2.5 mg/m^3 TWA EU WEL
Sodium Silicate	None Established
Diatomaceous Earth, Natural (kieselguhr)	80 mg/m^3 OSHA PEL (total dust) % SiO_2 10 mg/m^3 TWA Belgium OEL 1 mg/m^3 TWA DFG MAK (inhalable) 1.2 mg/m^3 (respirable) TWA UK WEL
Crystalline Silica as Quartz	0.025 mg/m^3 TWA ACGIH TLV (respirable) 0.05 mg/m^3 TWA OSHA PEL (respirable) 0.1 mg/m^3 TWA Belgium OEL

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. Safety glasses are recommended for bulk handling.

Specific Skin Protection: None required during the normal use of this product. Wear impervious gloves recommended as needed for bulk handling.

Specific Respiratory Protection: None should be needed for normal use. If exposure limits are exceeded, an approved respirator with dust/mist 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
Color:	Various colors	**Physical State:**	Liquid
Odor:	Characteristic	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Relative Vapor Pressure @20ºC: (Air = 1)**	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: (n-BuAc = 1)	Not determined	**Decomposition temperature:**	Not determined
Flammability:	Not applicable	**Kinematic Viscosity:**	Not applicable

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards: None determined.

9.2.2 Other Safety Characteristics: None determined

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 mild irritation with redness and tearing. Injury may occur from mechanical irritation.
Skin: Prolonged skin contact may cause mild irritation.
Ingestion: 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: None expected under normal use. 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 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.

Eye Irritation/ Damage: Based on available data, the classification criteria are not met.

Skin Irritation / Corrosivity: Based on available data, the classification criteria are not met.

Sensitization: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met. Crystalline silica is classified as a Group 1 carcinogen by IARC, and "Known to be a Human Carcinogen" by NTP. Crystalline silica is listed as an OSHA carcinogen. 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: Based on available data, the classification criteria are not met.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

ATE Oral: 2970 mg/kg

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: 148.5 mg/kg

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

Diatomaceous Earth, Natural: Not classified as acutely toxic.

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

Reproductive Toxicity Data: Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Single Exposure (STOT-SE):
Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):
Based on available data, the classification criteria are not met.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

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).

Sodium Fluoride, Sodium Silicate, and Crystalline Silica Quartz: 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 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

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 IMO Instruments: 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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

State Regulations

California: This product contains Crystalline Silica which is known to the state of California to cause cancer. However, the Crystalline Silica is bound within the chemical matrix of the product and no exposure can occur.

International Regulations

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.

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:
Acute Tox. 3 Acute Toxicity Category 3
Carc 1 Carcinogen Category 1
Eye Irrit. 2 Eye Irritant Category 2
Skin Irrit. 2 Skin Irritant Category 2
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
STOT RE 1 Specific Target Organ Toxicity Repeated Exposure Category 1
H301 Toxic 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: 12 July 2021
Date Revised: 20 December 2023
Revision Summary: Section 1: Added item numbers that were inadvertently removed.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.