



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: 21 July 2010
Document Number: 801363
Date Revised: 6 August 2021
Revision Number: 6

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

1.1 Product Identifier:

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

Part/Item Number: 801510, 801511, 801512, 801513, 801514, 801515, 801516, 801517, 801518, 801519, 801520, 801521, 801522, 801523, 801524, 801525, 801528, 801529, 801530, 801531, 801534, 801535, 801536, 801537, 801540, 801541

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

Recommended Use: Cleaning and polishing procedures part of dental prophylaxis treatment.

Restrictions on Use: For Professional Use Only

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
Skin Irritation Category 2 (H315) Eye Irritation Category 2 (H319)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Contains: Sodium Silicate

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation. H319 Causes serious eye irritation. EUH032 Contact with acids liberates very toxic gas.	P264 Wash thoroughly after handling. P280 Wear protective gloves and eye protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P332 + P313 If skin irritation occurs: Get medical attention. P362 + P364 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 # / REACH Registration #	Classification	WT %
Glycerin	56-81-5	200-289-5 /	Not Applicable	30-50
Sodium Silicate	1344-09-8	215-687-4	Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) STOT SE 3 (H335)	3-7
Titanium Dioxide	13463-67-7	236-675-5	Carc. 2 (H351)	2-6
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	0-5
Crystalline Silica (Quartz)	14808-60-7	238-878-4	STOT RE 1 (H372) Carc. 1 (H350)	<1%

*Only used in Prophy Paste with Fluoride.

Note: The Titanium Dioxide and Crystalline Silica in this product are encapsulated in a viscous liquid and not available in respirable form. 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 Classifications.**

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush eyes with plenty of water for at least 15 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get medical attention if irritation or discomfort develops or persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use.
Inhalation	None expected with normal use. 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, rinse 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 causes eye and skin irritation. May be harmful if swallowed and may cause gastrointestinal upset.	
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 monoxide, carbon dioxide, and acrolein.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:	
Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. 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 Handling:

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment. 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:**

Glycerin	15 mg/m ³ (total dust), 5 mg/m ³ (respirable fraction) TWA OSHA PEL as mist 10 mg/m ³ TWA UK WEL 10 mg/m ³ TWA France OEL 200 mg/m ³ TWA, 400 mg/m ³ STEL DFG MAK 10 mg/m ³ TWA Belgium OEL
Sodium Silicate	None Established
Titanium Dioxide	10 mg/m ³ TWA ACGIH TLV (respirable) 15 mg/m ³ TWA OSHA PEL (total dust) 10 mg/m ³ (inhalable), 4 mg/m ³ (respirable) TWA UK WEL 11 mg/m ³ TWA France OEL (inhalable) 0.3 mg/m ³ TWA (respirable), 2.4 mg/m ³ STEL (respirable) DFG MAK 10 mg/m ³ TWA Belgium OEL
Sodium Fluoride (As Fluoride F)*	2.5 mg/m ³ TWA ACGIH TLV 2.5 mg/m ³ TWA OSHA PEL 2.5 mg/m ³ TWA France OEL 1 mg/m ³ TWA (inhalable), 4 mg/m ³ STEL (inhalable) DFG MAK 2.5 mg/m ³ TWA Belgium OEL
Crystalline Silica (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.

*Only used in Prophy Paste with Fluoride.

The Titanium Dioxide and Crystalline Silica in this product are encapsulated in a viscous liquid and not available in respirable form. Therefore, no warning is required.

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: None required for normal use. Chemical safety goggles are recommended for bulk handling.

Specific Skin Protection: None required for normal use. Wear impervious gloves such as natural rubber gloves for bulk handling. Impervious clothing as needed to avoid contamination of personal clothing 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
Color:	Various colors	Physical State:	Liquid
Odor:	Characteristic	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Relative Vapor Pressure @20°C: (Air = 1)	Not determined
pH:	9.5-10.5	Density (Relative):	Not determined
Melting/freezing point:	Not determined	Solubility(ies):	Slightly soluble in water.
Initial boiling point and 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 determined

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards:

Percent Volatile by Volume: < 10%

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 irritation with redness and tearing. Injury may occur from mechanical irritation.

Skin: May cause skin 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: 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; no exposure is expected to occur.

*Only pertains to Prophy Paste with Fluoride.

Eye Irritation/ Damage: Contact causes serious eye irritation.

Skin Irritation / Corrosivity: Irritating to skin.

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. Titanium dioxide: Titanium dioxide is listed by IARC as a Group 2B carcinogen (Possibly carcinogenic to humans). In this product, the crystalline silica and titanium dioxide are incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable crystalline silica or titanium dioxide 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: LD50: 2,970 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 Silicate: Oral rat LC50: 3,400 mg/kg; Skin rabbit LD50: >5,000 mg/kg

Titanium dioxide: Oral rat LD50: >20,000 mg/kg; Skin hamster LD50: >10,000 mg/kg

Sodium Fluoride: Oral Rat LD50: 148.5 mg/kg

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. 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.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):

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

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

12. ECOLOGICAL INFORMATION

12.1 Toxicity: This product is not expected to cause harm to the environment.

Glycerin: 24 hr LC50 Goldfish: >5000 mg/L; 48 hr EC50 Daphnia magna: 10,000 mg/L

Sodium Silicate: 96 hr LC50 Zebra fish – 3185 mg/L; 96 hr EC50 Daphnia magna: 216 mg/L

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

12.6 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat 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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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 for Sodium Fluoride of 1,000 lbs. present at 5% maximum. 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): 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 and Titanium Dioxide which are known to the state of California to cause cancer. However, the Crystalline Silica and Titanium Dioxide are chemically 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 Canada Hazardous Products Regulation.

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

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 – 2 Flammability – 1 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

Carc 2 Carcinogen Category 2

Eye Irrit 2 Eye Irritant Category 2

Skin Irrit 2 Skin Irritant Category 2

STOT RE 1 Specific Target Organ Toxicity Repeated Exposure Category 1

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H350 May cause cancer.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

EUH032 Contact with acids liberates very toxic gas.

Supersedes: 25 August 2017

Date Updated: 06 August 2021

Revision Summary: General content and format update. Classification change. Removed EU classifications. Revised for Regulation (EC) 2020/878, Changes to all sections.

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