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: 3 December 2004
Document Number: 801358
Date Revised: 06 February 2014
Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled): **NUPRO® Shimmer™ Polishing Paste for Dental Restorations with Fluoride**

Part/Item Number: **801350, 801351**

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

Recommended Use: **Polishing paste for dental restorations.**

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 Oral Toxicity Category 4 (H302) Eye Irritant Category 2 (H319) Skin Irritant Category 2 (H315)	Not Hazardous	Not Hazardous

EU Classification: Not a dangerous preparation.

2.2 Label Elements:

Signal Word: Warning

Hazard Phrases	Precautionary Phrases
H302 Harmful if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation.	P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protections 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. P337+P313 If eye irritation persists: Get medical attention. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P332+P313 If skin irritation occurs: Get medical attention. P362 Take off contaminated clothing and wash before reuse. 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 %
Glycerin	56-81-5	200-289-5	Not Applicable	40-60
Aluminum Oxide	1344-28-1	215-691-6	Not Applicable	30-50
Sodium Silicate	1344-09-8	215-687-4	Xi R36/38 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315	1-10
Flavoring	Proprietary	Proprietary	Not Applicable	1-5
Sodium Fluoride	7681-49-4	231-667-8	T, Xi R25, R36/38, R32 Acute Tox. Cat 3, H301 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315	<3

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 least 15 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. Get medical attention if irritation occurs. Launder clothing before re-use.
Inhalation	Remove victim to fresh air.
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 cause eye and skin irritation. Harmful if swallowed.

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 foam, carbon dioxide or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:
Decomposition may release oxides of carbon and sodium.

5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Cool fire exposed containers and structures with water. 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.		
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. Ventilate area. 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 spill from entering sewers and water courses. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Wipe up with an 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.

Do not reuse containers. 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, 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:		
Glycerin	United States	5 mg/m3 (Respirable fraction), 15 mg/m3 (Total Dust) TWA OSHA PEL (As mist)
	Germany	50 mg/m3 TWA, 100 mg/m3 STEL DFG MAK (Inhalable)
	United Kingdom	10 mg/m3 TWA UK WEL
	European Union	Belgium: 10 mg/m3 TWA
Aluminum Oxide	United States	1 mg/ m3 TWA ACGIH TLV (respirable) (As Aluminum, Al) 5 mg/m3 (respirable fraction), 15 mg/m3 (total dust) TWA OSHA PEL
	Germany	4 mg/m3 TWA DFG MAK (Inhalable) 1.5 mg/m3 TWA DFG MAK (Respirable)
	United Kingdom	4 mg/m3 TWA UK WEL (inhalable) 10 mg/m3 TWA UK WEL (respirable)
	European Union	None Established
Sodium Silicate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Flavoring	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Sodium Fluoride (as Fluoride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 TWA, 4 mg/m3 STEL DFG MAK (inhalable)
	United Kingdom	None Established
	European Union	Belgium: 2.5 mg/m3 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: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits.
Individual Protection Measures (PPE): **Specific Eye/face Protection:** Chemical safety goggles are recommended. **Specific Skin Protection:** Wear impervious gloves such as butyl rubber or neoprene to avoid skin contact. **Specific Respiratory Protection:** None should be needed for normal use. If the 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.			
Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	White paste with a mint flavor	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Mint odor	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Vapor density:**	Not determined
pH:	9-10	**Relative density:**	1.9 g/cm3
Melting/freezing point:	Not determined	**Solubility(ies):**	Partially soluble in water.
Initial boiling point and boiling range:	Not determined	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	154°C (309°F) (similar material)	**Auto-ignition temperature:**	Not determined
Evaporation rate:	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not applicable	**Viscosity:**	Not applicable
Explosive Properties:	Not 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 under normal storage and handling conditions.
10.3 Possibility of Hazardous Reactions: Sodium fluoride when in contact with acids liberates toxic gas.

10.4 Conditions to Avoid: Avoid temperatures above 50°C (122°F).

10.5 Incompatible materials: Avoid oxidizing agents and acids.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce oxides of carbon and sodium.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Direct contact may cause irritation with redness and tearing. Rubbing the eye may cause mechanical irritation.
Skin: May cause irritation. Rubbing the skin may cause mechanical irritation. Prolonged exposure may cause dryness.
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: Not an expected route of exposure.

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 fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel. Sodium fluoride has been shown to cause reproductive effects and birth defects studies with in laboratory animals.

Irritation: Glycerin: Non-irritating to rabbit skin and eyes. Aluminum Oxide: Slightly irritating to rabbit skin and eyes. Sodium Fluoride: Not irritating to rabbit skin and slightly irritating to rabbit eyes.

Corrosivity: Sodium silicate: Corrosive to rabbit skin. This product is not classified as a corrosive material.

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

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

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Glycerin: Oral rabbit LD50- >12,600 mg/kg; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >2.75 mg/L/4hr

Aluminum Oxide: Oral rat LD50 - > 5000 mg/kg

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

Flavoring: No toxicity data available

Sodium Fluoride: Oral Rat LD50 - 32 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: A 75 day reproductive study with rats with 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 place 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, salvation 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, kidney 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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
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

12.2 Persistence and Degradability: Glycerin is readily biodegradable (96% in 24 hours). Biodegradation is not applicable to inorganic substances such as aluminum oxide, sodium silicate, and sodium fluoride.

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: 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 an RQ of 33,333 lbs (based on the RQ of sodium fluoride of 1,000 lbs present at <3%). 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:

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 %
None		

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: 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:
T Toxic
Xi Irritant
R25 Toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R36/38 Irritating to eyes and skin.
Acute Tox. Cat 3 Acute Toxicity Category 3
Acute Tox. Cat 4 Acute Toxicity Category 4
Eye Irrit. Cat 2 Eye Irritant Category 2
Skin Irrit. Cat 2 Skin Irritation Category 2
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Cause skin irritation.
H319 Causes serious eye irritation.

Supersedes: 18 November 2010
Date Revised: 06 February 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.