

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: 130032
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Revision Number: 11

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

1.1 Product Identifier:

Trade Name (as labeled): NUPRO® (Gel, Rinse) Topical Neutral 2.0% Sodium Fluoride

Part/Item Number: 130034, 130036, 130038, 130040, 130074, 130076, 130078

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

Recommended Use: Topical 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
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not classified

2.2 Label Elements:

Signal Word: None

Contains:

Hazard Phrases	Precautionary Phrases
None Required	None Required

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 (Oral) (H301), Skin Irrit Cat 2 (H315), Eye Irrit Cat 2 (H319), EUH032	2

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 eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention if symptoms develop and persist.
Ingestion	Do not induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water and drink 8 of water to dilute. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if large quantities are consumed.

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

May cause mild eye irritation. May cause skin irritation with prolonged contact. 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:

None known.



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

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 safety glasses or chemical splash goggles are recommended to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as butyl rubber gloves to avoid prolonged 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 of sodium fluoride	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:	6.5-7.5	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 may cause mild irritation.

Skin: Repeated or prolonged contact may cause irritation.

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

<u>Inhalation:</u> Mists may cause upper respiratory tract irritation, coughing or sneezing.
<u>Chronic Health Effects:</u> Prolonged overexposure may cause skin drying and irritation. Prolonged over exposure to sodium fluorides may fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.
<u>Irritation:</u> Sodium fluoride: No data available.
<u>Corrosivity:</u> This product is not a corrosive material.
<u>Sensitisation:</u> Sodium Fluoride: Not sensitizing in Buehler test.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP Directive.
<u>Mutagenicity:</u> No data available. This product is not expected to cause mutagenic activity.
<u>Medical Conditions Aggravated by Exposure:</u> Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.
<u>Acute Toxicity Data:</u> Sodium fluoride: Oral Rabbit LD50: 320 mg/kg ATE: Oral: 15,873 mg/kg
<u>Reproductive Toxicity Data:</u> 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.
<u>Specific Target Organ Toxicity (STOT):</u> <u>Single Exposure:</u> 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. <u>Repeated Exposure:</u> 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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Sodium Fluoride: Rainbow Trout 96hr LC50: 317 ppm; Daphnia magna 48hr EC50:352 mg/kg
12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride.
12.3 Bio-accumulative Potential: No data available

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 50,000 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:	No	Pressure Hazard:	No
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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): 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 – 1 Flammability – 0 Physical Hazard – 0

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

T Toxic
Xi Irritant
R25 Toxic if swallowed
R36/38 Irrigating to eyes and skin
R32 Contact with acids liberates very toxic gas
Acute Tox Cat 3 Acute Toxicity Category 3
Eye Irrit Cat 2 Eye Irritant Category 2
Skin Irrit Cat 2 Skin Irritant Category 2
H301 Toxic if swallowed.
H315 Causes skin irritation
H319 Causes serious eye irritation
EU032 Contact with acids liberates very toxic gas

Supersedes: 01 February 2013

Date Revised: 25 August 2014

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

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