SAFETY DATA SHEETS

This SDS packet was issued with item:

070374835

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070374819 070374876 071183201 071183219 071183227 071183276 071183284 071183292

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070374884 070374892 070496430 070496448 070496455 070496489 070496497 070496513 071183367 071183375

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: 12 December 2012
Document Number: 130208
Date Revised: 03/08/2013
Revision Number: 1

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**NUPRO® 5% Sodium Fluoride White Varnish**
Product Identifier (Part/Item Number):	**130210, 130211, 130212, 130213, 130214, 130215**
U.N. Number:	**UN1219**
U.N. Dangerous Goods Classification:	**3**
Recommended Use: **Restrictions on Use:**	**One-step application that reduces dentinal hypersensitivity** **For Professional Use Only**
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)**
Transportation Emergency Contact Telephone Number:	**800-424-9300 Chemtrec**
Email address:	**ProfessionalMSDS@dentsply.com**

2. HAZARD(s) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 Skin Sensitizer Category 1 Eye Irritant Category 2 Specific Target Organ Toxicity –Single Exposure Category 3	Non-Hazardous	Flammable Liquid Category 2

GHS Labeling Elements: Contains 2-Propanol and Sodium Fluoride

Signal Word: Danger

Hazard Statements

H225 Highly flammable liquid and vapor
H302 Harmful if swallowed
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Precautionary Statements

Prevention:
P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking.
P233 Keep container tightly closed.
P261 Avoid breathing vapors.
P264 Wash exposed skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection, and face protection.
Response:
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
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
P304+P340 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
P312 Call a POISON CENTER or doctor/physician if you feel unwell.
P301+P312 IF SWALLOWED: Call a POISON CENTER, doctor if you feel unwell
P330 Rinse mouth.
P370+P378 In case of fire: Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray to extinguish.
Storage:
P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
Disposal:
P501 Dispose of contents and container in accordance with local and national regulations.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Urethane Dimethacrylate Resin	72869-86-4	276-957-5	Skin Sens.1 (H317)	30-40
2-Propanol	67-63-0	200-661-7	Flam. Liq. 2 (H225), Eye Irrit. 2 (H319), STOT SE 3 (H336)	20-30
Sodium Fluoride	7681-49-4	231-667-8	Acute Tox. 3 (H301), Eye Irrit. 2 (H319), Skin Irrit. 2 (H315)	4-6
Titanium Dioxide	13463-67-7	236-675-5	Carc. 2 (H351)	<1

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

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin with soap and water. Get medical attention if irritation develops. 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 immediate medical attention.
Ingestion	Rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.
Most important symptoms of exposure	May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed. Vapors may cause drowsiness and dizziness.
Note to Physicians (Treatment, Testing, and Monitoring) Treat symptomatically.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray.
Fire Fighting Procedures:	Cool fire exposed containers with water spray.
Specific Hazards Arising from the Chemical:	Highly flammable liquid and vapor. Closed containers exposed to heat from fire may build pressure and explode.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Environmental Precautions: Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

Methods and Materials for Containment and Clean-up: Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

7. HANDLING AND STORAGE

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 after handling. Keep away from heat, sparks, flames, and other sources of ignition.

Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Store away from acids and oxidizing agents. Keep out of reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:		
Urethane Dimethacrylate Resin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
2-Propanol	United States	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
	Germany	200 ppm TWA, 40 ppm STEL DFG MAK
	United Kingdom	400 ppm TWA, 500 ppm STEL UK OEL
	European Union	None Established
Sodium Fluoride (As Flouride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 (Inhalable) TWA, 4 mg/m3 STEL DFG MAK
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL

Titanium Dioxide	United States	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (Total Dust) TWA OSHA PEL
	Germany	None Established
	United Kingdom	10 mg/m3 (Inhalable), 4 mg/m3 (Respirable) TWA UK OEL
	European Union	None Established

Biological Exposure Limits:
Sodium Fluoride (as fluorides) - Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

Environmental Exposure Controls: None required for normal use.

General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	**White opaque viscous liquid**	**Explosive limits:**	**LEL: 2.0 % (2-Propanol) UEL: 12.7 % @ 93°C (200°F) (2-Propanol)**
Odor:	**Fruit odor**	**Vapor pressure:**	**Not applicable**
Odor threshold:	**Not determined**	**Vapor density:**	**Not applicable**
pH:	**Not determined**	**Relative density:**	**1.04 g/mL**

Melting/freezing point:	**Not determined**	**Solubility:**	**Insoluble in water**
Initial boiling point and range:	**106°C (222.8°F)**	**Partition coefficient: n-octanol/water:**	**Not determined**
Flash point:	**16.9°C (62.4°F)** **Method: Closed Cup**	**Auto-ignition temperature:**	**Not determined**
Evaporation rate:	**Not applicable**	**Decomposition temperature:**	**Not determined**
Flammability:	**Highly flammable under fire conditions.**	**Viscosity:**	**1,500-3,500 cP @ 25°C**
Explosive Properties:	**None**	**Oxidizing Properties:**	**None**

10. STABILITY AND REACTIVITY

Reactivity: None known.
Chemical Stability: Stable.
Possibility of Hazardous Reactions: Contact with acids liberates toxic gas.
Conditions to Avoid: Keep away from heat, sparks, flames and other sources of ignition.
Incompatible materials: Avoid acids and oxidizing materials.
Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, phosgene, hydrogen chloride and/or hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:
Eyes: May cause moderate irritation with redness, tearing and blurred vision.
Skin: Prolonged or repeated contact may cause mild skin irritation redness, rash and swelling. May cause allergic skin reaction (sensitization).
Ingestion: Ingestion may cause irritation to the mouth, throat and stomach with abdominal pain and nausea. May cause gastrointestinal irritation and central nervous system depression with symptoms similar to those described under inhalation.
Inhalation: Inhalation may cause nose and throat irritation with the possibility of central nervous system depression. Symptoms of central nervous system depression include headache, dizziness, drowsiness, nausea and unconsciousness.

Chronic Health Effects: 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.

Carcinogenicity: 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. This product contains small amount of titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. In this product, the titanium dioxide is incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable 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, ACGIH, the EU CLP, or NTP.

Mutagenicity: 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, skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Urethane dimethacrylate Resin: Oral Rat LD50- >5000 mg/kg

2-Propanol: Oral rat LD50- 5045 mg/kg; Inhalation rat LC50 – 16000 ppm /8hr; Skin rabbit LD50- 12800 mg/kg

Sodium Fluoride: Oral Rat LD50-32 mg/kg

Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 ->10000 mg/kg

Reproductive Toxicity Data: 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: 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: 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

Toxicity:

Urethane dimethacrylate Resin: 48hr EC50 Daphnia magna - >1.2 mg/l; 72 hr EC50 Desmodesmus subspicatus (algae)- >0.68 mg/L (growth rate)

2-Propanol: 96 hr LC50 Fathead minnow – 9640 mg/L; 24 hr EC50 Water flea- 9714 mg/L

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

Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Urethane dimethacrylate Resin: 22% after 28 days - Not readily biodegradable. 2-Propanol: 95% after 21 days- Readily biodegradable.

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

Other Adverse Effects: No data available

Results of PBT/vPvB Assessment: No data available

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: None currently known.
Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN1219	IMDG: UN1219	IATA: UN1219	DOT: UN1219
UN proper shipping name:	ADR/RID: Isopropanol Solution IMDG: Isopropanol Solution IATA: Isopropanol Solution DOT: Isopropanol Solution			
Transport hazard class(es):	ADR/RID: 3	IMDG: 3	IATA: 3	DOT: 3
Packaging group:	ADR/RID: II	IMDG: II	IATA: II	DOT: II
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Irritant, Sensitizer, Flammable liquid

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 16,666 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 6%). 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.

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:	**Yes**		

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

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		

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

International Regulations

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

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

This MSDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the MSDS 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.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health –2 Flammability – 3 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3:
Acute Tox. 3 Acute Toxicity Category 3
Acute Tox. 4 Acute Toxicity Category 4
Carc. 2 Carcinogen Category 2

Eye Irrit. 2 Eye Irritant Category 2
Flam. Liq. 2 Flammable Liquid Category 2
Skin Irrit. 2 Skin Irritant Category 2
Skin Sens. 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly Flammable Liquid and Vapor
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H351 Suspected of causing cancer.

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

Supersedes: Revision 0 Date Issued December 12, 2012

Revision Summary: Revision 1 March 08, 2013- Section 1: Emergency Contact Telephone Number was revised to Transportation Emergency Contact Telephone Number