

SAFETY DATA SHEET

SECTION 1: Product and Company Identification			
Product Identity: NovaBright™ 5% NaF Varnish For Dental Professional Use Only, Use as Directed NovaBright™ 5% Sodium Fluoride Varnish is a fluoride containing preparation for use as a cavity varnish and for the treatment of dentin hypersensitivity. Date Issued: 11/29/2017			
SECTION 2: Hazardous Identification			
This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.			
Product Description: Off white liquid with flavored odor			
Hazard Statement	Caution! Contact with acids may produce very toxic gas. May cause mild skin irritation. May cause moderate eye irritation. Ingestion of large amounts may be harmful. Possible mild dermatitis. May cause skin sensitization. Ethanol has been shown to cause mutagenic effects but at extremely high oral doses, which are not applicable in a clinical setting.		
Inhalation	Not an expected route of entry	Eyes	May cause moderate eye irritation
Skin	May cause mild skin irritation	Ingestion	May cause irritation to the mouth, throat, and stomach
Effects of long-term (chronic) exposure		Prolonged or repeated skin contact may result in irritation and possible dermatitis.	
Carcinogenic status		See Toxicological information, Section 11	
Potential environmental effects		See Ecological information, Section 12	
Section 3: Composition/Information on Ingredients			
Chemical Name	C.A.S. NO.	Percent	
Rosin	8050-09-7	50-70	
Ethanol	64-17-5	10-30	
Sodium Fluoride	7681-49-4	1-10	
Section 4: First Aid Measures			
The following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed.			
Eye Contact	Flush eyes with large amount of water. If irritation persists, seek medical attention		
Skin Contact	Remove contaminated clothing and shoes. Immediately wash exposed area thoroughly with soap and water for 15 minutes. Get medical attention.		
Inhalation	Remove person to fresh air. If irritation persists, seek medical attention		
If Swallowed	Wash out mouth with water. Do not induce vomiting. Seek medical attention		
Section 5: Fire-Fighting Measures			
OSHA Fire Hazard Class	Class IIIB Flammable Liquid		
NFPA Hazard Code	Health: 1	Fire: 1	Reactivity: 0
Not flammable under normal conditions of use			
Extinguishing media	Use media suitable to the surrounding fire such as water, alcohol foams, carbon dioxide, and dry chemical.		
Section 6: Accidental Release Measures			
Spill Response	Ventilate area. Extinguish all ignition sources. Collect spilled material. Other sections of SDS contain information regarding physical and health hazards, respiratory protection, ventilation, and ignition sources.		
Recommended Disposal	Dispose of contents/container in accordance with applicable local/regional/national/international regulations.		
US EPA Hazardous Waste Number	D001 ; If a spill/release in excess of the EPA reportable quantity is made into the environment, immediately notify the national response center in the United States (phone: 1-800-424-8802)		

Section 7: Handling and Storage			
Eye Protection	Avoid eye contact. Safety glass with side shield is recommended.		
Skin Protection	Avoid skin contact. Wear nitrile gloves when handling this material. A not touch technique is recommended. If skin contact occurs, wash with soap and water.		
Ventilation Protection	Do not use in a confined area or areas with limited air movement. Use in well-ventilated area. Avoid prolonged breathing of vapors.		
Prevention of Accidental Ingestion	Do not eat, drink, or smoke when utilizing this product. Wash exposed areas thoroughly with soap and water. Wash hands between handling and eating. Do not ingest.		
Recommended Storage	Store in a cool place away from acids, heat, and light. Inspect periodically for damage or leaks.		
Section 8: Exposure Controls and Personal Protection			
Exposure limits	Source of Exposure Limit Data: ACGIH- American Conference of Governmental Industrial Hygienists, OSHA- Occupational Safety Administration.		
Ingredients	ACGIH TLV		OSHA PEL
	TWA	STEL	PEL STEL
Sodium Fluoride	2.5 mg/m3	N/Av	2.5 mg/m3 N/Av
Ethanol	N/Av	1000 ppm	1000 ppm N/Av
Personal Protection	See Section 7: Handling and Storage for suggested protective equipment.		
Other Protective Equipment	Eye wash and safety shower should be made available in immediate working area. Remove wash contaminated clothing before re-use.		
Section 9: Physical and Chemical Properties			
Specific Physical Form	Paste	Specific Gravity	~1.1 g/ml
Odor, Color, Grade	Off white liquid with flavored odor	Solubility in Water	Moderate
General Physical Form	Liquid	Vapor Pressure	Not Applicable
Boiling Point	No Data Available	Evaporation rate	Negligible
Section 10: Stability and Reactivity			
Stability and Reactivity	Stable under recommended storage conditions.		
Hazardous Polymerization	Hazardous polymerization does not occur.		
Conditions to Avoid	Keep out of direct sunlight. Keep from excessive heat, open flames, sparks, and other possible ignition sources. Do not use in areas without adequate ventilation. Contact with acids may produce very toxic gas.		
Section 11: Toxicological Information			
Target organs	Eyes, skin, and digestive system		
Routes of Exposure	Skin & Eyes, and Ingestion		
Toxicological Data	There is no available data for the product itself, only for the ingredients. See below for individual ingredient acute toxicity data.		
Ingredients	LC50(4hr)		LD50
	inh, rat	Oral, rat	Rabbit, dermal
Sodium Fluoride	N/Av	52 mg/kg	175 mg/kg
Ethanol	>32380 ppm	7060 mg/kg	>15800 mg/kg
Rosin	N/Av	3 mg/kg	N/Av
Carcinogenic status: Not known to be carcinogenic. Note that this product contains ethanol, a confirmed animal carcinogen (A3) by the ACGIH and human carcinogen (Group 1) by the IARC; however, this is only applicable when the chemical is present in alcoholic beverages.			
Section 12: Ecological Information			
Ecotoxicity	The product should not be allowed to enter drains or water courses, or be deposited where it can affect ground or surface waters. Toxicity to fish: LC50/96h/rainbow trout = 51-108 mg/L Toxicity to invertebrates EC50/48h/Daphnia magna (water flea) = 97-153 mg/L Toxicity to algae EC50/96h/skeletonema costatum = 122 mg/L		
Section 12: Ecological Information (continued)			
Mobility/bioaccumulation potential/other adverse environmental effects: No data is available on the product itself. Persistence: Active ingredient is readily biodegradable.			

Section 13: Disposal Considerations	
Recommended Disposal	Dispose of contents/container in accordance with applicable local/regional/ national/international regulations. Contact your local, state, provincial, or federal agency for specific rules.
RCRA	It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies
Section 14: Transport Information	
49CFR/DOT	Not regulated
Section 15: Regulatory Information	
California Proposition 65	This product does contain ethyl alcohol, which is known to the State of California to cause developmental harm; however, this is only applicable when the chemical is present in alcoholic beverages.
Other U.S. State "Right to Know" Lists:	The following chemicals are specifically listed by individual States: Sodium Fluoride (MA, NJ, CA, PA, RI), Rosin (MN); Ethanol (MA, MN, NJ, CA, PA, RI).
CERCLA Reportable Quantity (RQ) (40 CFR 117.302): None reported.	
Section 16: Other Information	
The information in this Safety Data Sheet (SDS) is believed to be correct as of the date issued. Nanova Biomaterials Inc. makes no warranties, expressed or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose or course of performance or usage of trade. User is responsible for determining whether the Nanova Biomaterials Inc. product is fit for particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and applications of a Nanova Biomaterials Inc. product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the Nanova Biomaterials Inc. product to determine whether it is fit for a particular purpose and suitable for the user's method of use or application. Nanova Biomaterials Inc. provides information in electronic form as a service to its customers. Due to the remote possibility that electronic transfer may have resulted in errors, omissions or alterations in this information, Nanova Biomaterials Inc. makes no representations as to its completeness or accuracy. In addition, information obtained from a database may not be as current as the information in the SDS available directly from Nanova.	

Product Description

NovaBright™ 5% Sodium Fluoride Varnish is a topical treatment for application to enamel and dentine for the treatment of hypersensitive teeth. 1mL of NovaBright contains 50 mg of sodium fluoride, which is equivalent to 22.6 mg of fluorine in an alcohol-based suspension of natural resins. The product is sweetened with xylitol.

INDICATIONS FOR USE

NovaBright™ 5% Sodium Fluoride Varnish is a fluoride containing preparation for use as a cavity varnish and for the treatment of dentin hypersensitivity.

CONTRADICTIONS

1. Known allergic reactions to fluoride.
2. Ulcerative gingivitis and stomatitis.
3. Avoid ingestion during application.
4. Known allergies to colophony or similar rosin materials.

PRECAUTIONARY INFORMATION FOR DENTAL PERSONNEL

Use only as directed. To limit ingestion, determine the proper dosage amount for the patient. Discontinue patient's use of other prescriptive fluoride preparations (i.e. gels, rinses) for 24 hours. Patients taking fluoride supplements should discontinue use of supplements for 2-3 days following treatment. Store at a controlled room temperature. Keep away from open flame and direct sunlight.

WARNING

Contains ingredients that may be irritating to the skin and eyes. Edematous swelling has been reported only in rare instances, especially following application to extensive surfaces with fluoride varnish. Dyspnea, although extremely rare, has occurred in asthmatic people.

Customer Information - No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Please Note: Due to the nature of the ingredients inside this product, a color change and/or separation of materials may occur over time in an unopened **NovaBright™ 5% Sodium Fluoride Varnish** unit-dose. The product performance should not be affected if used within the stated expiration date.

Directions for Use

1. Clean teeth and remove obvious plaque and calculus from area to be treated. For best results, remove any excess moisture from the tooth surface.
2. Open the unit-dose of **NovaBright™ 5% Sodium Fluoride Varnish** by gripping the rigid tray and slowly peeling back the foil cover, exposing the brush applicator and varnish well.
3. Remove applicator brush and thoroughly stir the **NovaBright™ 5% Sodium Fluoride Varnish** in the well until the varnish appears to be uniformly mixed.
4. Paint a thin layer of varnish onto treatment area using broad and even strokes.
5. Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
6. When dry, any excess varnish may appear "spotty" and may slide off the tooth surface. This will not affect the efficacy of the product as there is still a full layer of varnish on the tooth.
7. Dispose package and applicator after use.
8. Patient may leave immediately after treatment. Patient should be advised to not brush teeth for a minimum of 2 to 4 hrs.

STORAGE

Store at a controlled room temperature. Keep away from open flame and direct sunlight.

WARRANTY

Nanova Biomaterials, Inc. warrants this product will be free from defects in material and manufacture. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Nanova Biomaterials, Inc.'s sole obligation shall be repair or replacement of the Nanova Biomaterials, Inc. product.

LIMITATION OF LIABILITY

Except where prohibited by law, Nanova Biomaterials, Inc. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Caution: Federal US law restricts this device to sale by or on the order of a dental professional