

Material Safety Data Sheet

IDENTITY (As used on Label and List) VARNISHAMERICA™																						
Section I																						
Manufacturer's Name Medical Products Laboratories, Inc. 9990 Global Road Philadelphia, PA 19115		Emergency Telephone Number (215) 677-2700																				
Date Prepared 5/1/07		Telephone Number for Information (215) 677-2700																				
Section II - Hazardous Ingredients/Identity Information																						
<table><tr><td>(Hazardous Components: Specific Chemical Identity)</td><td>Fluoride</td></tr><tr><td>Common Name(s)</td><td>OSHA PEL</td></tr><tr><td>Sodium Fluoride</td><td>2.5mg/m3</td></tr><tr><td>Ethyl Alcohol</td><td>1000 ppm</td></tr><tr><td></td><td>ACGIH TLV</td></tr><tr><td></td><td>2.5mg/m3</td></tr><tr><td></td><td>1000 ppm</td></tr><tr><td></td><td>%</td></tr><tr><td></td><td>5</td></tr><tr><td></td><td>--</td></tr></table>			(Hazardous Components: Specific Chemical Identity)	Fluoride	Common Name(s)	OSHA PEL	Sodium Fluoride	2.5mg/m3	Ethyl Alcohol	1000 ppm		ACGIH TLV		2.5mg/m3		1000 ppm		%		5		--
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Section III - Physical/Chemical Characteristics																						
Boiling Point: N/A																						
Specific Gravity (water = 1) : 1.0 (approximately)																						
Vapor Pressure (mm Hg.): N/A																						
Melting Point: N/A																						
Vapor Density (AIR = 1) : N/A																						
Evaporation Rate (Butyl Acetate = 1) : N/A																						
Solubility in Water: Insoluble																						
Appearance and Odor: Yellow to amber colored viscous liquid, characteristic odor																						
Section IV - Fire and Explosion Hazard Data																						
Flash Point (Method Used): 80 F (Open cup)																						
Flammable Limits: Nonflammable																						
Extinguishing Media Carbon Dioxide, water spray, or dry chemical																						
Special Fire Fighting Procedures: None																						
Unusual Fire and Explosion Hazards: None																						
HAZARDOUS MATERIALS IDENTIFICATION SYSTEM:																						
<table><tr><td>HEALTH</td><td>1</td></tr><tr><td>FIRE</td><td>1</td></tr><tr><td>REACTIVITY</td><td>0</td></tr></table>			HEALTH	1	FIRE	1	REACTIVITY	0														
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Section V - Reactivity Data																						
Stability	Unstable ☐ Stable ☒	Condition to Avoid: Keep away from ignition source.																				
Incompatibility (Materials to Avoid): Oxidizing materials																						
Hazardous Decomposition or Byproducts: If heated, it can produce carbon dioxide, carbon monoxide.																						
Hazardous	May Occur ☐	Conditions to Avoid: None under anticipated normal use.																				
Polymerization	Will not Occur ☒																					

VARNISH America

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Section VI - Health Hazard Data		
Route(s) of Entry:		Inhalation: YES
Skin: YES		Ingestion: YES
Health Hazards (Acute and Chronic): Poisonous when taken internally. Long term exposure can lead to muscular weakness, fluorosis, dermatitis.		
Eyes: May cause irritation upon contact.		
Carcinogenicity:	NTP: N/A	IARC Monographs: N/A
OSHA Regulated: N/A		
Signs and Symptoms of Exposure: Nausea and vomiting. Abdominal distress. Mild irritation to skin and eyes.		
Medical Conditions Generally Aggravated by Exposure: Hypersensitivity to the material. Kidney and liver disorders.		
Emergency and First Aid Procedures: Move person to a well ventilated area. Get medical attention. In case of eye contact, flush with large quantities of water.		
Section VII - Precautions for Safe Handling and Use		
Steps to be taken in case Material is Released or Spilled: Clean up immediately with an absorbent material wetted with alcohol. Avoid skin contact and inhalation.		
Waste Disposal Method: Follow applicable federal, state and local regulations. Ventilate the area. Wash with alcohol after handling.		
Precautions to be Taken in Handling and Storing: Avoid skin and eye contact.		
Other Precautions: Keep out of reach of children. Keep away from heat.		
Section VIII - Control Measures		
Respiratory Protection: (specify type): to be used as needed		
Ventilation:		Local Exhaust: Room Ventilation
		Mechanical: (general) N/A
		Special: N/A
		Other: N/A
Protective Gloves: Recommended		Eye Protection: Safety Goggles
Other Protective Clothing or Equipment: None		
Work/Hygienic Practices: Avoid eye and skin contact. Wash hands with soap and water after handling.		
Section IX - Transportation		
Applicable Regulations: N/A		
NOTE: While MPL believes that the information provided herein is given in good faith, it is offered solely for your consideration, investigation and verification without any warranty, expressed or implied, regarding its correctness or accuracy. It is the user's responsibility both to determine the safe conditions for use and to assume liability for loss, injury, damage or expense resulting from the use of this product.		

Instructions for Use

DESCRIPTION: VarnishAmerica™ is a fluoride varnish which has a strong desensitizing action when applied to dental surfaces. VarnishAmerica™ may be used on moist teeth and leaves a film of varnish which sets in the mouth and may allow visual control and verification.

INDICATIONS: VarnishAmerica™ is a fluoride-containing preparation for the treatment of dental hypersensitivity, and for the reduction of post operative sensitivity. 1mL of VarnishAmerica™ fluoride varnish contains: 50 mg of sodium fluoride, equivalent to 22.6 mg fluoride ion.

DOSAGE: For the treatment of dentin hypersensitivity, two applications at several days' interval are sufficient in most cases. The fluoride content of VarnishAmerica™ is dosed in such a way that neither acute nor chronic side effects are to be expected if applied according to instructions.

INSTRUCTIONS TO APPLY VARNISHAMERICA™:

1. Peel open the foil hiding material starting from the unsealed tab on the left side of the package.
2. If desired, the varnish cup can be broken off and inserted into the included metal (propoxy paste) finger ring.
3. Remove brush and mix varnish until it reaches an even consistency.
4. For best results, dry teeth prior to application by rubbing a 2X2 (or other disposable cotton sponge) along the tooth surfaces to remove any existing bio-film.
5. Apply a very thin coat of varnish evenly to all of the desired tooth surfaces.
6. Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
7. Varnish hardens on contact with saliva so the patient may leave immediately after application.
8. 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.
9. It is recommended that the patient be instructed to only eat soft foods and drink cold liquids for two hours after treatment.

CAUTION: Federal (U.S.A.) Law restricts the use of this device to sale by or on the order of a medical or dental professional. For use in the oral cavity.

CONTRAINDICATIONS: Ulcerative gingivitis and stomatitis.

INTERACTIONS: When VarnishAmerica™ is applied, other fluoride preparations such as fluoride gels, should not be administered during the same day. The routine use of fluoride tablets should be interrupted for several days after treatment.

ADVERSE REACTIONS:

Edeematous swellings have been reported only in rare instances in some fluoride varnish products, especially after application to extensive surfaces. Dyspnea, although extremely rare, has occurred in asthmatic children. Nausea has been reported when extensive applications have been made. If required, varnish film can be removed with a thorough brushing.

SUPPLY: Cups of 0.25 mL or 0.4 mL VarnishAmerica™ sodium fluoride varnish.

REORDER: Reorder by calling 1-800-523-0191 • 215-677-2700 or by fax 215-677-7736.

ITEM # For Reorder

#070010 .25mL/box of 32 bubble gum
#070030 .25mL/box of 200 bubble gum
#070000 .4mL/box of 32 bubble gum
#070020 .4mL/box of 200 bubble gum
#070011 .25mL/box of 32 raspberry
#070031 .25mL/box of 200 raspberry
#070001 .4mL/box of 32 raspberry
#070021 .4mL/box of 200 raspberry



Manufactured by:

MEDICAL PRODUCTS LABORATORIES, INC.
9990 Global Road • Philadelphia, PA 19115-1083
800-523-0191 fax 215-677-7736
www.medicalproductslaboratories.com

MADE IN U.S.A.

