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## TOPEX® DURASHIELD® 5% SODIUM FLUORIDE VARNISH



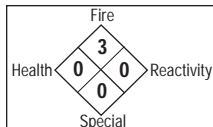
HAZARD RATING  
4=Extreme 3=High 2=Moderate 1=Slight 0=Insignificant

### PRODUCT IDENTIFICATION

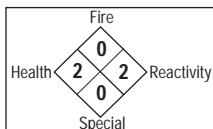
PRODUCT NAME: Topex® DuraShield® 5% Sodium Fluoride Varnish  
 SYNONYMS: Topex® Varnish, DuraShield®, 5% Sodium  
 CHEMICAL NAME: Ethyl Alcohol Solution  
 MOLECULAR FORMULA:  
 CHEMICAL FAMILY:

### COMPONENT INFORMATION

Ethyl Alcohol  
 Proper Shipping Name: Ethyl Alcohol  
 CAS: 64-17-5  
 UN Designation: UN-1170  
 Class: 3, Flammable Liquid  
 Packing Group: II



Sodium Fluoride (5% by weight)  
 Proper Shipping Name: Sodium Fluoride  
 CAS: 7681-49-4  
 UN Designation: UN-1690  
 Class: 6.1 Tox  
 Packing Group: III



### PHYSICAL & CHEMICAL PROPERTIES

Appearance: Yellow to orange color, thick liquid  
 pH: N/A Odor: Colophony odor  
 Melting Point/Range: N/A  
 Boiling Point/Range: ~173°F (~78.3°C)  
 Flash Point: ~61°F (~16°C)  
 Auto-Ignition Temperature: ca 400°C  
 Flammability: Yes  
 Explosive Limits in Air: 3.3 -19 vol.%  
 Vapor Pressure (mm Hg): ca 44.6

### FIRE & EXPLOSION DATA

SUITABLE EXTINGUISHING MEDIA: Use dry chemical, "alcohol" foam, or carbon dioxide. Water may be ineffective, but water should be used to keep fire-exposed containers cool.  
 UNUSUAL FIRE & EXPLOSION HAZARDS: None in quantities as packaged.  
 SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS: Fire fighters should wear self-contained breathing apparatus in the positive pressure mode with a full face-piece when there is a possibility of exposure to smoke, fumes or hazardous decomposition products.

### HEALTH HAZARD DATA / SPECIAL PROTECTION INFORMATION

INHALATION: Exposure to over 1,000ppm may cause headache, drowsiness and lassitude, loss of appetite and inability to concentrate. Irritation of the throat.  
 SKIN CONTACT: May Cause irritation and defatting of skin on prolonged contact. Seek medical attention in case of serious irritation or burns.  
 EYE CONTACT: Liquid or vapor may cause irritation. Seek medical attention as soon as possible.  
 INGESTION: Can cause depression of central nervous system, nausea, vomiting, & diarrhea.

### ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Avoid contact with skin or eyes. Wash hands with soap and water if skin contact occurs.

# MATERIAL SAFETY DATA SHEET

## TOPEX® DURASHIELD 5% SODIUM FLUORIDE VARNISH

### ENVIRONMENTAL PRECAUTIONS

Avoid uncontrolled releases of this material. When spills are possible, a comprehensive spill response plan should be developed and implemented.

### ACCIDENTAL RELEASE MEASURES (CONTD)

METHODS FOR CLEANING UP: Wear appropriate respiratory and protective clothing. Collect using absorbent media.

### HANDLING & STORAGE

HANDLING PRECAUTIONS: All ignition sources should be eliminated. Smoking should be prohibited in storage areas. Isolated from oxidizers, chemicals capable of spontaneous heating, materials reacting with the air or moisture to liberate heat, ignition sources or explosives.  
 SELF STORAGE CONDITIONS: Store out of sun and away from heat. Remove closure carefully. Keep closure up to prevent leakage.  
 OTHER RESTRICTIONS OR RECOMMENDATIONS: For industrial use only. Not for household use.

### EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION & VENTILATION: Where exposure is likely to exceed acceptable criteria use NIOSH/MSHA approved respiratory protection equipment. Respirators should be selected based on the form and concentration of containment in air and in accordance with OSHA (29 CFR 1910.134)  
 PROTECTIVE CLOTHING OR EQUIPMENT: Wear gloves and protective clothing which are impervious to this product for the duration of anticipated exposure if there is potential for skin contact.  
 UNUSUAL WORK/HYGIENE PRACTICES: Avoid prolonged contact with skin; wash with soap and water.

### STABILITY AND REACTIVITY

STABILITY: Generally Stable  
 CONDITIONS OF INSTABILITY: N/A  
 INCOMPATIBILITY WITH VARIOUS SUBSTANCES: Acetyl chloride and wide a range of oxidizing

agents may react violently.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide can form on incomplete combustion.  
 HAZARDOUS POLYMERIZATION: Not Likely  
 CONDITIONS TO AVOID: Acetyl Chloride and oxidizing agents.

### DISPOSAL CONSIDERATIONS

Do Not dispose in sink. Dispose of in accordance with all federal, state, and local regulations.

### REGULATORY INFORMATION

US FDA DENTAL DEVICE: Class II product  
 EC MEDICAL DEVICE DIRECTIVE: Class IIa product

### OTHER INFORMATION

*Some of the information presented and conclusions herein are from sources other than direct test data on the product itself. The information in this MSDS was obtained from sources that we believe are reliable. However, the information provided is without any warranty, express or implied, regarding its correctness. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use, or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by Sultan Dental Products, this MSDS information may not be applicable.*

### EMERGENCY RESPONSE

Info Trac (800) 535-5053

### DISTRIBUTED BY:

Sultan Dental Products  
 Englewood, NJ 07631 USA  
 800-238-6739 • www.sultandental.com



## USAGE INSTRUCTIONS & MATERIAL SAFETY DATA SHEET

### for **Topex® DuraShield®** **5% Sodium Fluoride Varnish** with UltraBrush™ 2.0 Bristle Brush Applicator Bubble Fun® Flavor

Contains  
XYLITOL

12/04

#### GENERAL INFORMATION & INDICATIONS

DuraShield® is flavored topical varnish containing 5% sodium fluoride for use as a desensitizing agent to relieve hypersensitivity on areas of teeth where dentin or cementum is exposed, but can also be used to line cavity preparations under amalgam restorations. Due to its high endurance against salivary fluids and moisture, DuraShield® will adhere to wet surfaces.

#### ACTIVE INGREDIENT

Sodium Fluoride 5%

#### OTHER INGREDIENTS

Colophony resin, synthetic inert polymer, alcohol, silica and flavoring. Sweetened with Xylitol. Contains no dyes.

#### PREPARATION & PROPERTIES

1 mL of DuraShield® contains 50 mg sodium fluoride, equivalent to 22.6 mg fluorine in a moisture tolerant, alcohol-based suspension of natural resins. DuraShield® displays strong desensitizing effects when applied to affected dentinal surfaces. This highly water-tolerant preparation adheres to even moist teeth and hardens upon contact with moisture or saliva and obturates orifices of the dentinal tubules.

#### CONTRAINDICATIONS

In case of adverse reaction, remove varnish with a soft toothbrush and floss, and then rinse with warm water. Patients allergic or sensitive to colophony (kolophonium or resembling agents), stomatitis or ulcerative gingivitis should avoid use of this product. Direct ingestion should be avoided. Dyspnea (difficult or labored breathing) associated with asthmatic children, has been reported in unique situations. Patients having sensitive digestive systems may experience nausea, usually after prolonged treatment.

#### INTERACTIONS

During treatment, patients should abstain from other fluorides, including: gels, foams, and rinses. Patients under prescription of supplemental fluoride should cease ingestion for at least 3-4 days unless otherwise instructed by dentist or physician.

#### SUGGESTED INSTRUCTIONS FOR USE

1. Remove any obvious calculus or plaque; prophylaxis is not necessary
2. For best results, eliminate any excessive moisture/saliva from area to be treated
3. Remove UltraBrush™ 2.0 Bristle Brush Applicator from sealed package and bend to desired angle
4. Because the natural resins may settle during storage, use UltraBrush™ to mix varnish in pre-measured well before delivering product to tooth surface
5. Uniformly apply DuraShield®, covering the entire surface to be treated
6. Allow area to become wet, either by rinsing or natural salivary flow
7. Instruct patient to remain on a soft-food diet for the remainder of the day; avoid rinses containing fluoride or alcohol; avoid brushing or flossing treated area for 4-6 hrs. after application (Patient instructions are available for post-application distribution)

#### RE-ORDER

32/box.....#31101

200/box.....#31102

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**Sultan**  
DENTAL PRODUCTS

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