

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
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 Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled):	Topex® Durashield® 5% Sodium Fluoride Varnish
Part/Item Number:	AD31101, AD31102

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

Recommended Use:	Desensitizing agent
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Transportation Emergency Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture

GHS SDS Classification

Health	Environmental	Physical
Acute Toxicity Category 4 H302 Eye Irritation Category 2 H319 Skin Sensitization Category 1 H317	Not Hazardous	Flammable Liquid Category 2

EU Classification (1999/45/EC as amended): Highly Flammable (F), Harmful (Xn), Irritant (Xi)

EU Risk (R) Phrases: R11, R22, R43

Labeling Elements: Contains Sodium Fluoride, Rosin



Signal Word: Warning!

Hazard Statements	Precautionary Statements
H225 Highly flammable liquid and vapour. H302 Harmful if swallowed. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P210 Keep away from heat, sparks, open flames, and hot surfaces. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment P241 Use explosion-proof electrical, ventilating and lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P261 Avoid breathing mist, vapors or spray. P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, skin protection and eye protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P333 + P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. 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. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. P370 + P378 In case of fire: Use dry chemical, alcohol foam or carbon dioxide to extinguish. P403 + P235 Store in a well-ventilated place. Keep cool. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %

Sodium Fluoride	7681-49-4 / 231-667-8	Sodium Fluoride	T R25, R36/38, R32 Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Irrit. 2; H315	5%
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flam. Liq. 2, H225 Eye Irrit 2 H319	Proprietary
Rosin	8050-09-7 / 232-475-7	2,4,6-tritert- butylphenol	Xi R43 Skin Sens. 1; H317	Proprietary

The exact concentration is being withheld as a trade secret.





Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES



4.1 Description of First Aid Measures:	
Routes of Exposure	First Aid Instructions
Eye	Immediately flush eyes with large quantities of water for 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Wash skin with soap and water. Get medical attention if irritation or symptoms develop.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If over normal dose is swallowed, DO NOT induce vomiting. Drink large quantities of water, milk or several ounces of milk of magnesia. Contact poison control.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
May cause eye and skin irritation. Vapors may cause irritation and central nervous system effects. May cause allergic skin reaction (sensitization). May be harmful if large amounts are swallowed.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
If large amounts are swallowed, get immediate medical attention.	
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media	
Use dry chemical, alcohol foam or carbon dioxide.	
5.2 Special Hazards Arising from the Substance or Mixture:	
Flammable liquid and vapor. Vapors are heavier than air and may travel to a remote ignition source and flashback.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Specific Hazards Arising from the Chemical:	Flammable liquid and vapor. Vapors are heavier than air and may travel to a remote ignition source and flashback.

Precautions for Fire Fighters:		Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.	
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
For large spills, wear protective clothing, eye protection and gloves. For small spills, wear eye protection and gloves.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			
6.2 Environmental Precautions:			
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.			
6.3 Methods and Material for Containment and Cleaning up:			
Methods and Materials for Containment and Clean-up: Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.			
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 and skin. Avoid breathing vapors. Keep product away from heat, sparks, flames and other sources of ignition. Use with adequate ventilation. Use in accordance with package instructions.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store in a cool, well ventilated area away from oxidizing agents and direct sunlight. Avoid excessive heat and ignition sources.
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	.5 mg/m ³ ACGIH TLV TWA 2.5 mg/m ³ US OSHA PEL TWA
	Germany	2.5 mg/m ³ TWA EU IOEL
	United Kingdom	2.5 mg/m ³ TWA UK OEL
	France	2 mg/m ³ INRS VME
	Spain	2.5 mg/m ³ VLA-ED
	Italy	2.5 mg/m ³ 8 hr Italy Value Limit
	European Union	2.5 mg/m ³ TWA EU IOEL
Ethanol	United States	1000 ppm TWA OSHA PEL 1000 ppm TWA ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm TWA UK OEL
	France	1000 ppm TWA INRS VME, 5000 ppm VLCT
	Spain	1000 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established
Rosin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	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 (ACGIH)

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general and local ventilate to minimize exposure levels.



Individual Protection Measures (PPE)

Specific Eye/Face Protection: Safety glasses should be worn if contact is likely.

Specific Skin Protection: Wear plastic or rubber gloves to avoid contact. Recommended glove: Rubber gloves. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Yellow to orange paste	Explosive limits:	LEL: 3.3 (ethanol) UEL: 19 (ethanol)
Odor:	Colophony odor	Vapor pressure:	44.6 mmHg
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	Not available
Initial boiling point and range:	78.3°C / 173°F	Partition coefficient: n-octanol/water:	Not available
Flash point:	22.5°C / 72.5°F	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Causes irritation with redness, tearing and swelling of conjunctiva.

Skin: Prolonged skin contact may cause irritation. May cause sensitization by skin contact.

Ingestion: Swallowing may cause nausea, vomiting, diarrhea and central nervous system depression. Large doses of fluorides can bind with serum calcium resulting in hypocalcemia with toxic effects, including cardiac effects, due to electrolyte imbalance.

Inhalation: None expected from normal use. Large vapor concentrations may cause headache, dizziness, drowsiness and other central nervous system effects.

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. Ethanol: In a skin painting study with mice, a 50% solution was placed on the skin three times a day for 829 days. No skin tumors were observed. None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

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. Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Fluoride: Oral Rat LD50 32 mg/kg

Ethanol: LD50 Rat oral 7,060 mg/kg, LC50 Rat inhalation 20,000 ppm/ 10 hr

Reproductive Toxicity Data: Sodium Fluoride: A 75 day reproductive study with rats with 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. Ethanol: Ingestion of alcohol is known to have adverse effects on reproduction and development in humans.

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, 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.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidney 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. Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m³. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day.

12. ECOLOGICAL INFORMATION**12.1 Toxicity:**

Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 83.7 mg/L, 48 hr EC50 daphnia magna 98 mg/L
Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna
Rosin: 48 hr EC50 daphnia magna 3.8 mg/L

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Ethanol: Readily biodegradable (84% after 20 days). Rosin has been shown to degrade 36-42% in 21 days.

12.3 Bio-accumulative Potential: No data is available to evaluate the potential for bioaccumulation of components of this product.

12.4 Mobility in Soil: Ethanol has a high mobility in soil.

12.5 Other Adverse Effects: No adverse effects are expected.

12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS**13.1 Waste Treatment Methods:**

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

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 (49 CFR 172.102 Special Provision 47)	None	None	No
ADR/RID	None	Not Regulated (Special	None	None	No

		Provision 216)			
IMDG	None	Not Regulated (Dangerous Good Code Special Provision 216)	None	None	Marine Pollutant-No
IATA/ICAO	None	Not Regulated (Special Provision A46	None	None	No

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 – product is transported only in packaged form.

If special provision is not used, the proper shipping name for all modes is:
UN3175, Solids containing flammable liquid, 4.1, II

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 an RQ of 83,333 lbs based on the RQ of sodium fluoride of 1,000 lbs present at 1.2%. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): This product is a drug and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

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:	Yes	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 chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %

None		
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International Regulations

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

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

F Highly Flammable

T Toxic

Xi Irritant

F11 Highly Flammable

R25 Toxic if swallowed.

R36/38 Irritating to eyes and skin.

R32 Contact with acids liberates very toxic gas.

R43 May cause sensitization by skin contact.

Flamm. Liq. 2 Flammable Liquid Category 2

Acute Tox. 3 Acute Toxicity Category 3

Skin Irrit. 2 Skin Irritation Category 2

Eye Irrit. 2 Eye Irritant Category 2

Skin Sens. 1 Skin Sensitizer Category 2

H225 Highly flammable liquid and vapor.

H301 Toxic if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Supersedes: 26 August 2011

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 6 October 2014

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