

## 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  
 Document Number: AD31165MS  
 Date Revised: 02 September, 2014  
 Revision Number: 4

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

**1.1 Product Identifier:**

Trade Name (as labeled):	<b>Topex® Neutral Fluoride Foam</b>
Part/Item Number:	AD31165

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

Recommended Use:	Topical fluoride treatment
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:	<a href="mailto:customer.service@sultanhc.com">customer.service@sultanhc.com</a>

**1.4 Emergency Telephone Number:**

Emergency Contact 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
Eye Irritation Category 2	Not hazardous	Flammable Aerosol Category 1 Gases Under Pressure - Compressed Gas

**EU Classification (1999/45/EC as amended):** Extremely Flammable (F+)

**EU Risk (R) Phrases:** R12

**Refer to Section 16 for the full text of the EU Classifications and R Phrases.**

## 2.2 Labeling Elements:



**Signal Word: Danger!**

Hazard Statements	Precautionary Statements
H222 Extremely flammable aerosol. H280 Contains gas under pressure; may explode if heated. H319 Causes serious eye irritation.	P210 Keep away from heat, sparks, open flames or hot surfaces. No smoking. P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use. P264 Wash thoroughly after handling. P280 Wear eye protection and face protection. 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. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C/ 122 F. Store in a well-ventilated place.

**2.3 Other Hazards:** None

## 3. COMPOSITION AND INFORMATION ON INGREDIENTS

### 3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Heptafluoropropane	431-89-0 / 207-079-2	1,1,1,2,3,3,3- heptafluoropropane	Not classified as dangerous Liq Gas H280	10-20
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flam Liq 2 H225 Eye Irrit 2 H319	1-10
Sodium Fluoride	7681-49-4 / 231-667-8	Sodium Fluoride	T R25, R36/38, R32 Acute Tox 3 H301 Skin Irrit 2 H315 Eye Irrit 2 H319 EUH032	0.9

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

<b>4.1 Description of First Aid Measures:</b>	
<b>Routes of Exposure</b>	<b>First Aid Instructions</b>
<b>Eye</b>	Flush eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
<b>Skin</b>	Wash skin thoroughly with soap and water. Get medical attention if irritation persists.
<b>Inhalation</b>	None needed under normal use conditions. If irritation develops, remove to fresh air.
<b>Ingestion</b>	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.

<b>4.2 Most Important Symptoms and Effects, Both Acute and Delayed:</b>
May cause mild eye irritation. May be harmful if large amounts are swallowed.

<b>4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:</b>
None required under normal use
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

## 5. FIRE-FIGHTING MEASURES



<b>5.1 Extinguishing Media</b>			
Use media appropriate for surrounding fire.			
<b>5.2 Special Hazards Arising from the Substance or Mixture:</b>			
Contents under pressure. Keep away from heat and open flames. Containers may rupture or explode under fire conditions.			
<b>5.3 Advice for Fire-Fighters:</b>			
<b>Fire Fighting Procedures:</b>	Cool fire exposed containers and structures with water. Use shielding to protect from bursting cans.		
<b>Precautions for Fire Fighters:</b>	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.		
<b>Recommended Protective Equipment for Fire Fighters:</b>			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

## 6. ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal Precautions, Protective Equipment and Emergency Procedures:</b>

For large spills, wear gloves and eye protection. Small spills do not require special precautions.

**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:**

Eliminate ignition sources and ventilate area. 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 eyes. Wash exposed skin thoroughly with soap and water after use. Keep away from excessive heat. Contents under pressure. Do not puncture or incinerate container. Use in accordance with package instructions.

**7.2 Conditions for Safe Storage, Including Any Incompatibilities:**


Store in a cool, well-ventilated area at temperatures below 120°F (50°C). Store away from heat and direct sunlight. Store away from oxidizers and other incompatible materials.

**7.3 Specific End Use (s):** For professional use only.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>8.1 Control Parameters:</b>		
<b>Occupational Exposure Limits:</b>		
Ethanol	United States	1000 ppm OSHA PEL 1000 ppm ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	1000 ppm INRS VME, 5000 ppm VLCT
	Spain	1000 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established
Heptafluoropropane	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Sodium Fluoride (as Fluoride)	United States	2.5 mg/m <sup>3</sup> ACGIH TLV TWA 2.5 mg/m <sup>3</sup> US OSHA PEL TWA
	Germany	1 mg/m <sup>3</sup> (Inhalable, skin) DFG MAK
	United Kingdom	2.5 mg/m <sup>3</sup> TWA UK OEL
	France	2 mg/m <sup>3</sup> INRS VME
	Spain	2.5 mg/m <sup>3</sup> VLA-ED
	Italy	2.5 mg/m <sup>3</sup> 8 hr
	European Union	.5 mg/m <sup>3</sup> TWA EU IOEL
<b>Biological Exposure Limits:</b> Sodium Fluoride (as fluorides) - Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine.		

<b>8.2 Exposure Controls:</b>
<b>Appropriate Engineering Controls:</b> No special controls required.
<b>Individual Protection Measures (PPE)</b> <b>Specific Eye/face Protection:</b> Avoid eye contact. Safety glasses should be worn if contact is likely. <b>Specific Skin Protection:</b> None normally required. <b>Specific Respiratory Protection:</b> None required under normal use conditions. <b>Specific Thermal Hazards:</b> 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:

<b>Appearance:</b>	White foam	<b>Explosive limits:</b>	Not applicable
<b>Odor:</b>	Mixed Berry odor	<b>Vapor pressure:</b>	45-55 mmHg
<b>Odor threshold:</b>	Not available	<b>Vapor density:</b>	<1
<b>pH:</b>	6.5-7.5	<b>Relative density:</b>	0.95
<b>Melting/freezing point:</b>	Not available	<b>Solubility:</b>	90%
<b>Initial boiling point and range:</b>	Not available	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	Not determined	<b>Auto-ignition temperature:</b>	Not available
<b>Evaporation rate:</b>	Not available	<b>Decomposition temperature:</b>	Not available
<b>Flammability:</b>	Flammable Aerosol	<b>Viscosity:</b>	Not available
<b>Explosive Properties:</b>	None	<b>Oxidizing Properties:</b>	None

**9.2 Other Information:** None available

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** Not normally reactive.

**10.2 Chemical Stability:** Stable

**10.3 Possibility of Hazardous Reactions:** Keep away from heat, sparks and open flames.

**10.4 Conditions to Avoid:** Dropping containers may cause bursting.

**10.5 Incompatible materials:** Avoid oxidizing agents.

**10.6 Hazardous Decomposition Products:** Thermal decomposition may produce carbon oxides, carbonyl fluoride and hydrogen fluoride.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

#### **Potential Health Effects:**

Eyes: Direct contact may cause irritation with redness, stinging and tearing.

Skin: No adverse effects are expected.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea. 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.

**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:** None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives. 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. 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. Titanium dioxide is listed by IARC as a group 2B carcinogen (possible human carcinogen).

**Mutagenicity:** 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. 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:** Employees with pre-existing skin disorders may be at increased risk from exposure.

#### **Acute Toxicity Data:**

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

Sodium Fluoride: Oral Rat LD50 32 mg/kg

Heptafluoropropane: Inhalation rat LC50 800,000 ppm/4 hr

**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. 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. Full strength ethanol causes reversible irritation to rabbit eyes.

**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. In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of mucous membranes. Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m<sup>3</sup>. 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:**

Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna

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

**12.2 Persistence and Degradability:**

Ethanol: Readily biodegradable 84% after 20 days. Biodegradation is not applicable to inorganic substances such as sodium fluoride.

**12.3 Bio-accumulative Potential:** This product is expected to have a low potential to bioaccumulate.

**12.4 Mobility in Soil:** This product is expected to have moderate to 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	Consumer Commodity	ORM-D	None	No



<b>ADR/RID</b>	<b>UN1950</b>	Aerosols	2.1	None	No
<b>IMDG</b>	<b>UN1950</b>	Aerosols	2.1	None	Marine Pollutant-No
<b>IATA/ICAO</b>	<b>UN1950</b>	Aerosols, flammable	2.1	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.

## 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 81,300 lbs based on the RQ of sodium fluoride of 1,000 lbs present at 0.9%. 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:**

<b>Immediate Hazard:</b>	<b>Yes</b>	<b>Pressure Hazard:</b>	<b>Yes</b>
<b>Delayed Hazard:</b>	<b>No</b>	<b>Reactivity Hazard:</b>	<b>No</b>
<b>Fire Hazard:</b>	<b>Yes</b>		

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
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:

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
None		

#### **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+ Extremely Flammable

F Highly Flammable

T Toxic

R11 Highly Flammable

R12 Extremely Flammable

R25 Toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R36/38 Irritating to eyes and skin.

Liq Gas Liquefied Gas

Flam Liq 2 Flammable Liquid Category 2

Acute Tox 3 Acute Toxicity Category 3

Skin Irrit 2 Skin Irritation Category 2

Eye Irrit 2 Eye Irritation Category 2

H225 Highly flammable liquid and vapour

H280 Contains gas under pressure; may explode if heated

H301 Toxic if swallowed

H315 Causes skin irritation

H319 Causes serious eye irritation

EO032 Contact with acids liberates very toxic gas

Supersedes: 26 August 2011

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 06 August, 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.