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: AD31150MS
Date Revised: 26 August 2011
Revision Number: 3

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Topex® 60 Second A.P.F. Foam**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	AD31150, AD31151, AD31152, AD31153, AD31154
U.N. Number:	UN1950 (International), None (North America)
U.N. Dangerous Goods Classification:	2.1 (International), ORM-D (North America)
Recommended Use:	Topical fluoride treatment
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9th Floor Hackensack, NJ
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)
Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Extremely Flammable (F+), R12

EU Labelling:

 Extremely Flammable	S16 Keep away from sources of ignition - No Smoking! S51 Use only in well ventilated areas. Do not spray on naked flame or any incandescent material. Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use.

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Heptafluoropropane	431-89-0 / 207-079-2	1,1,1,2,3,3,3-heptafluoropropane	Not classified as dangerous	10-20
Ethanol	64-17-5 / 200-578-6	ethanol	F R11	1-10
Sodium Fluoride	7681-49-4 / 231-667-8	Sodium Fluoride	T R25, R32, R36/38	1.23

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

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation persists.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air.
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.
Most important symptoms of exposure	May cause mild eye irritation. May be harmful if large amounts are swallowed.
Other	None known.
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

Suitable Extinguishing Media:	Use media appropriate for surrounding fire.
Fire Fighting Procedures:	Cool fire exposed containers and structures with water. Use shielding to protect from bursting cans.
Specific Hazards Arising from the Chemical:	Contents under pressure. Keep away from heat and open flames. Containers may rupture or explode under fire conditions.
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

Personal Precautions, PPE and Emergency Procedures: For large spills, wear gloves and eye protection. Small spills do not require special precautions.
Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
Methods and Materials for Containment and Clean-up: Eliminate ignition sources and ventilate area. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**SKIN**	**RESPIRATORY**	**THERMAL**
			

7. HANDLING AND STORAGE

Precautions for Safe Handing: 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.
Conditions for Safe Storage: 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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

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
Heptafuoropropane	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/m3 ACGIH TLV TWA 2.5 mg/m3 US OSHA PEL TWA
	Germany	1 mg/m3 (Inhalable, skin) DFG MAK
	United Kingdom	2.5 mg/m3 TWA UK OEL
	France	2 mg/m3 INRS VME
	Spain	2.5 mg/m3 VLA-ED
	Italy	2.5 mg/m3 8 hr
	European Union	.5 mg/m3 TWA EU IOEL

Biological Exposure Limits: Sodium Fluoride (as fluorides) - Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine.

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses should be worn if contact is likely.
Specific Skin Protection: None normally required.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable.

Recommended Personal Protective Equipment:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Routine hand washing after use recommended.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.			

9. PHYSICAL AND CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

Reactivity: No reactive.

Chemical Stability: Stable.

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

Conditions to Avoid: Dropping containers may cause bursting.

Incompatible materials: Avoid oxidizing agents.

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

11. TOXICOLOGICAL INFORMATION

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 and 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, 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, salvation 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/m3. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day.

12. ECOLOGICAL INFORMATION

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

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

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

Mobility in Soil: This product is expected to have moderate to high mobility in soil.

Other Adverse Effects: No adverse effects are expected.

Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

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

UN Number:	ADR/RID: UN1950	IMDG: UN1950	IATA: UN1950	DOT: None
UN proper shipping name:	ADR/RID: Aerosols IMDG: Aerosols IATA: Aerosols, flammable DOT: Consumer Commodity			
Transport hazard class(es):	ADR/RID: 2.1	IMDG: 2.1	IATA: 2.1	DOT: ORM-D
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

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.

OSHA Hazard Classification: Irritant, Flammable aerosol

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:**	**Yes**
Delayed Hazard:	**No**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

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

Components	C.A.S. #	WT %
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.

Date of SDS Preparation/Revision: 26 August 2011

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