Topex APF gel

Safety Data Sheet

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

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Topex® A.P.F. Fluoride Gel**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	AD31111, AD31112, AD31114, AD31115, AD31117
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Topical fluoride treatment
Restrictions on Use:	Use only as directed
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)
Email address:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

Hazard/Danger Classification (Regulation EC) No. 1272/2008 [CLP] / Hazcom 2012:

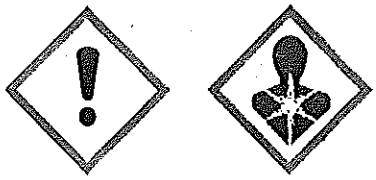
Health	Environmental	Physical
Acute Toxicity Category 4 Carcinogen Category 2 Skin Irritant Category 2 Eye Irritant Category 2	Non-Hazardous	Non-Hazardous

EU Classification (1999/45/EC as amended): Not a dangerous preparation

EU Labeling: None

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

Labeling Elements: Contains Sodium Fluoride, Phosphoric Acid, and Titanium Dioxide



Signal Word: Warning

Hazard Statements	Precautionary Statements
H302 Harmful if swallowed H315 Causes skin irritation H319 Causes serious eye irritation H351 Suspected of causing cancer by inhalation.	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P362 Take off contaminated clothing. P264 Wash exposed skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, and eye protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER, doctor if you feel unwell P330 Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of water. P332 + P313 If skin irritation occurs: Get medical attention. 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 P308 + P313 IF exposed or concerned: Get medical advice. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	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; EUH 032	2.7
Phosphoric Acid	7664-38-2 / 231-633-2	phosphoric acid	C R34 Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Irrit. 2A; H319	<2

Titanium Dioxide	13463-67-7 / 236-675-5	dioxotitanium	Carc. 2; H351	0.1-1

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 several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	No first aid should be needed. Rinse off with water. Get medical attention if irritation develops.
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.
Most important symptoms of exposure	May cause 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.
Specific Hazards Arising from the Chemical:	None known.
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 eye protection and gloves. 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: 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 the eyes. Use in accordance with package instructions.
Conditions for Safe Storage: Avoid excessive cold and heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:		
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 Italy Value Limit
	European Union	2.5 mg/m3 TWA EU IOEL
Phosphoric Acid	United States	1 ppm TWA US OSHA PEL 1 ppm TWA ACGIH TLV, 3 ppm STEL
	Germany	2 ppm TWA DFG MAK (inhalable)
	United Kingdom	1 ppm TWA, 2 ppm STEL UK OEL
	France	1 mg/m3 TWA INRS VME, 2 mg/m3 VLCT
	Spain	1 mg/m3 TWA VLA-ED, 2 mg/m3 VLA-EC
	Italy	1 ppm 8 hr Italy Value Limit, 2 ppm Short Term
	European Union	None Established
Titanium Dioxide	United States	15 mg/m3 TWA US OSHA PEL (total dust) 10 mg/m3 TWA ACGIH TLV
	Germany	1.5 mg/m3 (respirable dust) DFG MAK
	United Kingdom	10 mg/m3 (inhalable) 4 mg/m3 (respirable dust) TWA UK WEL

	France	10 mg/m3 INRS VME
	Spain	10 mg/m3 VLA-ED
	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

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:	Aqueous gel	**Explosive limits:**	Not applicable
Odor:	Characteristic of flavor	**Vapor pressure:**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	Not available	**Relative density:**	Not available
Melting/freezing point:	Not available	**Solubility:**	Complete
Initial boiling point and range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	>200°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

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize.
Chemical Stability: Stable.
Possibility of Hazardous Reactions: None known.
Conditions to Avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous Decomposition Products: Thermal decomposition may produce carbon and sodium oxides and hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

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

Skin: Prolonged or repeated skin contact may cause irritation.

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. High concentration of mists may cause upper respiratory tract irritation.

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. Titanium dioxide is listed by IARC as a group 2B carcinogen (possible human carcinogen). None of the other 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 in a mouse lymphoma cell 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:

Sodium Fluoride: Oral Rat LD50 32 mg/kg

Phosphoric Acid: Oral rat LD50 1,530 mg/mg; Skin rabbit LD50 2,740 mg/kg

Titanium Dioxide: Oral Rat LD50 >10,000 mg/kg

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.

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.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys 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.

12. ECOLOGICAL INFORMATION

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

Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride, phosphoric acid and titanium dioxide.

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

Mobility in Soil: No data is available.

Other Adverse Effects: None known.

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: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es)	ADR/RID: None	IMDG: None	IATA: None	DOT: None
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 37,037 lbs based on the RQ of sodium fluoride of 1,000 lbs present at 2.7%. 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, Carcinogen

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

Components	C.A.S. #	WT %
Titanium Dioxide	13463-67-7	0.1 – 1.0

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:
C Corrosive
T Toxic
R25 Toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R34 Causes burns.
R36/38 Irritating to eyes and skin.
Acute Tox. 3 Acute Toxicity Category 3
Acute Tox. 4 Acute Toxicity Category 4
Carc. 2 – Carcinogen Category 2
Eye Irrit. 2 Eye Irritant Category 2
Skin Corr 1B Skin Corrosion Category 1B
Skin Irrit. 2 Skin Irritation Category 2
EUH 032 Contact with acids liberates very toxic gas.
H301 Toxic if swallowed.
H302 Harmful if swallowed
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer by inhalation.

Date of SDS Preparation/Revision: 5 October 2012

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