

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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 Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled):	Topex® A.P.F. Fluoride Gel
Part/Item Number:	AD31111, AD31112, AD31114, AD31115, AD31117

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

Recommended Use:	Topical fluoride treatment
Restrictions on Use:	Use only as directed

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:

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
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

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

2.2 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.

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 %
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

* The titanium dioxide in this product is inextricably bound in a manner that no exposure occurs during normal use

and handling. Therefore this product is not classified as a carcinogen.

The exact concentration is being withheld as a trade secret.

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





4. FIRST-AID MEASURES

4.1 Description of 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.

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

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
None required under normal conditions of use.
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 media appropriate for surrounding fire.			
5.2 Special Hazards Arising from the Substance or Mixture:			
None known			
5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.		
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
			



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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

For large spills, wear eye protection and gloves. 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:

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. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Avoid excessive cold and heat.

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

8.2 Exposure Controls:

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
			

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic 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

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: None Known

10.4 Conditions to Avoid: None Known

10.5 Incompatible materials: Avoid strong oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and sodium oxides and hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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, 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, 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

12.1 Toxicity:

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

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: No data is available

12.5 Other Adverse Effects: None Known

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	None	None	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	Marine Pollutant-No
IATA/ICAO	None	Not Regulated	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.

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 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.

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 %
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.

Supersedes: 5 October 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 4 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.