

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: 4

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

1.1 Product Identifier:

Trade Name (as labeled): **Topex® Take Home Care® 0.4% Stannous Fluoride Gel**

Part/Item Number: AD30210, AD30211, AD30212

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

Recommended Use: Desensitizing toothpaste
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)

2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture

GHS SDS Classification

Health	Environmental	Physical
Non-Hazardous	Not Hazardous	Not Hazardous

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

2.2 Labeling Elements: None

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 %
Stannous Fluoride	7783-47-3 / 231-999-3	difluorotin	T R25, R38, R41 Acute Tox. 3 H301 Skin Irrit. 2 H315 Eye Irrit. 2 H319	0.4
Glycerin	56-81-5 / 200- 289-5	propane-1,2,3- triol	Not classified as hazardous	>90

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	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 mild 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
			

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:

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:

Glycerin	United States	5 mg/m ³ TWA US OSHA PEL (respirable fraction) 10 mg/m ³ TWA ACGIH TLV
	Germany	50 mg/m ³ DFG MAK (inhalable)
	United Kingdom	10 mg/m ³ TWA UK OEL
	France	10 mg/m ³ INRS VME
	Spain	10 mg/m ³ TWA VLA-ED
	Italy	None Established
	European Union	None Established
Stannous Fluoride	United States	2.5 mg/m ³ ACGIH TLV TWA (as fluoride) 2 mg/m ³ ACGIH TLV TWA (as tin organic compounds) 2.5 mg/m ³ US OSHA PEL TWA (as fluoride) 2 mg/m ³ US OSHA PEL TWA (as tin organic compounds)
	Germany	1 mg/m ³ (Inhalable, skin) DFG MAK (as fluoride)
	United Kingdom	2.5 mg/m ³ TWA UK OEL (as fluoride) 2 mg/m ³ TWA UK OEL (as tin organic compounds)
	France	2 mg/m ³ INRS VME (as fluoride)
	Spain	2.5 mg/m ³ VLA-ED (as fluoride) 2 mg/m ³ VLA-ED (as tin organic compounds)
	Italy	2.5 mg/m ³ 8 hr Italy Value Limit (as fluoride) 2 mg/m ³ 8 hr Italy Value Limit (as tin organic compounds)
	European Union	2.5 mg/m ³ TWA EU IOEL (as fluoride) 2 mg/m ³ TWA EU IOEL (as tin organic compounds)

Biological Exposure Limits:

Stannous 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: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: 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
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Colored gel	Explosive limits:	Not applicable
Odor:	Characteristic odor and flavor	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	1.3
Melting/freezing point:	Not available	Solubility:	Soluble
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	320°C / 608°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: None Known

10.5 Incompatible materials: Avoid oxidizing agents and acids.

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause mild irritation with redness and tearing. Glycerin is slightly irritating to rabbit eyes.

Skin: No adverse effects are expected. Glycerin is not irritating to rabbit or human skin.

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 stannous fluoride 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.

Mutagenicity: Glycerin was negative in AMES test, in-vitro sister chromatid exchange and unscheduled DNA synthesis.

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

Acute Toxicity Data:

Glycerin: Oral Rat LD50 >12,600 mg/kg

Stannous Fluoride: Oral Rat LD50 200 mg/kg

Reproductive Toxicity Data: High doses of stannous fluoride (greater than or equal to 10 mg/kg body wt) were reported to cause varying degrees of embryoletality and teratogenicity in groups of five to seven mice. 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. Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. Dermal effects from soluble stannous fluoride in skin scratches in the upper epidermis in rabbits produced destructive reaction with intraepidermal polymorphonuclear leukocyte pustules occurring on each side of scratch when scratches were covered for 18 hours.

Repeated Exposure: In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of

mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Glycerin: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 54,000 mg/L, 48 hr EC50 daphnia magna 10,000 mg/L

Stannous 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

Glycerin is readily biodegradable (63% after 14 days). Biodegradation is not applicable to inorganic substances such as stannous fluoride.

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: Glycerin: Very high mobility in soil.

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 is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local 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:	No	Pressure Hazard:	No
Delayed Hazard:	No	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 %
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:

T Toxic

R25 Toxic if swallowed.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

Acute Tox 3 Acute Toxicity Category 3

Skin Irrit 2 Skin Irritation Category 2

Eye Irrit 2 Eye Irritation Category 2

H301 Toxic if swallowed.
H315 Causes skin irritation
H319 Causes serious eye irritation.

Supersedes: 26 August 2011

Revision Summary: Comprehensive review, new format

Date of SDS Preparation/Revision: 8 September 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.