

Safety Data Sheet

Data Sheet conforms to Regulation (EC) 1907/2006,
 Regulation (EC) 1272/2008 and Regulation (EC) 2020/878,
 US 29CFR1910.1200, Canada Hazardous Products
 Regulation

Date Issued: 22 June 2009
 Document Number: 003000MS
 Date Revised: 21 September 2021
 Revision Number: 8

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

1.1 Product Identifier:

Trade Name (as labeled):	Topex® Prophylaxis Paste with Fluoride
Part/Item Number:	AD30000, AD30001, AD30002, AD30004, AD30007, AD30008, AD30009, AD30011, AD30012, AD30014, AD30015, AD30017, AD30018, AD30019, AD30021, AD30022, AD30024, AD30025, AD30031, AD30032, AD30034, AD30041, AD30042

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

Recommended Use:	Cleaning and polishing paste
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 17404, 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 Classification:		
Health	Environmental	Physical
Not hazardous	Non-Hazardous	Non-Hazardous

2.2 Labeling Elements:

Signal Word:

Hazard Statements	Precautionary Statements
EUH032 Contact with acids liberates very toxic gas.	

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Glycerin	56-81-5	200-289-5 /	Not classified as hazardous	< 40
Polyethylene glycol	25322-68-3	500-038-2 /	Not classified as hazardous	30 - 35
Titanium Dioxide*	13463-67-7	236-675-5 /	Carc. 2; H351	0 - 4
Sodium Fluoride	7681-49-4	231-667-8 /	Acute Tox. 3 (H301) LD50-148.5 mg/kg Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) EUH032	2.72

* The titanium dioxide in this product is inextricably bound in a manner that no exposure occurs during normal use and handling. The following flavors do not contain Titanium Dioxide: Chocolate, Really Raspberry, Root Beer Float™

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush eyes with large quantities of water several minutes, holding the eyelids apart. Get medical attention if irritation develops or 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
Ingestion	Do not induce vomiting unless directed to do so by a medical professional. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if symptoms develop.
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.	

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 / Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

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	
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:	
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.	
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	15 mg/m ³ (total dust), 5 mg/m ³ (respirable fraction) TWA OSHA PEL as mist 10 mg/m ³ TWA UK WEL 10 mg/m ³ TWA France OEL 200 mg/m ³ TWA, 400 mg/m ³ STEL DFG MAK 10 mg/m ³ TWA Belgium OEL
Polyethylene Glycol	10 mg/m ³ TWA AIHA WEEL (aerosol) 250 mg/m ³ TWA (inhalable), 500 mg/m ³ STEL (inhalable) German MAK
Titanium Dioxide	10 mg/m ³ TWA ACGIH TLV (respirable) 15 mg/m ³ TWA OSHA PEL (total dust) 10 mg/m ³ (inhalable), 4 mg/m ³ (respirable) TWA UK WEL 11 mg/m ³ TWA France OEL (inhalable) 0.3 mg/m ³ TWA (respirable), 2.4 mg/m ³ STEL (respirable) DFG MAK 10 mg/m ³ TWA Belgium OEL

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Colored paste	Explosive limits:	Not applicable
Color:	Various	Physical State:	Liquid
Odor:	Characteristic of flavor	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Relative Vapor Pressure @20°C: (Air = 1)	Not determined
pH:	Not applicable	Relative density:	Not determined
Melting/freezing point:	Not determined	Solubility(ies):	Insoluble
Initial boiling point and range:	Not determined	Partition coefficient: n-octanol/water:	Not required.
Flash point:	None	Auto-ignition temperature:	Not applicable
Evaporation rate: (n-BuAc = 1)	Not available	Decomposition temperature:	Not determined
Flammability:	Not flammable	Kinematic Viscosity:	Not determined

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards: None determined.

9.2.2 Other Safety Characteristics: None determined

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.

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 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 hypocalcaemia 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: Based on available data, the classification criteria are not met. 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). The titanium dioxide in this product is inextricably bound in a manner that no exposure occurs during normal use and handling. None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU CLP.

Mutagenicity: Based on available data, the classification criteria are not met. 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. Glycerin was negative in AMES test, in vitro sister chromatid exchange and unscheduled DNA synthesis.

Propylene glycol: In-vitro studies were negative

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

ATE Oral: >5,000 mg/kg

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

Polyethylene Glycol: Oral mouse LD50: 28,900 mg/kg

Sodium Fluoride: Oral Rat LD50: 148.5 mg/kg

Titanium Dioxide: Oral rat LD50: >20000 mg/kg; Skin hamster LD50: >10000 mg/kg

Reproductive Toxicity Data: Based on available data, the classification criteria are not met. 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. 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 Single Exposure (STOT-SE): Based on available data, the classification criteria are not met. 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. When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Based on available data, the classification criteria are not met. 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. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Based on available data, the classification criteria are not met.

Glycerin: 96 hr LC50 *Oncorhynchus mykiss* (Rainbow trout) 54,000 mg/L, 48 hr EC50 *daphnia magna* 10,000 mg/L
Sodium Fluoride: 96 hr LC50 *Oncorhynchus mykiss* (Rainbow trout) 83.7 mg/L, 48 hr EC50 *daphnia magna* 98 mg/L
Propylene glycol: *Salmo salar* (Atlantic salmon) >1,000 mg/L

12.2 Persistence and Degradability: Glycerin is readily biodegradable (63% after 14 days). Biodegradation is not applicable to inorganic substances such as sodium fluoride 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: Glycerin: Very high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not required.

12.6 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

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.

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	No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to IMO Instruments: 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 36,764 lbs. based on the RQ of sodium fluoride of 1,000 lbs. present at 2.72%. 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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product contains titanium dioxide which is known to the state of California to cause cancer. However, the titanium dioxide is inextricably bound within the chemical matrix of the product and no exposure can occur.

International Regulations

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 0 Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

Acute Tox. 3 - Acute Toxicity Category 3

Carc. 2 – Carcinogen Category 2

Eye Irrit. 2 - Eye Irritant Category 2

Skin Irrit. 2 - Skin Irritation Category 2

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer by inhalation.

EUH032 Contact with acids liberates very toxic gas.

Supersedes: 23 October 2017

Date revised: 21 September 2021

Revision Summary: General content and format update. Classification change. Removed EU classifications. Revised for Regulation (EC) 2020/878, Changes to all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.