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

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

1.1 Product Identifier:

Trade Name (as labeled):	**Topex® Prophylaxis Paste Non-Fluoride**
Part/Item Number:	AD60002, AD60011, AD30040

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

Recommended Use:	Cleaning and polishing paste
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 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)

2. HAZARD IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:		
Health	**Environmental**	**Physical**
Not hazardous	Not hazardous	Not hazardous

2.2 Labeling Elements: None required

2.3 Other Hazards: None known.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	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

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

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 water, holding the eyelids apart. Do not rub eyes. Get medical attention if irritation persists.
Skin	No first aid should be needed. Rinse off with water.
Inhalation	None needed under normal use conditions
Ingestion	If large amounts are swallowed, seek medical advice.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Direct contact may cause mild eye irritation.	
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.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
For large spills, wear eye protection. 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:
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 Handing:
Avoid contact with the eyes. Use in accordance with package instructions.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Avoid excess 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
Biological Exposure Limits: None Established	
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. If the exposure levels are exceeded, an approved respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice. **Specific Thermal Hazards:** Not applicable

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):**	<1 @ 20°C
Odor threshold:	Not determined	**Relative Vapor Pressure @20°C: (Air = 1)**	Not determined
pH:	8.55 (10% in water)	**Relative density:**	Not determined
Melting/freezing point:	Not available	**Solubility(ies):**	Miscible
Initial boiling point and range:	290°F / 143°C	**Partition coefficient: n-octanol/water:**	Not required.
Flash point:	390°F / 199°C	**Auto-ignition temperature:**	Not determined
Evaporation rate: (n-BuAc = 1)	Not available	**Decomposition temperature:**	Not determined
Flammability:	Not flammable	**Kinematic Viscosity:**	Not determined
Explosive Properties:	None	**Oxidizing Properties:**	None

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: Will not polymerize
10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Contact with strong oxidizing agents may cause fire.
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 oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects: Eyes: May cause irritation with redness and tearing. Mechanical (abrasive) irritation may also occur. Skin: No adverse effects expected. Glycerin is not irritating to rabbit or human skin. Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea. Inhalation: No adverse effects are expected.
Chronic Health Effects: None expected.
Eye Irritation/ Damage: Based on available data, the classification criteria are not met. Glycerin is slightly irritating to rabbit eyes.
Skin Irritation / Corrosivity: Based on available data, the classification criteria are not met.
Sensitization: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met. 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. Glycerin: 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: Glycerin: Oral Rat LD50 >12,600 mg/kg Polyethylene Glycol: Oral mouse LD50 28,900 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. 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. Glycerin: When place 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. 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
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 titanium dioxide.

12.3 Bio-accumulative Potential: Not expected to bio-accumulate.

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.

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 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 medical device 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: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 1 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
Carc. 2 – Carcinogen Category 2
H351 Suspected of causing cancer by inhalation.

Supersedes: 23 October 2017
Date revised: 21 September 2021

Revision Summary: General content and format update. Removed EU classifications. Revised for Regulation (EC) 2020/878, Changes to Sections 2, 3, 4, 8, 9, 11, 12, 14, 15 & 16.

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