

SAFETY DATA SHEETS

This SDS packet was issued with item:

076655500

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

076648208 076648224 076648232 076648240 076648265 076655443 076655450 076655468 076655476 076655484
076655518 076655526 076655534 076655542 076655559 076655567 076655575 076655583 076655591 076655609
076655617 076655625 076655633 076655641 076658629 076666291 076666309 076666333 076666457 076666473

Safety Data Sheet

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

Date Issued: 22 June 2009
Document Number: 0060002MS
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Revision Number: 4

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Topex[®] Prophy Paste Non-Fluoride
Chemical Name/Classification: Mixture
Product Identifier (Part/Item Number): AD60002, AD60011, AD30040
U.N. Number: None
U.N. Dangerous Goods Classification: None
Recommended Use: Cleaning and polishing paste
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
Non-Hazardous	Non-Hazardous	Non-Hazardous

EU Labeling: None

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

Labeling Elements: None

EU Labeling: 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 %
Glycerin	56-81-5 / 200-289-5	propane-1,2,3-triol	Not classified as hazardous	< 40
Polyethylene glycol	25322-68-3 / 500-038-2	poly(ethylene oxide)	Not classified as hazardous	30 - 35
Titanium Dioxide*	13463-67-7 / 236-675-5	dioxotitanium	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. Therefore this product is not classified as a carcinogen.





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 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.
Most important symptoms of exposure	Direct contact may cause eye irritation.
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. 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 Handling: 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:

Occupational Exposure Limits:

Glycerin	United States	5 mg/m3 TWA US OSHA PEL (respirable fraction)
		10 mg/m3 TWA ACGIH TLV
	Germany	50 mg/m3 DFG MAK (inhalable)
	United Kingdom	10 mg/m3 TWA UK OEL

	France	10 mg/m3 INRS VME	
	Spain	10 mg/m3 TWA VLA-ED	
	Italy	None Established	
	European Union	None Established	
Polyethylene Glycol	United States	10 mg/m3 TWA AIHA WEEL (aerosol)	
	Germany	1000 mg/m3 (inhalable) DFG MAK	
	United Kingdom	None Established	
	France	None Established	
	Spain	None Established	
	Italy	None Established	
	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 OEL	
	France	10 mg/m3 INRS VME	
	Spain	10 mg/m3 VLA-ED	
	Italy	None Established	
	European Union	None Established	
Biological Exposure Limits: None Established			
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:	Colored paste	Explosive limits:	Not applicable
Odor:	Characteristic of flavor	Vapor pressure:	< 1 mg Hg @ 20°C
Odor threshold:	Not available	Vapor density:	Not available
pH:	8.55 (10% in water)	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	Miscible
Initial boiling point and range:	290°F / 143°C	Partition coefficient: n-octanol/water:	Not available
Flash point:	390°F / 199°C	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: Contact with strong oxidizing agents may cause fire.

Conditions to Avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause irritation with redness and tearing. Mechanical (abrasive) irritation may also occur. Glycerin is slightly irritating to rabbit eyes.

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 known.
Carcinogenicity: 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: Glycerin: Negative in AMES test, in vitro sister chromatid exchange and unscheduled DNA synthesis. Propylene glycol: In-vitro studies were negative
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 Polyethylene Glycol: Oral mouse LD50 28,900 mg/kg Titanium Dioxide: No toxicity data available
Reproductive Toxicity Data: 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: 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. 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

Toxicity: 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
Persistence and Degradability: Glycerin is readily biodegradable (63% after 14 days). Biodegradation is not applicable to inorganic substances such as titanium dioxide.
Bio-accumulative Potential: Not expected to bio-accumulate.
Mobility in Soil: Glycerin: Very high mobility in soil.
Other Adverse Effects: No adverse effects are expected.
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.

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 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:

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 %
Titanium Dioxide	13463-67-7	< 5

International Regulations

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

16. OTHER INFORMATION

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

Carc. 2 – Carcinogen Category 2

H351 Suspected of causing cancer by inhalation.

Date of SDS Preparation/Revision: 19 November 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.