

SAFETY DATA SHEETS

This SDS packet was issued with item:

076655575

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
076655500 076655518 076655526 076655534 076655542 076655559 076655567 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
Date Revised: 4 August 2014
Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled):
Part/Item Number:

Topex® Prophy Paste Non-Fluoride
AD60002, AD60011, AD30040

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

Recommended Use:
Restrictions on Use:

Cleaning and polishing paste
Use only as directed

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:
Manufacturer/Supplier Address:

Sultan Healthcare
1301 Smile Way
York, PA, USA
1-201-871-1232 or 800-637-8582
(Product Information)-
customer.service@sultanhc.com

Manufacturer/Supplier Telephone Number:

Email address:

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
Not hazardous	Not hazardous	Not hazardous

EU labeling: None

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

2.2 Labeling Elements: None required

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 %
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.

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 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 eye irritation.

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.	
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. 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 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	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

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
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Colored Paste	Explosive limits:	Not applicable
Odor:	Characteristic of flavor	Vapor pressure:	<1 mmHg @ 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

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: 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. 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 expected.

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 eye and 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 placed 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

12.1 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

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 Other Adverse Effects: No adverse effects are expected

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.

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 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 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.

Supersedes: 19 November 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 04 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.