

## 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: 5

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

**1.1 Product Identifier:**

Trade Name (as labeled):	<b>Topex® Prophy Paste Non-Fluoride</b>
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, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	<a href="mailto:customer.service@sultanhc.com">customer.service@sultanhc.com</a>

**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 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.**

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**2.2 Labeling Elements:** None required

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### 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

<b>5.1 Extinguishing Media</b>			
Use media appropriate for surrounding fire.			
<b>5.2 Special Hazards Arising from the Substance or Mixture:</b>			
None known			
<b>5.3 Advice for Fire-Fighters:</b>			
<b>Fire Fighting Procedures:</b>	Cool fire exposed containers and structures with water.		
<b>Precautions for Fire Fighters:</b>	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.		
<b>Recommended Protective Equipment for Fire Fighters:</b>			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

## 6. ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal Precautions, Protective Equipment and Emergency Procedures:</b>			
For large spills, wear eye protection. Small spills do not require special precautions.			
<b>Recommended Personal Protective Equipment for Containment and Clean-up:</b>			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

<b>6.2 environmental precautions:</b>
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

<b>6.3 Methods and Material for Containment and Cleaning up:</b>
Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

<b>6.4 Reference to Other Sections:</b>
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/m <sup>3</sup> TWA US OSHA PEL (respirable fraction) 10 mg/m <sup>3</sup> TWA ACGIH TLV
	Germany	50 mg/m <sup>3</sup> DFG MAK (inhalable)
	United Kingdom	10 mg/m <sup>3</sup> TWA UK OEL
	France	10 mg/m <sup>3</sup> INRS VME
	Spain	10 mg/m <sup>3</sup> TWA VLA-ED
	Italy	None Established
	European Union	None Established
Polyethylene Glycol	United States	10 mg/m <sup>3</sup> TWA AIHA WEEL (aerosol)
	Germany	1000 mg/m <sup>3</sup> (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/m <sup>3</sup> TWA US OSHA PEL (total dust) 10 mg/m <sup>3</sup> TWA ACGIH TLV
	Germany	1.5 mg/m <sup>3</sup> (respirable dust) DFG MAK
	United Kingdom	10 mg/m <sup>3</sup> (inhalable) 4 mg/m <sup>3</sup> (respirable dust) TWA UK OEL
	France	10 mg/m <sup>3</sup> INRS VME
	Spain	10 mg/m <sup>3</sup> 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:**

<b>Appearance:</b>	Colored Paste	<b>Explosive limits:</b>	Not applicable
<b>Odor:</b>	Characteristic of flavor	<b>Vapor pressure:</b>	<1 mmHg @ 20°C
<b>Odor threshold:</b>	Not available	<b>Vapor density:</b>	Not available
<b>pH:</b>	8.55 (10% in water)	<b>Relative density:</b>	Not Available
<b>Melting/freezing point:</b>	Not available	<b>Solubility:</b>	Miscible
<b>Initial boiling point and range:</b>	290°F / 143°C	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	390°F / 199°C	<b>Auto-ignition temperature:</b>	Not available
<b>Evaporation rate:</b>	Not available	<b>Decomposition temperature:</b>	Not available
<b>Flammability:</b>	Not flammable	<b>Viscosity:</b>	Not available
<b>Explosive Properties:</b>	None	<b>Oxidizing Properties:</b>	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:**

<b>Immediate Hazard:</b>	No	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	No	<b>Reactivity Hazard:</b>	No
<b>Fire Hazard:</b>	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.