

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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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Topex[®] Prep and Polish Paste

Chemical Name/Classification: Mixture

Product Identifier (Part/Item Number): AD30045

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

EU Classification (1999/45/EC as amended): Not a dangerous preparation

EU Labeling: None

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS





Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Glycerin	56-81-5 / 200-289-5	propane- 1,2,3-triol	Not classified as hazardous	Proprietary

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:

Glycerin	United States	10 mg/m ³ TWA ACGIH TLV
		10 mg/m ³ TWA UK WEL
	Germany	50 mg/m ³ DFG MAK (inhalable)
	United Kingdom	None Established
	France	10 mg/m ³ INRS VME
	Spain	10 mg/m ³ TWA 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:	Gray colored paste	Explosive limits:	Not applicable
Odor:	Characteristic of flavor	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	Not available
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	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: None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives. No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg.

Mutagenicity: Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis.

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

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

Toxicity:

Glycerin: 96 hr LC50 *Oncorhynchus mykiss* (Rainbow trout) 54,000 mg/L, 48 hr EC50 *daphnia magna* 10,000 mg/L

Persistence and Degradability: Glycerin is readily biodegradable (63% after 14 days).

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.

OSHA Hazard Classification: Exposure Limits

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 %
None		

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:

None.

Date of SDS Preparation/Revision: 26 August 2011

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.