

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: AD31001MS
 Date Revised: 21 May 2014
 Revision Number: 5

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

- 1.1 Product Identifier:
 Trade Name (as labeled): Topex[®] Topical Anesthetic Gel/Liquid & HandiCaine Stix[®]
 Part/Item Number: AD31001, AD31002, AD31003, AD31004, AD31005, AD31006, AD31007, AD31011, AD31012, AD31014, AD31023, AD31024, AD31025, AD31026, AD31064, AD31065, AD31067, AD31068, CN31001, CN31002, CN31003, CN31004, CN31005, CN31006, CN31007
- 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:
 Recommended Use: Evacuation system cleaner
 Restrictions on Use: For professional use only
- 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: 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(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Skin Sensitization Category 1(H317)	Not hazardous	Not hazardous

EU Classification (1999/45/EC as amended): Irritant (Xi) R43

EU Risk (R) Phrases: R43

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

2.2 Labeling Elements:



Signal Word: **Danger**

Hazard Statements	Precautionary Statements
H317 May cause an allergic skin reaction.	P261 Avoid breathing mists, vapors or spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Polyethylene Glycol	25322-68-3 / 500-038-2	Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-Ethane-1,2-diol, ethoxylated	Not classified as hazardous Not classified as dangerous	30-50
Benzocaine	94-09-7 / 202-303-5	ethyl p-aminobenzoate	Sens 1 (H317) Xi, R43	20

The exact concentration is being withheld as a trade secret.

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

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation or other symptoms persist.
Skin	Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

If skin sensitization occurs, discontinue use and get medical attention.

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 for all fires involving chemicals.

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 gloves and 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.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes and skin. Wash thoroughly after handling. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Avoid prolonged storage at elevated temperatures as product degradation may occur.

7.3 Specific End Use (s): For professional use only.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Polyethylene Glycol	United States	10 mg/m ³ TWA AIHA WEEL (aerosol)
	Germany	1000 mg/m ³ (inhalable) DFG MAK
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established

Benzocaine	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	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: Avoid skin contact. Wear plastic or rubber gloves to avoid contact. Recommended glove: Plastic or rubber. Consult glove supplier for thickness and breakthrough times 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:	Gel	Explosive limits:	Not applicable
Odor:	Characteristic of flavor	Vapor pressure:	Negligible
Odor threshold:	Not available	Vapor density:	Not available
pH:	6.05	Relative density:	1.091 @ 25°C
Melting/freezing point:	Not available	Solubility:	Disperses
Initial boiling point and range:	>482°F / >250°C	Partition coefficient: n-octanol/water:	Not available

Flash point:	>300°F / >149°C	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	164,000 centipose
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: Hazardous reactions are unlikely.
10.4 Conditions to Avoid: None known.
10.5 Incompatible materials: Avoid oxidizing agents.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<u>Potential Health Effects:</u>
<u>Eyes:</u> Direct contact may cause irritation with redness and tearing. Numbness may occur.
<u>Skin:</u> Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.
<u>Ingestion:</u> Swallowing may cause nausea, vomiting and diarrhea. In rare cases, bezocaine has been shown to cause methemoglobinemia.
<u>Inhalation:</u> None expected from normal use. Inhalation of mists may cause respiratory irritation.
<u>Chronic Health Effects:</u> None expected.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.
<u>Mutagenicity:</u> No data available

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Polyethylene Glycol: Oral mouse LD50 28,900 mg/kg

Benzocaine: LD50 oral rat 3,042 mg/kg

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):

Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.

Repeated Exposure: Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Propylene glycol: Salmo salar (Atlantic salmon) >1000 mg/L

12.2 Persistence and Degradability: Benzocaine: Readily biodegradable

12.3 Bio-accumulative Potential: Benzocaine: Estimated BCF is 5. Potential for bioaccumulation is low.

12.4 Mobility in Soil: Benzocaine: Moderate mobility based upon an estimated Koc of 250.

12.5 Other Adverse Effects: None known.

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 for normal anticipated use.

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

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
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 drug 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:	Yes	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 chemical(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: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

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

Skin Sens 1 Skin Sensitization Category 1

H317 May cause an allergic skin reaction.

Xi Irritant

R43 May cause sensitization by skin contact.

Supersedes: : 21 May 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 21 May 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.