

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
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 Revision Number: 4


1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Topex[®] Topical Anesthetic Gel/Liquid & HandiCaine Stix[®]
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	AD31001, AD31002, AD31003, AD31004, AD31005, AD31006, AD31007, AD31011, AD31012, AD31014, AD31023, AD31024, AD31025, AD31026, AD31064, AD31065, AD31067, AD31068
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Topical anesthetic
Restrictions on Use:	Use only as directed
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9 th 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):: Irritant (Xi) R43

EU Labeling:

 Irritant	Contains benzocaine R43 May cause sensitization by skin contact. S24/25 Avoid contact with skin and eyes. S37 Wear suitable gloves
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US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Polyethylene Glycol	25322-68-3 / Not available	poly(ethylene oxide)	Not applicable	30-50
Benzocaine	94-09-7 / 202-303-5	ethyl p- aminobenzoate	Xi, R43	20





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 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.
Most important symptoms of exposure	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.
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 gloves and 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 and skin. Wash thoroughly after handling. Use in accordance with package instructions.

Conditions for Safe Storage: Avoid prolonged storage at elevated temperatures as product degradation may occur.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

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
			

Environmental Exposure Controls: None required for normal use.

General Hygiene Considerations and Work Practices: Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.

9. 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

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

Conditions to Avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness and tearing. Numbness may occur.

Skin: Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea. In rare cases, bezocaine has been shown to cause methemoglobinemia.

Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation.

Chronic Health Effects: None expected.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: 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

Toxicity:

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

Persistence and Degradability: Benzocaine: Readily biodegradable

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

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

Other Adverse Effects: None known.

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 for normal anticipated use.

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 drug and not subject to chemical notification requirements.

OSHA Hazard Classification: Sensitizer

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 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: 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: Xi Irritant R43 May cause sensitization by skin contact. Date of SDS Preparation/Revision: 21 May 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.