

## 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

<b>Trade Name (as labeled):</b>	<b>Sensicaine™ Topical Gel</b>
<b>Chemical Name/Classification:</b>	Mixture
<b>Product Identifier (Part/Item Number):</b>	1020420, 1020429, 1020436, 1020443, 1020452, 1020465
<b>U.N. Number:</b>	None
<b>U.N. Dangerous Goods Classification:</b>	None
<b>Recommended Use:</b>	Topical anesthetic
<b>Restrictions on Use:</b>	Use only as directed
<b>Manufacturer/Supplier Name:</b>	Sultan Healthcare
<b>Manufacturer/Supplier Address:</b>	1301 Smile Way York, PA, USA
<b>Manufacturer/Supplier Telephone Number:</b>	1-201-871-1232 or 800-637-8582 (Product Information)
<b>Emergency Contact Telephone Number:</b>	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
<b>Email address:</b>	<a href="mailto:customer.service@sultanhc.com">customer.service@sultanhc.com</a>

### 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
<b>Eye</b>	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.
<b>Skin</b>	Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist.
<b>Inhalation</b>	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
<b>Ingestion</b>	If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms of exposure</b>	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.
<b>Other</b>	None known.
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treatment of overexposure should be directed at the control of symptoms and clinical conditions.	

### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use media appropriate for surrounding fire.
<b>Fire Fighting Procedures:</b>	Cool fire exposed containers and structures with water.
<b>Specific Hazards Arising from the Chemical:</b>	None known.
<b>Precautions for Fire Fighters:</b>	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 <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

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

<b>Appearance:</b>	Gel	<b>Explosive limits:</b>	Not applicable
<b>Odor:</b>	Characteristic of flavor	<b>Vapor pressure:</b>	Negligible
<b>Odor threshold:</b>	Not available	<b>Vapor density:</b>	Not available
<b>pH:</b>	6.05	<b>Relative density:</b>	1.091 @ 25°C
<b>Melting/freezing point:</b>	Not available	<b>Solubility:</b>	Disperses
<b>Initial boiling point and range:</b>	>482°F / >250°C	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	>300°F / >149°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>	164,000 centipose
<b>Explosive Properties:</b>	None	<b>Oxidizing Properties:</b>	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, benzocaine 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

<b>UN Number:</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>UN proper shipping name:</b>	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
<b>Transport hazard class(es):</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>Packaging group:</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>Environmental hazards:</b>	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
<b>Special precautions for user:</b> 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:**

<b>Immediate Hazard:</b>	Yes	<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):**

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
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:

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
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: 27 September 2016

Periodic Review: 01 October 2019. This is a new SDS for a private label.

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