Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830, US 29CFR1910.1200, Canada Hazardous Products Regulation.

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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, CN31004, CN31005, CN31006, CN31007

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Topical anesthetic
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. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Eye Irritant Category 2A (H319) Skin Sensitizer Category 1 (H317)	Aquatic Chronic Toxicity Category 3 (H412)	Not Hazardous

2.2 Label Elements:

Signal Word: Warning

Contains: Benzocaine, Flavoring

Hazard Phrases	Precautionary Phrases
H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.	P261 Avoid breathing mist or vapors. P264 Wash thoroughly after handling. P272 Contaminated work clothing must not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear eye protection and protective gloves. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P302 + P352 IF ON SKIN: Wash with plenty of 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 known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Polyethylene Glycol	25322-68-3	500-038-2 /	Not Applicable	70-80%
Benzocaine	94-09-7	202-303-5 /	Eye Irrit. 2B (H320) Skin Sens. 1 (H317)	20%
Flavorant	Proprietary	Proprietary	Not Applicable	0-<5%

The Banana flavorant may contain the following components:

Isopentyl acetate	123-92-2	204-662-3 /	Flam. Liq. 3 (H226) EUH066	0-<4
Linalool	78-70-6	201-134-4 /	Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) Skin Sens. 1B (H317)	0-<0.5
Citral	5392-40-5	226-394-6 /	Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) Skin Sens. 1B (H317)	0-<0.5

Eugenol	97-53-0	202-589-1 /	Eye Irrit. 2 (H319) Skin Sens. 1B (H317)	0-<0.5
(R)-p-mentha-1,8-diene	5989-27-5	227-813-5 /	Flam. Liq. 3 (H226) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Asp. Tox. 1 (H304) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0-<0.5

The Cherry flavorant may contain the following components:

p-methoxybenzyl acetate	104-21-2	203-185-8 /	Skin Sens. 1B (H317)	0-<0.5

The Peppermint flavorant may contain the following components:

Oils, peppermint	8006-90-4 / 84082-70-2	282-015-4 /	Flam. Liq. 4 (H227) Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) Skin Sens. 1B (H317) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	0-<4
L-Menthan-3-One	14073-97-3	237-926-1 /	Skin Irrit. 2 (H315) Skin Sens. 1B (H317)	0-<1
Cineole	470-82-6	207-431-5 /	Flam. Liq. 3 (H226) Skin Sens. 1B (H317)	0-<0.5
Isomenthone	491-07-6	207-727-4 /	Flam. Liq. 4 (H227) Skin Sens. 1B (H317) Aquatic Chronic 3 (H412)	0-<0.5
l-Limonene	5989-54-8	227-815-6 /	Flam. Liq. 3 (H226) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Asp. Tox. 1 (H304) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0-<0.5

The Raspberry flavorant may contain the following components:

Ethyl acetate	141-78-6	205-500-4 /	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	0-<4

The Bubblegum flavorant may contain the following components:

Eugenol	97-53-0	202-589-1 /	Eye Irrit. 2 (H319) Skin Sens. 1B (H317)	0-<0.5
Cinnamaldehyde	104-55-2	203-213-9 /	Acute Tox. 4 (H312) Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) Skin Sens. 1 (H317)	0-<0.5

The Strawberry and Pina Colada flavorant components are below the listing limits. The Licorice Essence which is present in the Cherry and Mint flavors is below the listing limits.
The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush eyes thoroughly with water for several minutes, while holding the eyelids apart. Remove contact lenses if easy to do so. Continue rinsing. Get medical attention if irritation persists.
Skin	Remove contaminated clothing and shoes. Flush skin thoroughly with water for several minutes. Get medical attention if irritation or rash occurs. Launder clothing before re-use.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If swallowed, drink 1 or 2 glasses of water to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if discomfort persists.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Direct contact with eye may cause moderate eye irritation. 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. May cause skin sensitization.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
If skin sensitization occurs, discontinue use and get medical attention. 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 the surrounding fire.
5.2 Special Hazards Arising from the Substance or Mixture:	
Under fire conditions, this product will release oxides of carbon and nitrogen.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection. Contain water used in firefighting from entering sewers or natural waterways.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Avoid contact with eyes and skin. Wear protective clothing and equipment as described in Section 8. Avoid breathing mists and vapors.
6.2 Environmental Precautions:
Avoid releases to the environment. 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.
6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:
Avoid contact with eyes, skin and clothing. Wash hands thoroughly after handing. 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. Store in accordance with package instructions.
7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:	
Occupational Exposure Limits:	
Polyethylene Glycol	10 mg/m3 TWA AIHA WEEL
	1000 mg/m3 TWA, 8000 mg/m3 STEL DFG MAK (Inhalable Aerosol)
Benzocaine	None Established
Isopentyl acetate	50 ppm TWA, 100 ppm STEL ACGIH TLV 100 ppm TWA OSHA PEL
	50 ppm TWA, 50 ppm STEL DFG MAK
	50 ppm TWA, 100 ppm STEL UK WEL
	50 ppm TWA, 100 ppm STEL EU OEL
Oils, peppermint	None Established
Ethyl acetate	400 ppm TWA ACGIH TLV 400 ppm TWA OSHA PEL
	200 ppm TWA, 400 ppm STEL DFG MAK
	200 ppm TWA, 400 ppm STEL UK WEL
	200 ppm TWA, 400 ppm STEL EU OEL
L-Menthan-3-One	None Established
Linalool	None Established
Citral	5 ppm TWA ACGIH TLV (Inhalable fraction and vapor) (Skin; DSEN)
Eugenol	None Established
(R)-p-mentha-1,8-diene	5 ppm TWA, 20 ppm STEL DFG MAK (skin)
p-methoxybenzyl acetate	None Established
Cineole	None Established
Isomenthone	None Established

l-Limonene	None Established
Cinnamaldehyde	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: Chemical safety glasses or chemical goggles are recommended to avoid eye contact.
Specific Skin Protection: Wear impervious gloves such as plastic or rubber gloves to prevent skin contact. Contact your glove supplier for selection assistance.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Gel	**Explosive limits:**	**LEL:** Not applicable **UEL**: Not applicable
Odor:	Characteristic of flavor	**Vapor pressure (mmHg):**	Negligible
Odor threshold:	Not determined	**Vapor density:**	Not determined
pH:	6.05	**Relative density:**	1.091 @ 25°C (77°F)
Melting/freezing point:	Not determined	**Solubility(ies):**	Disperses
Initial boiling point and boiling range:	>250°C (>482°F)	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	>149°C (>300°F)	**Auto-ignition temperature:**	Not determined
Evaporation rate:	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not applicable	**Viscosity:**	164,000 centipose
Explosive Properties:	Not explosive	**Oxidizing Properties:**	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Non-reactive.

10.2 Chemical Stability: Stable under normal storage and handling conditions.
10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4 Conditions to Avoid: None known.
10.5 Incompatible materials: Avoid oxidizing agents.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce oxides of carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects: Eyes: Direct contact may cause moderate eye 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. May cause an allergic skin reaction (sensitization). Ingestion: Swallowing may cause nausea, vomiting and diarrhea. In rare cases, benzocaine has been shown to cause methemoglobemia. Inhalation: None expected from normal use. Inhalation of mists or vapors may cause respiratory irritation.
Chronic Health Effects: Prolonged exposure to be benzocaine may cause methemoglobinemia, (the formation of methemoglobin in the blood which causes deficient oxygenation of the blood due to decreased available hemoglobin). Signs and symptoms of methemoglobinemia include shortness of breath, cyanosis (a bluish discoloration of the mucous membranes and unpigmented areas of the body), mental status changes such as headache, mental impairment, fatigue, muscular weakness, exercise intolerance, light headness, dizziness, incoordination, seizures, and loss of consciousness.
Irritation: No data available. This product is expected to cause eye irritation.
Corrosivity: No data available. This product is not expected to be corrosive.
Sensitization: Benzocaine: When applied topically as recommended, benzocaine has been shown to cause sensitization.
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.
Mutagenicity: No data available. This product is not expected to cause mutagenic activity.
Aspiration Hazard: Not an aspiration hazard.
Acute Toxicity Data: Polyethylene Glycol: Oral rat LD50- >2000 mg/kg, Skin rat LD50->2000 mg/kg Benzocaine: Oral rat LD50- 3042 mg/kg Isopentyl acetate: Oral rat LD50- 7400 mg/kg Oils, peppermint: Oral rat LD50- 2426 mg/kg Ethyl acetate: Oral rat LD50- 4934 mg/kg, Skin rabbit LD50- >20000 mg/kg L-Menthan-3-One: Oral rat LD50- 2602 mg/kg Linalool: Oral rat LD50- 2790 mg/kg, Skin rabbit LD50- 5610 mg/kg Citral: Oral rat LD50- 6800 mg/kg, Skin rat LD50- >2000 mg/kg Eugenol: Oral rat LD50- >2000 mg/kg, Inhalation rat LD50->2.6 mg/L/4hr (R)-p-mentha-1,8-diene: Oral rat LD50- >5000 mg/kg, Skin rabbit LD50- >5000 mg/kg p-methoxybenzyl acetate: Oral rat LD50-> 5000 mg/kg, Skin rat LD50- >2000 mg/kg Cineole: Oral rat LD50-4500 mg/kg, Skin rat LD50- >2000 mg/kg Isomenthone: No toxicity data available l-Limonene: Oral rat LD50->5000 mg/kg, Skin rabbit LD50- >5000 mg/kg

Cinnamaldehyde: Oral rat LD50- 2220 mg/kg, Inhalation rat LC50- 68.889 ppm/4hr, Skin rat LD50- >2000 mg/kg
Reproductive Toxicity Data: No data available. This product is not expected to cause reproductive or developmental toxicity.
Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.
Specific Target Organ Toxicity Repeated Exposure (STOT-RE): No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
(R)-p-mentha-1,8-diene: 96 hr LC50 Fathead minnow- 0.72 mg/L, 48 hr EC50 Daphnia magna- 0.36 mg/L, 48 hr LC50 Daphnia magna- 0.577 mg/L, 21 days EC50 Daphnia magna- 0.188 mg/L, 21 days NOEC Daphnia magna- 0.08 mg/L
l-Limonene: 96 hr LC50 Fathead minnow- 720 ug/L, 48 hr EC50 Daphnia magna- 0.36 mg/L

This product is classified as harmful to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided.

12.2 Persistence and Degradability: Benzocaine: Readily biodegradable. (R)-p-mentha-1,8-diene: Readily biodegradable – 100% after 28 days. l-Limonene: 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 Results of PBT and vPvB Assessment: No data is currently available.

12.6 Other Adverse Effects: No data is currently available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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.

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 has an RQ of 125,000 lbs (based on the RQ of Isopentyl acetate of 5,000 lbs present at 0-<4%). 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): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

State Regulations

California: This product can expose you to chemicals including Acetaldehyde, Pulegone, and Estragole, which are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

International Regulations

Canadian Environmental Protection Act: This product is a medicinal product and not subject to registration requirements.

European Inventory of Existing Chemicals (EINECS): This product is a medicinal product and not subject to registration requirements.

EU REACH: This product is a medicinal product and not subject to registration requirements.

Australian Inventory of Chemical Substances: This product is a medicinal product and not subject to registration requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medicinal product and not subject to registration requirements.

Japanese Existing and New Chemical Substances: This product is a medicinal product and not subject to registration requirements.

Korean Existing Chemicals List: This product is a medicinal product and not subject to registration requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medicinal product and not subject to registration requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health –2 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
Acute Tox. 4 Acute Toxicity Category 4
Aquatic Acute 1 Aquatic Acute Toxicity Category 1
Aquatic Acute 2 Aquatic Acute Toxicity Category 2
Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1
Aquatic Chronic 2 Aquatic Chronic Toxicity Category 2
Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3
Asp. Tox. 1 Aspiration Toxicity Category 1
Eye Irrit. 2 Eye Irritant Category 2
Flam. Liq. 2 Flammable Liquid Category 2
Flam. Liq. 3 Flammable Liquid Category 3
Flam. Liq. 4 Flammable Liquid Category 4
Skin Irrit. 2 Skin Irritant Category 2
Skin Sens. 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H225Highly flammable liquid and vapor.
H226 Flammable liquid and vapor.
H227 Combustible liquid.
H304 May be fatal if swallowed and enters airways.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H320 Causes eye irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

Supersedes: 20 Dec 2016
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Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.