



Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Document Number: SDS 080.001
Date Revised: 12/03/2018

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

1.1 Product Identifier:

Trade Name (as labeled): Alpha-Caine® Topical Anesthetic Gel
Part/Item Number: 029-0100-002; 029-0200-002; 029-0300-002; 029-0400-002; 029-0500-002

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: Dental Technologies, Inc.
Manufacturer/Supplier Address: 6901 N. Hamlin Avenue
 Lincolnwood, IL 60712
Manufacturer/Supplier Telephone Number: 800-835-0885 or 847-677-5500 (Product Information)
Email address: info@dentaltech.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: Chemtrec
 800-424-9300 (USA)
 001-703-527-3887 (Outside USA)

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)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Hazard Phrases	Precautionary Phrases
H319 Causes serious eye irritation H315 Causes skin irritation H317 May cause an allergic skin reaction	P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. P302+P352 IF ON SKIN: wash with plenty of water. P333+P313 IF SKIN irritation or rash occurs: Get medical advice/attention. P362 Take off contaminated clothing and wash before reuse.

2.3 Other Hazards: None known.

2.3 Unknown acute toxicity (GHS-US): No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	Classification	WT %
Polyethylene Glycol	25322-68-3	Not Applicable	60-90%
Benzocaine	94-09-7	Eye Irrit. 2, (H319) Skin Irrit. 2, (H315) Skin Sens. 1B (H317) STOT SE 3 (H335)	20%
Flavor	Proprietary	Not Applicable	0-5%

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 with plenty of water. Seek medical attention by an ophthalmologist.
Skin	Wash off with soap and water. Remove contaminated clothing. If irritation persists, consult a physician.
Inhalation	Remove to fresh air, give oxygen and seek immediately medical attention.
Ingestion	Do not induce vomiting, seek medical attention.

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

May cause eye burns. May cause skin burns. Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation. Inhalation is not expected for this product.

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

Not applicable.

Note to Physicians (Treatment, Testing, and Monitoring): Not applicable.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: See Fire Fighting Equipment under Section 5.3.

5.2 Special Hazards Arising from the Substance or Mixture:





None known.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures: General: Evacuate all personnel; use protective equipment for firefighting.

Precautions for Fire Fighters: Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

Recommended Protective Equipment for Fire Fighters:



EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

6.3 Methods and Material for Containment and Cleaning up:

Clean up with absorbent material and remove residue with damp wipe. Rinse spill area with water.

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 Handling:

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly after handling. See product labeling.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool-dry place. See product labeling.

7.3 Specific End Use (s): Topical Anesthetic.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters: Not determined.

8.2 Exposure Controls:



Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. Good ventilation should be sufficient.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Physical state:	Gel	Relative density:	1.05-1.15 g/mL
Appearance:	Semi-opaque gel	Explosive limits:	Not Determined
Odor:	Characteristic of flavor	Vapor pressure (mmHg):	Not Determined
Odor threshold:	Not Determined	Vapor density:	Not Determined
pH:	Not Determined	Solubility(ies):	Miscible in water
Melting/freezing point:	Not Determined	Partition coefficient: n-octanol/water:	Not Determined

Initial boiling point and boiling range:	Not Determined	Auto-ignition temperature:	Not Determined
Flash point:	Not Determined	Decomposition temperature:	Not Determined
Evaporation rate:	Not Determined	Viscosity:	Not Determined
Flammability (solid, gas):	Not Flammable	Oxidizing Properties:	Not Determined
Explosive Properties:	Not Determined		

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Stable at ambient temperature and under normal conditions of use.

10.2 Chemical Stability: Stable at standard temperature and pressure.

10.3 Possibility of Hazardous Reactions: May occur in large quantities.

10.4 Conditions to Avoid: Keep away from heat, sparks, flames, and other sources of ignition.

10.5 Incompatible materials: High temperatures, visible light sources, strong oxidizing agents. Keep away from sunlight and open flames.

10.6 Hazardous Decomposition Products: Oxides of carbon when burned.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Polyethylene Glycol	
LD50 Oral Rat	>2000 mg/kg (rat)
LD50 Dermal Rat	>3042 mg/kg (rat)
Benzocaine	
LD50 Oral Rat	>2000 mg/kg (rat)

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

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 Results of PBT and vPvB Assessment: Not Determined.

12.6 Other Adverse Effects: Not Determined.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: None currently known.

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

14. TRANSPORT INFORMATION

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not dangerous goods.

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture: Please refer to Medical Device Directive 93/42/EEC.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health: 1	Flammability: 0	Reactivity: 0
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Full text of Classification abbreviations used in Section 2 and 3:

H315	Skin corrosion/irritation Category 2
H317	Skin Sensitizer Category 1
H319	Serious eye irritation Category 2A
H335	May cause respiratory irritation Category 3

Supersedes: MSDS-080 Rev000

Date updated: December 3, 2018

Change Control Document #: DCN 6400

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

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

Manufacturer disclaimer:

FOR DENTAL USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.