

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Trade Name (as labeled): Cetacaine® Gel Topical Anesthetic

Synonyms: N/A

CAS No: Mixture

1.2 Product Use: Topical gel anesthetic

1.3 Company Name: Cetylite

Company Address: 9051 River Road

Company Address Cont: Pennsauken, NJ 08110

Business Phone: (800) 257-7740 or (856) 665-6111

Website: www.cetylite.com

1.4 Emergency Telephone Number: (800) 257-7740

Date of Current Revision: March 26, 2022

Date of Last Revision: April 24, 2017

SECTION 2 - HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a pink or green colored liquid gel with a either a slight strawberry or mint, ethereal odor. May cause serious eye damage. Prolonged contact with skin may cause irritation. Possible Allergen. Contact with eyes may cause irritation or other effects. May be harmful if swallowed.

This product is a Non-Flammable liquid with a flash point of >250°F

The Environmental effects of this product have not been investigated. Release of this product is not anticipated to have significant adverse effects in the aquatic environment.

US DOT Symbols: None Applicable



EU and GHS Symbols:

Signal Word: Warning!

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 or the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS:

Index Number:

EC# 264-151-6 Annex VI Index # 612-140-00-5

EC# 500-038-2 this substance is not classified in the Annex VI

EC# 202-303-5 this substance is not classified in the Annex VI

EC# 202-317-1 this substance is not classified in the Annex VI

EC# 205-248-5 this substance is not classified in the Annex VI

EC# 201-321-0 this substance is not classified in the Annex VI

Substances not listed either individually or in group entries must be self-classified.

Components Contributing to Classification: Benzocaine, Tetracaine Hydrochloride, 50% Benalkonium Chloride, Butamben

2.2 Label Elements:

GHS Hazard Classifications:

Acute Toxicity Category 4 (Oral)

Skin Irritant Category 3

Eye Irritant Category 2B

Skin Sensitizer Category 1

Acute Aquatic Toxicity Category 3

Hazard Statements:

H302 Harmful if swallowed

H315: Causes skin irritation

H320: Causes eye irritation

H317: May cause allergic skin reaction

H402: Harmful to aquatic life

Cetylite**Cetacaine® Gel Topical Anesthetic****Prevention Statements:**

P261: Avoid breathing mist/vapors/spray
 P264: Wash hands thoroughly after handling
 P270: Do not eat, drink or smoke when using this product.
 P272: Contaminated work clothing should not be allowed out of the workplace.
 P280: Wear protective gloves/protective clothing/eye protection/face protection

Response Statements:

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P330: Rinse mouth.
 P302+ P352 IF ON SKIN: Wash with plenty of water.
 P332+P313 If skin irritation occurs: Get medical advice/ attention.
 P333+P313 If skin irritation or rash occurs: Get medical advice/ attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P273 Avoid release to the environment
 P337+P313: If eye irritation persists: Get medical advice/attention.
 None Applicable
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Storage Statements:**Disposal Statements:****2.3 Other Hazards:**

None Applicable

SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS No.	EINECS No.	Hazard Classification
Polyethylene Glycol	70 - 85%	25322-68-3	500-038-2	Not Classified
Benzocaine	10 - 20%	94-09-7	202-303-5	Skin Sensitizer Cat 1
Butamben	1 - 5%	94-25-7	202-317-1	Skin Irritant Cat 2, Eye Irritant Cat 2, STOT SE 3, Skin Sensitizer Cat 1
Tetracaine Hydrochloride	1 - 5%	136-47-0	205-248-5	Acute Tox Cat 3(Oral), Eye Irritant Cat 2, Skin Sensitizer Cat 1
Saccharin	1 - 5%	81-07-2	201-321-0	Not Classified
50% Benalkonium Chloride	0.5 – 2%	63449-41-2	264-151-6	Acute Tox Cat 4 (Oral, Dermal), Skin Corrosion Cat 1, Aquatic Acute Cat 1

Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).

SECTION 4 - FIRST AID MEASURES**4.1 Description of First Aid Measures:**

Eye Contact:	If product enters the eyes, flush with plenty of water or eye wash solution for several minutes. Remove contacts if present and easy to do. Seek medical attention if irritation persists.
Skin Contact:	Wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.
Inhalation:	If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.
Ingestion:	If product is swallowed, call physician or poison center immediately. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.
Medical Conditions Generally Aggravated by Exposure:	Pre-existing skin or eye problems may be aggravated by prolonged contact.

6.3 Spill and Leak Response:**Small Spills:**

- Collect material via broom or mop. Place in tightly sealed container for proper disposal. Approach spill areas with caution.
- If liquid was introduced, create a dike or trench to contain material. Soak up with absorbent material such as clay, sand or other suitable non-reactive material.
- Place in leak-proof containers. Seal tightly for proper disposal.
- Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces, those of Australia, Japan and EU Member States (see Section 13, Disposal Considerations).

Large Spills:**SECTION 7 - HANDLING AND STORAGE****7.1 Precautions for Safe Handling:**

To prevent eye contact under the foreseeable conditions of use, wear appropriate safety eyewear. When handling, do not eat, drink, or smoke. Wash thoroughly after handling. Do not handle or store near heat, sparks, or flame.

7.2 Storage and Handling Practices:

Keep away from incompatible materials. Keep container closed when not in use and store in well ventilated area.

7.3 Specific Uses:

Various uses.

SECTION 8 - EXPOSURE CONTROL/PERSONAL PROTECTION**8.1 Exposure Parameters:**

Ingredients	CAS No.	OSHA PEL	NIOSH PEL
Polyethylene Glycol	25322-68-3	Not Listed	Not Listed
Benzocaine	94-09-7	Not Listed	Not Listed
Butamben	94-25-7	Not Listed	Not Listed
Tetracaine Hydrochloride	136-47-0	Not Listed	Not Listed
Saccharin	81-07-2	Not Listed	Not Listed
50% Benalkonium Chloride	63449-41-2	Not Listed	Not Listed

8.2 Exposure Controls:

Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

Ventilation and Engineering Controls:

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132), or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

Respiratory Protection:

Not required for properly ventilated areas. Maintain airborne contaminant concentrations below guidelines listed above, if applicable. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

Eye Protection:

Safety glasses or goggles are recommended. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Hand Protection:

Chemical resistant gloves are recommended to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

Use body protect appropriate to task being performed.

If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

Body Protection:

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance (Physical State and Color): This product is a pink or green colored liquid gel with a either a slight strawberry or mint, ethereal odor.

Odor: Slight strawberry or mint, ethereal odor

Odor Threshold: No data available

pH: Not Available

Melting/Freezing Point: No data available

Boiling Point: No data available

Flash Point: Not Available

Evaporation Rate: No data available

Flammability (Solid; Gas): No data available

Upper/Lower Flammability or Explosion Limits: No data available

Vapor Pressure (mm Hg @ 20°C (68° F): Approximately 0.02 mmHg @ 25°C

Vapor Density: No data available

Relative Density: Not Available

Specific Gravity: 1.05 @25°C

Solubility in Water: No data available

Weight per Gallon: No data available

Partition Coefficient (n-octanol/water): No data available

Auto-Ignition Temperature: No data available

Decomposition Temperature: No data available

Viscosity: No data available

9.2 Other Information:

No data available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity:

This product is not reactive.

10.2 Stability:

Stable under conditions of normal storage and use.

10.3 Possibility of Hazardous Reactions:

Not identified.

10.4 Conditions to Avoid:

Contact with incompatible materials.

10.5 Incompatible Substances:

Strong oxidizing agents.

10.6 Hazardous Decomposition Products:

When heated to decomposition this product may contain carbon monoxide; carbon dioxide; and nitrogen and sulfur oxides.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Toxicity Data:

Tetracaine HCL	136-47-0	LD50 Oral – Rat	160 mg/kg
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Acute toxicity	Acute Toxicity Category 4 (Oral)
Skin corrosion / irritation	Skin Irritant Category 3
Serious eye damage / irritation	Eye Irritant Category 2B
Respiratory or skin sensitization	Skin Sensitizer Category 1
Germ cell mutagenicity	Based on available data, the classification criteria are not met
Carcinogenicity	Based on available data, the classification criteria are not met
Reproductive toxicity	Based on available data, the classification criteria are not met
STOT-single exposure	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
Aspiration hazard	Based on available data, the classification criteria are not met

Routes of Exposure:**Symptoms of Overexposure by Route of Exposure:**

The most significant routes of overexposure for this product are by contact with skin or eyes. The symptoms of overexposure are described in the following paragraphs.

Acute:

- Inhalation: May cause respiratory system irritation.
 Skin Contact: May cause irritation to skin. May cause allergic reaction to the skin.
 Eye Contact: Vapors and direct contact to the eyes may be irritating.
 Ingestion: May be harmful if swallowed.

Chronic: None known

Target Organs:

- Acute: Skin, Eyes, Respiratory System, Digestive system
 Chronic: None known

Suspected Cancer Agent:

Ingredients within this product are found on one or more of the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are considered to be cancer-causing agents by these agencies. Saccharin CAS# 81-07-2 IARC Group 3

Irritancy:

This product is expected to be an eye irritant.

Sensitization to the Product:

This product is expected to cause skin sensitization.

Germ Cell Mutagenicity:

This product does not contain ingredients that are suspected to be a germ cell mutagenic.

Reproductive Toxicity:

This product is not expected to be a human reproductive toxicant.

SECTION 12 - ECOLOGICAL INFORMATION**12.1 Toxicity:**

No specific data available on this product.

12.2 Persistence and Degradability:

No specific data available on this product.

12.3 Bioaccumulative Potential:

No specific data available on this product.

12.4 Mobility in Soil:

No specific data available on this product.

12.5 Results of PBT and vPvB Assessment:

No specific data available on this product.

12.6 Other Adverse Effects:

No data available.

12.7 Water Endangerment Class:

At present, there are no ecotoxicological assessments for this product.

SECTION 13 - DISPOSAL CONSIDERATIONS**13.1 Waste Treatment Methods:**

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined

SECTION 14 - TRANSPORTATION INFORMATION**14.1 U.S. Department of Transportation (DOT) Shipping Regulations:**

This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

- UN Identification Number:** None
Proper Shipping Name: Non-Regulated
Hazard Class Number and Description: None
Packing Group: None
DOT Label(s) Required: None
North American Emergency Response Guidebook Number: None

14.2 Environmental Hazards:**Marine Pollutant:**

The components of this product are not designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.3 Special Precaution for User:

None

14.4 International Air Transport Association Shipping Information (IATA):

This product is not considered as dangerous goods.

14.5 International Maritime Organization Shipping Information (IMO):

This product is not considered as dangerous goods.

SECTION 15 - REGULATORY INFORMATION**15.1 Safety, Health and Environmental Regulations Specific for the Substance or Mixture:**United States Regulations:**U.S. SARA Reporting Requirements:**

The components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA 311/312:

Acute Health: Yes; Chronic Health: No; Fire: Yes; Reactivity: No

U.S. SARA 313: None known**U.S. CERCLA Reportable Quantity:**

Saccharin Insoluble (CAS# 81-07-2) 100 Lbs.

U.S. TSCA Inventory Status:

The components of this product are listed on the TSCA Inventory or are exempted from listing.

Other U.S. Federal Regulations:

None known

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain ingredients on the Proposition 65 Lists.

15.2 Canadian Regulations:**Canadian DSL/NDSL Inventory Status:**

Components are DSL Listed, NDSL Listed and/or are exempt from listing

Other Canadian Regulations:

Not applicable

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

Canadian WHMIS Classification and Symbols:

Classified per WHMIS 2015 Controlled Product Regulations.

15.3 European Economic Community Information:

This product meets the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives. See Section 2 for Details.

Chemical Safety Assessment:

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

15.4 Australian Information for Product:

Components of this product are listed on the International Chemical Inventory list.

15.5 Japanese Information for Product:

Japanese Minister of International Trade and Industry (MITI) Status: The components of this product are not listed as Class I specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

15.6 International Chemical Inventories:

Listing of the components on individual country Chemical Inventories is as follows:

Australian Inventory of Chemical Substances (AICS): Listed

Korean Existing Chemicals List (ECL): Listed

Japanese Existing National Inventory of Chemical Substances (ENCS): Listed

Philippines Inventory of Chemicals and Chemical Substances (PICCS): Listed

U.S. TSCA: Listed

SECTION 16 - ADDITIONAL INFORMATION

Prepared By: Chris Eigbrett (MSDS to GHS Compliance)
Date of Printing: March 27, 2022

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. This safety sheet cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers. Cetylite assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Cetylite assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.

Revision History:

- June 3, 2013** - Document creation.
- August 15 2016** - Updated template with *corrected GHS elements and added data elements for EU compliance.*
- April 21 2017** -*Update made to color/flavor description in Sections 2 and 9.*
- April 24, 2017** -*Update to components in Section 3.*
- March 26, 2022** - SDS Review / Update

END OF SDS SHEET