

**SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: **Cetacaine® Gel Topical Anesthetic**
 CHEMICAL NAME: Mixture
 PRODUCT USE: Topical gel anesthetic
 U.N. NUMBER: None
 U.N. DANGEROUS GOODS CLASS: Non-Regulated Material
 SUPPLIER/MANUFACTURER'S NAME: **Cetylite Industries, Inc.**
 ADDRESS: 9051 River Road, Pennsauken, NJ 08110 USA
EMERGENCY PHONE: (800) 257-7740
 BUSINESS PHONE: (800) 257-7740 or (856) 665-6111
 FAX NUMBER: (856) 665-5408
 DATE OF PREPARATION: July 22, 2013
 DATE OF LAST REVISION: March 3, 2011

SECTION 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This product is a light yellow colored liquid gel with a slight strawberry, 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 adverse effects in the aquatic environment.

US DOT SYMBOLS

CANADA (WHMIS) SYMBOLS

EUROPEAN and (GHS) Hazard Symbols

Non-Regulated Material

Signal Word: **Warning!****EU LABELING AND CLASSIFICATION:****Classification of the substance or mixture according to Regulation (EC) No1272/2008 Annex 1****EC# 246-770-3 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 202-303-5 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 202-317-1 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 205-248-5 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 201-321-0 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 264-151-6 this substance are not classified in the Annex I of Directive 67/548/EEC****EC# 264-151-6 Annex I Index# 612-140-00-5****Substances not listed either individually or in group entries must be self classified.****Component(s) Contributing to Classification(s)**

Dipropylene Glycol, Tetracaine Hydrochloride, 50% Benalkonium Chloride

GHS Hazard Classification(s):

Eye Irritant Category 2A

Skin Irritant Category 3

Acute Aquatic Toxicity Category 3

Skin Sensitizer Category 1

Hazard Statement(s):

H317: May cause allergic skin reaction

H320: Causes eye irritation

H336: May cause drowsiness or dizziness

H402: Harmful to aquatic life

Precautionary Statement(s):

P261: Avoid breathing mist/vapors/spray

P264: Wash hands thoroughly after handling

P273: Avoid release to the environment

EU HAZARD CLASSIFICATION PER DIRECTIVE 1999/45/EC:

[Xn] Harmful, [Xi] Irritant

**Cetacaine® Gel Topical Anesthetic****Risk Phrases:**

- R21/22: Harmful in contact with skin and if swallowed
- R36/37/38: Irritating to eye, respiratory system and skin
- R43: May cause sensitization by skin contact
- R51: Toxic to aquatic organisms
- R67: Vapors may cause drowsiness and dizziness

Safety Phrases:

- S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S36/37: Wear suitable protective clothing and gloves.
- S45: In case of an accident or if you feel unwell, seek medical advice immediately
- S61: Avoid release to the environment

HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of overexposure for this product are by contact with skin or eyes, ingestion or inhalation. The symptoms of overexposure are described in the following paragraphs.

INHALATION: Inhalation of vapors may irritation of the upper respiratory system.

CONTACT WITH SKIN: Topical anesthetic. Contact with skin may cause irritation and allergen.

EYE CONTACT: Contact with the eyes can cause irritation, and/or redness. Will anesthetize mucous membranes and may act as an allergen.

INGESTION: Not expected to be a normal route of entry. Topical anesthetic. May induce CNS depression, drowsiness and possible respiratory depression.

CHRONIC: Anesthetic. Tetracaine hydrochloride may cause sensitization and allergic reaction.

TARGET ORGANS: **Acute:** Skin, eyes, respiratory tract **Chronic:** Skin

SECTION 3 - COMPOSITION and INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS:	CAS #	EINECS #	ICSC #	WT %	HAZARD CLASSIFICATION; RISK PHRASES
Dipropylene Glycol	25265-71-8	246-770-3	Not Listed	70 - 85%	HAZARD CLASSIFICATION: [Xi] Irritant RISK PHRASES: R36/38
Benzocaine	94-09-7	202-303-5	Not Listed	10 - 20%	HAZARD CLASSIFICATION: [Xi] Irritant RISK PHRASES: R36/38
Butamben	94-25-7	202-317-1	Not Listed	1 - 5%	HAZARD CLASSIFICATION: [Xi] Irritant RISK PHRASES: R36/38
Tetracaine Hydrochloride	136-47-0	205-248-5	Not Listed	1 - 5%	HAZARD CLASSIFICATION: [Xi] Irritant RISK PHRASES: R36/37/38, R43
Saccharin	81-07-2	201-321-0	Not Listed	0.5 - 2%	HAZARD CLASSIFICATION: [Xi] Irritant RISK PHRASES: R36/38
50% Benalkonium Chloride	63449-41-2	264-151-6	1584	0.5 - 2%	HAZARD CLASSIFICATION: [Xn] Harmful, [C] Corrosive RISK PHRASES: R21/22, R34
Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).					

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR, EU Directives, Latin America, South America and the Japanese Industrial Standard *JIS Z 7250: 2000*.

SECTION 4 - FIRST-AID MEASURES

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to health professional with contaminated individual.

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Remove contact lenses if present. Seek medical attention if irritation persists or blurred vision occurs.

SKIN CONTACT: Wash skin thoroughly after handling. Seek medical attention if irritation persists. Remove contaminated clothing. Launder before re-use.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if breathing difficulty continues.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to



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someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or MSDS with the victim to the health professional.

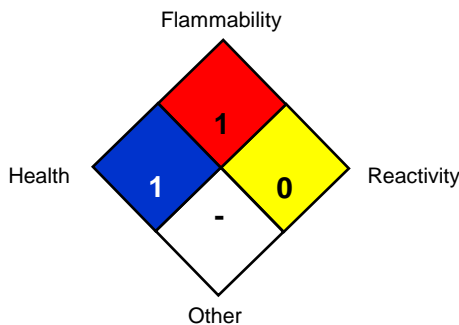
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin problems may be aggravated by prolonged exposure to this product.

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and reduce over-exposure.

SECTION 5 - FIRE-FIGHTING MEASURES

FLASH POINT: >250°F (121°C)
AUTOIGNITION TEMPERATURE: Not Established
FLAMMABLE LIMITS (in air by volume, %): Lower (LEL): Not Established Upper (UEL): Not Established
FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding area - Dry chemical, foam, carbon dioxide or water fog.
UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may produce hazardous combustion by-products.
Explosion Sensitivity to Mechanical Impact: No
Explosion Sensitivity to Static Discharge: Yes
SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD (BLUE)	1		
FLAMMABILITY HAZARD (RED)	1		
PHYSICAL HAZARD (YELLOW)	0		
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8
For Routine Industrial Use and Handling Applications			

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

SECTION 6 - ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE: Personnel should be trained for spill response operations.

SPILLS: Contain spill if safe to do so. Soak up with an absorbent material and place in an appropriate closed container for disposal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

SECTION 7 - HANDLING and STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing vapors/mists/sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

STORAGE AND HANDLING PRACTICES: Containers of this product must be properly labeled. Store containers in a cool, dry location away from heat and sources of ignition. Keep container tightly closed when not in use. Store away from incompatible materials.

**SECTION 8 - EXPOSURE CONTROLS - PERSONAL PROTECTION****EXPOSURE LIMITS/GUIDELINES:**

Chemical Name	CAS#	ACGIH TWA	OSHA TWA
Dipropylene Glycol	25265-71-8	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

Currently, International exposure limits are not established for the components of this product. Please check with competent authority in each country for the most recent limits in place.

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided below. Use local exhaust ventilation to control airborne mist/vapor/dust. Ensure eyewash/safety shower stations are available near areas where this product is used.

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 equivalent standard of Canada, 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: 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: Splash goggles or safety glasses with side shields recommended where splashing is possible. 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: Compatible protective gloves recommended as appropriate for task. Wash hands after removing gloves. 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.

BODY PROTECTION: Not normally required when using this product. Use body protection appropriate to prevent contact (e.g. lab coat, overalls). If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards.

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES**PHYSICAL STATE:**

Liquid

APPEARANCE & ODOR:

This product is a light yellow colored liquid gel with a slight strawberry, ethereal odor

ODOR THRESHOLD (PPM):

Not Available

VAPOR PRESSURE (mmHg):

Approximately 0.02 mmHg @ 25°C

VAPOR DENSITY (AIR=1):

Not Available

EVAPORATION RATE (nBuAc = 1):

Not Available

BOILING POINT (C°):

Approximately 450°F

FREEZING POINT (C°):

Not Available

pH:

Not Available

SPECIFIC GRAVITY 20°C: (WATER =1)

1.05 @ 25°C

SOLUBILITY IN WATER (%)

Not Available

VOC:

Not Available

**SECTION 10 - STABILITY and REACTIVITY**

STABILITY: Product is stable

DECOMPOSITION PRODUCTS: When heated to decomposition this product may contain carbon dioxide, carbon monoxide and unidentified toxic and/or irritating compounds.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong oxidizing agents

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Contact with incompatible materials.

SECTION 11 - TOXICOLOGICAL INFORMATION

TOXICITY DATA: Toxicity data not available for mixture:

CAS# 25265-71-8

Oral LD50 Rat: = 14850 mg/kg

CAS# 136-47-0

Oral LD50 Rat: = 160 mg/kg

SUSPECTED CANCER AGENT: one or more of the ingredients are found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, IARC and therefore is not considered to be, nor suspected to be a cancer-causing agent by these agencies.

Saccharin CAS# 81-07-2 IARC Group 3

IRRITANCY OF PRODUCT: Contact with this product can be irritating to exposed skin, eyes and respiratory system.

SENSITIZATION OF PRODUCT: An ingredient in this product is considered a skin sensitizer.

REPRODUCTIVE TOXICITY INFORMATION: No data available

SECTION 12 - ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: No Data available at this time.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No Data available at this time.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No Data available at this time.

SECTION 13 - DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations, those of Canada, EU Member States and Japan.

SECTION 14 - TRANSPORTATION INFORMATION

US DOT; IATA; IMO; ADR:

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Non-Regulated Material

HAZARD CLASS NUMBER and DESCRIPTION: None

UN IDENTIFICATION NUMBER: None

PACKING GROUP: None

DOT LABEL(S) REQUIRED: None

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): None

MARINE POLLUTANT: None of the ingredients are classified by the DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B)

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:

This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:

This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):

This product is not classified as Dangerous Goods, by rules of IATA:

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:

This product is not classified as Dangerous Goods by the International Maritime Organization.

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EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):

This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

SECTION 15 - REGULATORY INFORMATION**UNITED STATES REGULATIONS**

SARA REPORTING REQUIREMENTS: This product is subject to the reporting requirements of Sections 302, 304 and 313 of Title III of the Superfund Amendments and Reauthorization Act., as follows: None

TSCA: All components in this product are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals.

SARA 311/312:

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

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): Saccharin Insoluble (CAS# 81-07-2) 100 Lbs.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): This product does not contain ingredient(s) are on the California Proposition 65 list.

CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS:All of the components of this product are on the DSL Inventory

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the CEPA First Priorities Substance Lists.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: This product is categorized as a Class D Division 2B materials causing other toxic effects, as per the Controlled Product Regulations

EUROPEAN ECONOMIC COMMUNITY INFORMATION:**EU LABELING AND CLASSIFICATION:**

Classification of the mixture according to Regulation (EC) No1272/2008. See section 2 for details.

AUSTRALIAN INFORMATION FOR PRODUCT:

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) STATUS: All components of this product are listed on the AICS.

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS: Not applicable.

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.

INTERNATIONAL CHEMICAL INVENTORIES:

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

Asia-Pac:	Listed
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
Swiss Giftlist of Toxic Substances:	Listed
U.S. TSCA:	Listed

SECTION 16 - OTHER INFORMATION

PREPARED BY: Paul Eigbrett

GHS MSDS Compliance PLUS
www.ghsmtdscomplianceplus.com

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