

MATERIAL SAFETY DATA SHEET

Cetacaine® Gel Topical Anesthetic

Last Updated March 3, 2011



1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: **Cetacaine® Gel Topical Anesthetic**

CAS Number: Mixture

Product Description: Topical Anesthetic

Manufacturers Name:

Cetylite Industries, Inc.
9051 River Road
Pennsauken, NJ 08110 USA
(800) 257-7740 or (856) 665-6111 For Product Information
(856) 665-5408 Fax

www.cetylite.com

NOTICE: This MSDS is written to address potential worker health and safety issues associated with the handling of the formulated final product. Consumers of this product should consult the packaging and/or package insert for user information.

2. COMPOSITION / INFORMATION ON INGREDIENTS

CONTAINING: HAZARDOUS AND/OR REGULATED COMPONENTS

<u>Chemical Name</u>	<u>CAS Number</u>	<u>OSHA PEL (TWA)</u>	<u>ACGIH TWA</u>
Polyethylene 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
50% Benzalkonium Chloride	63449-41-2	Not Listed	Not Listed
Saccharin	81-07-2	Not Listed	Not Listed
Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).			

CALIFORNIA PROP 65: This product does not contain an ingredient(s), above the safe harbor limits, which are known to the state of California to cause cancer, birth defects, or other reproductive harm.

HAZARDS DISCLOSURE: This product does contain known hazardous materials in reportable levels as defined by the OSHA Hazard Communication Standard 29 CFR 1910.1200. As defined under Sara 311 and 312, this product contains known hazardous materials.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

WARNING! PROLONGED CONTACT WITH SKIN MAY CAUSE IRRITATION. POSSIBLE ALLERGEN. CONTACT WITH EYES MAY CAUSE IRRITATION OR OTHER EFFECTS. MAY BE HARMFUL IF SWALLOWED.

POTENTIAL HEALTH EFFECTS:

ROUTES OF ENTRY: Eyes, Skin.

TARGET ORGANS: None

MATERIAL SAFETY DATA SHEET

Cetacaine® Gel Topical Anesthetic

Last Updated March 3, 2011

INHALATION: Not expected to be a normal route of entry.

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

SKIN CONTACT: 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.

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

AGGRAVATION OF PRE-EXISTING CONDITIONS: Persons with pre-existing eye or skin conditions may be more susceptible to the effects of the substance.

4. FIRST AID MEASURES

INHALATION FIRST AID: If breathing difficulty develops, remove victim to fresh air. Provide oxygen if breathing continues to be difficult. If not breathing, give artificial respiration, preferably mouth to mouth. GET MEDICAL ATTENTION IMMEDIATELY.

SKIN CONTACT FIRST AID: If irritation develops wash with soap and water. GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

EYE CONTACT FIRST AID: If contact with eyes, flush eyes with plenty of water lifting upper and lower eyelids occasionally. GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

INGESTION FIRST AID: Induce vomiting ONLY as directed by medical personnel. Never give anything by mouth to an unconscious person. GET MEDICAL ADVICE IMMEDIATELY.

NOTE TO PHYSICIANS: Treat symptoms.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

AUTO IGNITION TEMPERATURE: Not Available

FLASH POINT: Approximately 250°F

FLAMMABLE LIMITS IN AIR, % by Volume: lel: NA.; uel: NA

EXTINGUISHING MEDIA: Use fire extinguishing materials appropriate for surrounding fire including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.

FIRE & EXPLOSION HAZARDS: This product may product hazardous combustion by-products.

SPECIAL INFORMATION: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. ACCIDENTAL RELEASE MEASURES

SPILL CLEAN-UP PROCEDURES: Maintain adequate ventilation. Follow personal protective equipment recommendations found in section 8. Contain and recover if possible. Absorb spilled material using polypads or other suitable absorbent material. Always dispose of wastes in accordance with local, state and federal regulations.

7. HANDLING AND STORAGE

RECOMMENDED STORAGE CONDITIONS: Protect against physical damage. Store containers in a cool, dry location. Observe all warnings and precautions listed for the product.

HANDLING (PERSONNEL): Handle in accordance with good industrial hygiene and safety practices.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

AIRBORNE EXPOSURE LIMITS: See Section 2 above.

MATERIAL SAFETY DATA SHEET

Cetacaine® Gel Topical Anesthetic

Last Updated March 3, 2011

VENTILATION SYSTEM: A system of local and/or general exhaust is recommended to keep exposures below the Airborne Exposure Limits.

PERSONAL RESPIRATORS (NIOSH APPROVED): Not required with this product. If the exposure limit is exceeded and engineering controls are not feasible, a respirator may be required. Where respirators are required, you must have a written program covering the basic requirements in the OSHA respirator standard. These include training, fit testing, medical approval, cleaning, maintenance, cartridge change schedules, etc. See 29CFR1910.134 for details.

SKIN PROTECTION: Wear gloves appropriate for task.

EYE PROTECTION: Use safety glasses and/or goggles, as appropriate.

GOOD HYGIENE CONDITIONS: Wash with soap and water before meals and at the end of each work shift. Good manufacturing practices require amounts of any chemical be removed from the skin as soon as practical, especially before eating or smoking.

9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid Gel

ODOR: Banana, ethereal odor

SOLUBILITY IN WATER: Not Determined

MELTING POINT: Not Applicable

AUTO IGNITION TEMPERATURE: Not Established

pH: No Data

COLOR: Light yellow

BOILING POINT: Approximately 450°F

SPECIFIC GRAVITY: Approximately 1.05 at 25°C

EVAPORATION RATE (BuAc=1): No Data

FLASH POINT: >250°F

VAPOR PRESSURE: Approx. 0.02 mm Hg at 25°C

10. STABILITY AND REACTIVITY

STABILITY: Stable under ordinary conditions of use and storage.

CONDITIONS TO AVOID: Incompatible materials

HAZARDOUS POLYMERIZATION: Will not occur

INCOMPATIBILITY WITH OTHER MATERIALS: Oxidizing agents.

HAZARDOUS DECOMPOSITION: Thermal degradation produces carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

TOXICOLOGICAL DATA:

This is a personal care product that is safe for consumers and other users under intended and reasonably foreseeable use.

LD50/LC50:

CAS# 25265-71-8:

Oral, rat: LD50 = 14850 mg/kg;

Skin, rabbit: LD50 = >20 mL/kg;

Carcinogenic effects: Not available.

Mutagenic effects: Not available.

Teratogenic effects: Not available.

Reproductive effects: Not available

Cancer Lists:

<u>Ingredient</u>	<u>Known</u>	<u>Anticipated</u>	<u>IARC Category</u>
Saccharin	No	No	Group 3
Balance of ingredients	No	No	None

MATERIAL SAFETY DATA SHEET

Cetacaine® Gel Topical Anesthetic

Last Updated March 3, 2011

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:

These products have not been tested for environmental fate.

ENVIRONMENTAL TOXICITY:

This product is not expected to be hazardous to the aquatic environment.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL:

Recover, reclaim or recycle when practical.

Dispose of material in accordance with all federal, state and local requirements.

14. TRANSPORTATION INFORMATION

DOMESTIC (LAND, D.O.T.), INTERNATIONAL (WATER, I.M.O.), INTERNATIONAL (AIR, I.C.A.O.)

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

15. REGULATORY INFORMATION

FEDERAL REGULATORY STATUS:

UNITED STATES REGULATIONS:

All components of this product are included on the TSCA Chemical Inventory or are not required to be listed on the TSCA Chemical Inventory.

SARA SECTION 302: None of the chemicals in this product have a TPQ.

SARA SECTION 304: None

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

SARA SECTION 311/312: Acute: Yes Chronic: No Fire: Yes Pressure: No

Reactivity: Yes (Pure / Liquid)

SARA SECTION 313 TOXIC CHEMICAL LIST: No chemicals are reportable under Section 313.

CLEAN AIR ACT: This product does not contain any hazardous air pollutants. This product does not contain any Class 1 Ozone depleters. This product does not contain any Class 2 Ozone depleters.

STATE REGULATIONS:

CALIFORNIA

PROP 65 - WARNING: THIS PRODUCT DOES NOT CONTAIN A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

INTERNATIONAL REGULATIONS:

CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.

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

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Not Classified

MATERIAL SAFETY DATA SHEET

Cetacaine® Gel Topical Anesthetic

Last Updated March 3, 2011

This material or all of its components are listed on the Inventory of Existing Chemical Substances under the Toxic Substance Control Act (TSCA). This material or all of its components are listed on the Canadian Domestic Substances List (DSL). This material or all of its components are listed (or considered as having been notified) on the European Inventory of Existing Chemical Substances (EINECS). Other inventory lists: Korea (TCCL), Australia (AICS), China (Draft), PICCS (Philippines-RA6969), Japan (ENCS METI/MOL).

16. OTHER INFORMATION

Label Requirements:

WARNING! PROLONGED CONTACT WITH SKIN MAY CAUSE IRRITATION. POSSIBLE ALLERGEN. CONTACT WITH EYES MAY CAUSE IRRITATION OR OTHER EFFECTS. MAY BE HARMFUL IF SWALLOWED.

Hazardous Material Information System (HMIS):	Health	1
	Flammability	1
	Reactivity	0
	Personal Protection	A

National Fire Protection Association (NFPA) 1-Health, 1-Flammability, 0-Reactivity

NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

Protective Equipment: SAFETY GLASSES; PROPER GLOVES;

Prepared By: Paul Eigbrett (MSDS Authoring PLUS)

Date: March 3, 2011

Part Number: --

Supersedes Date: 9/13/2010

ADDITIONAL INFORMATION:

The data in this Material Safety Data Sheet relates only to the specific material designated herein. It does not relate to use in combination with any other material or in any process. This Material Safety Data Sheet (MSDS) has been reviewed to fully comply with the guidance contained in the ANSI MSDS standard (ANSI Z400.1-2004)

The information herein given was derived solely from the Main Hazardous Chemical Ingredients MSDS's on file at the time of this MSDS preparation. The information is given in good faith but no warranty, express or implied to the accuracy, completeness or adequacy of the information contained in this MSDS is made. We assume no warranties of fitness or liability from the use of this product. Since the conditions for use, handling, storage and disposal of this product are beyond Cetylite control, users should make their own investigations to determine the suitability of the information for their particular purposes. Users assume liability for damage, or expense arising out of product's improper use. Various Federal, State, or Provincial agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in this MSDS. The user should review these regulations to ensure full compliance.

END OF MSDS