Safety Data Sheet

Lidocaine Ointment 5%, USP **SDS DATE:** 9/22/11

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lidocaine Ointment 5%, USP

NDC #: Tube 57539-0221-5
Jar 57539-0221-1

Chemical Name (for active ingredient): 2-(Diethylamino)-*N*-(2,6-dimethylphenyl)-acetamide

Chemical Family (for active ingredient): Acetamide

Formula (for active ingredient): $C_{14}H_{22}N_2O$

Product Use: Pharmaceutical for Human Use

Manufacturer:
Septodont Confi-Dental Division.
Address: 416 S. Taylor Ave.
Louisville, CO USA 80027
Telephone: (800) 383-5158

Emergency Information Chemtrec:
(800) 424-9300

Section 2: Hazards Identification

Emergency Overview

Warning: May Cause Skin Irritation
This Product is Combustible

Routes of Entry:
Skin Contact, Ingestion

Potential Acute Health Effects:

Eyes:
May cause irritation

Skin:
May cause irritation

Inhalation:
Unlikely due to form of product. May cause irritation

Potential Chronic Health Effects:
Chronic overexposure may have skin, GI, and vascular effects.

Section 3: Composition/Information on Ingredients

COMPONENT:	CAS NO.	% WT
Lidocaine	137-58-6	5.0 %
Polyethylene Glycol 1450	25322-68-3	Proprietary
Polyethylene Glycol 300	25322-68-3	Proprietary

Section 4: First Aid Measures

Eyes: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then “roll” eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Skin: If adverse skin effects occur, discontinue use. Seek medical attention.

Ingestion: If this 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 someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

Inhalation: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Section 5: Fire-Fighting Measures

Flammable/Explosive Limits:
Upper: Not applicable
Lower: Not applicable

Flash Point:
Not established

Method Used:
Not applicable

Extinguishing Media:
Water Spray, Carbon Dioxide, Foam, Dry Chemical, Halon

Special Fire Fighting Measures:
Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

Unusual Fire and Explosion Hazards:
This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides). The Lidocaine component of this product is a skin sensitizer, and so it poses a contact hazard to firefighters.

Section 6: Accidental Release Measures

General Information:
Proper protective equipment should be used. In the event of a spill, clear the area and protect people. T

Environmental precautions:
Prevent material from entering sewer or confined spaces, waterways, soil or public waters.

Process for cleaning and take-up:
Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill area should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is serious matter and should be treated as such. Absorb spilled liquid using polypads or other suitable absorbent material.

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures. (see Section 13, Disposal Considerations).

Section 7: Handling and Storage

Handling:
Handling advice:
As with all chemicals, avoid getting this product on your in you. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow specific use instructions supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

Fire and explosion protection:
Keep away from heat, spark, and open flames.

Storage:
Store this product away from incompatible materials. Store this product in original container.

Section 8: Exposure Controls/Personal Protection

Exposure Guidelines: Not established

Engineering Controls:

Ventilation:
Use with adequate ventilation. Follow standard medical product handling procedures.

Personal Protection:

Respiratory Protection:
A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02.

Hand Protection:
For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

Eye Protection:
Not normally needed during normal use.

Body Protection:
During patient administration, use of lightweight cotton gown or other medical attire is recommended.

Section 9: Physical and Chemical Properties

General description:

State: Ointment
Odor: Peppermint
Color(s): White

Designation:	Value	Method
Boiling Point:	225ºC (437ºF)	no information
Freezing/Melting Point:	40ºC (104ºF)	no information
Vapor Pressure:	Not established	no information
Specific Gravity @ 20ºC (water=1):	1.053	no information

Section 10: Stability and Reactivity

Stability:

Dangerous decomposition products:
None if used for intended purpose.

Decomposition advices:
No decomposition if used according to specifications.

Reactivity:

Materials to avoid:
Acids, caustics, and other chemicals that could affect its performance should be avoided.

Hazardous polymerization:
Will not occur.

Conditions to avoid:
Avoid heat, light, and contact with materials listed to avoid.

Section 11: Toxicological Information

General toxicological information:

Individuals who have had allergic reactions to products containing the active ingredient, Lidocaine, other amide-type local anesthetics, or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following: numbness and irritation.

Toxicity Data:

The toxicity data available for the active component of this product, Lidocaine, is presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS.

LIDOCAINE:
TDLo (Oral-Child) 21 mg/kg: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: respiratory depression
TDLo (Oral-Child) 300 mg/kg/5 days-intermittent: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Nutritional and Gross Metabolic: body temperature increase
TDLo (Oral-Woman) 39 mg/kg: Behavioral: hallucinations, distorted perceptions, excitement; Cardiac: change in rate
TDLo (Intraspinal-Woman) 1 mL/kg: Behavioral: euphoria, hallucinations, distorted perceptions
TDLo (Intravenous-Woman) 16 mg/kg: Cardiac: change in rate; Respiration: dyspnea
TDLo (Intravenous-Man) 8643 µg/kg/4 hourscontinuous: Behavioral: toxic psychosis
TDLo (Intravenous-Man) 1700 µg/kg/2 minutescontinuous: Behavioral: coma; Cardiac: pulse rate; Respiration: respiratory depression
TDLo (Intravenous-Human) 23 mg/kg: Behavioral:
muscle contraction or spasticity; Lungs, Thorax, or Respiration: dyspnea
TDLo (Parenteral-Human) 0.71 mg/kg: Peripheral Nerve and Sensation: local anesthetic; Vascular: BP lowering not characterized in autonomic section
TDLo (Parenteral-Woman) 0.95 mg/kg: Peripheral Nerve and Sensation: local anesthetic; Vascular: regional or general arteriolar constriction
TDLo (Parenteral-Woman) 540 µg/kg: female 39 week(s) after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System
TDLo (Skin-Woman) 1.72 mg/kg: Peripheral Nerve and Sensation: local anesthetic; Vascular: regional or general arteriolar constriction

LIDOCAINE (continued):
TDLo (Subcutaneous-Human) 33.3 µg/kg: Behavioral: analgesia
LD50 (Oral-Rat) 317 mg/kg
LD50 (Oral-Mouse) 220 mg/kg: Behavioral: convulsions or effect on seizure threshold, rigidity (including catalepsy); Lungs, Thorax, or Respiration: respiratory stimulation
LD50 (Intraperitoneal-Rat) 133 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: other changes
LD50 (Intraperitoneal-Mouse) 102 mg/kg: Peripheral Nerve & Sensation: local anesthetic; Behavioral: convulsions or effect on seizure threshold, ataxia
LD50 (Subcutaneous-Rat) 335 mg/kg
LD50 (Subcutaneous-Mouse) 238 mg/kg
LD50 (Subcutaneous-Guinea Pig) 120 mg/kg
LD50 (Intravenous-Rat) 18 mg/kg
LD50 (Intravenous-Mouse) 20 mg/kg: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: other changes
LD50 (Intravenous-Mouse) 39.4 mg/kg
LD50 (Unreported-Rat) 39,400 µg/kg
LDLo (Intravenous-Rabbit) 41 mg/kg
LDLo (Intravenous-Guinea Pig) 65 mg/kg
TDLo (Intradermal-Rabbit) 0.024 mg/kg
TDLo (Intravenous-Rat) 5 mg/kg: Vascular: BP lowering not characterized in autonomic section
TDLo (Intravenous-Rat) 2343 µg/kg/5 minutes: Cardiac: change in rate
TDLo (Intravenous-Rat) 4688 µg/kg/5 minutes: Vascular: BP lowering not characterized in autonomic section
TDLo (Intravenous-Dog) 2 mg/kg: Cardiac: change in rate
TDLo (Intravenous-Dog) 5 mg/kg: Vascular: measurement of regional blood flow

LIDOCAINE (continued):
TDLo (Intravenous-Mammal) 182.5 mg/kg/72 hrcontinuous: Brain & Coverings: other degenerative changes
TDLo (Intraperitoneal-Rat) 2 mg/kg: Blood changes
TDLo (Subcutaneous-Mouse) 50 mg/kg: Peripheral Nerve and Sensation: local anesthetic4
TDLo (Parenteral-Rat) 6.67 mg/kg: Peripheral Nerve and Sensation: local anesthetic
TDLo (Parenteral-Rat) 6 mg/kg: female 11 days after conception: Reproductive: Effects on Newborn: sex ratio
TDLo (Parenteral-Rat) 6 mg/kg: female 18 days after conception: Reproductive: Effects on Newborn: behavioral
TDLo (Intramuscular-Rat) 50 mg/kg/3 days-intermittent: Blood: change in clotting factors; Immunological Including Allergic: increased immune response; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects
TDLo (Intramuscular-Rat) 6 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Newborn: behavioral
TDLo (Intraspinal-Rabbit) 5 mg/kg: Peripheral Nerve and Sensation: local anesthetic
TDLo (Intradermal-Rabbit) 0.024 mg/kg: Behavioral: general anesthetic, analgesia
TDLo (Implant-Rat) 7500 mg/kg: female 3-17 day(s) after conception: Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Unreported-Rat) 0.5 pph: Peripheral Nerve and Sensation: local anesthetic
TDLo (Unreported-Guinea Pig) 0.25 pph: Peripheral Nerve and Sensation: local anesthetic
TDLo (Unreported-Frog) 0.1 pph: Peripheral Nerve and Sensation: local anesthetic
TCLo (Inhalation-Rabbit) 10,000 gm/m 3: Lungs, Thorax, or Respiration: structural or functional change in trachea or bronchi
Mutation in Micro

Section 12: Ecological Information

General ecological information:

No data available.

Section 13: Disposal Considerations

Waste disposal of product:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

Section 14: Transport Information

U.S. Department of Transportation Shipping Regulations:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101

Transport Canada Transportation of Dangerous Goods Regulations:

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

Section 15: Regulatory Information

United States Regulations:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

California Safe Drinking Water And Toxic Enforcement Act (Proposition 65): The components of this product are not on the California Proposition 65 lists.

Other U.S. Federal Regulations: Not applicable.

Canadian Regulations:

Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Other Canadian Regulations: Not applicable.

Canadian WHMIS Classification and Symbols:

Class D2B Poisonous and infectious material (Sensitization

Section 16: Other Information

All information, recommendations, and suggestions appearing herein concerning our product are based upon tests and data believed to be reliable. However, it is the user's responsibility to determine the safety, toxicity, and suitability for his own use of the product described herein. Since the actual use by others is beyond our control, no guarantee, express or implied, is being made as to the effects of such use, the results obtained, or the safety and toxicity of the product nor is there any assumed liability arising out of use, by others, of the product referred to herein. The information herein is not to be construed as absolutely complete since additional information may be necessary or desirable when particular or exceptional conditions or circumstances exist or because of applicable laws or government regulations.