

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Product Name: EMLA Cream
Manufacturer Name: APP Pharmaceuticals, LLC
Address: 1501 East Woodfield Road
 Suite 300 East
 Schaumburg, IL 60173-5837
General Phone Number: (847) 706-2084
Customer Service Phone Number: (888) 386-1300
Emergency Phone Number: (800) 424-9300
CHEMTREC: For emergencies in the US, call CHEMTREC: 800-424-9300
MSDS Revision Date: September 02, 2010

HMIS	
Health Hazard	2
Fire Hazard	0
Reactivity	0
Personal Protection	X

* Chronic Health Effects

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Lidocaine	137-58-6	25 mg/gm	
Prilocaine	721-50-6	25 mg/gm	
Polyoxyethylene Fatty Acid Esters	61788-85-0	See Note	
Carboxypolymethylene	9007-16-3	See Note	
Purified Water	7732-18-5	See Note	
Note:	Polyoxyethylene fatty acid ester added as emulsifier, carboxypolymethylene added as a thickening agent, and purified water added to form cream mixture.		

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. EMLA Cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on: normal intact skin for local analgesia and genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation in abnormal conditions. Accidental Ingestion. Accidental Eye contact. Skin Absorption. Accidental Injection.

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Potential adverse reactions from prescribed doses are described in the package insert and include: paleness, redness, alterations in temperature sensation, edema, itching, and rash. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a known hypersensitivity to local anesthetics of the amide type or to any other component of the product.

SECTION 4 - FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176 or (847) 706-2084.

SECTION 5 - FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 - HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F).
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION - EXPOSURE GUIDELINES

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended topical purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist. (In abnormal conditions, such as when cleaning a large spill involving this material).
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended topical purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions in abnormal conditions (such as in a fire involving this product in large quantities). If so, a NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Paste.
Color:	White
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Approximately 9
Molecular Formula:	Mixture
Molecular Weight:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 - STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.
Hazardous Polymerization: Not reported.
Incompatible Materials: Water reactive materials.

SECTION 11 - TOXICOLOGICAL INFORMATION

Teratogenicity: Pregnancy Category B: No adequate and well-controlled studies in pregnant women.

Lidocaine :

RTECS Number: AN7525000

Ingestion: Oral - Rat LD50: 317 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Oral - Mouse LD50: 220 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - rigidity (including catalepsy) Lungs, Thorax, or Respiration - respiratory stimulation]

Other Toxicological Information: Intravenous. - Human TDLo: 23 mg/kg [Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Mouse LD50: 20 mg/kg [Behavioral - convulsions or effect on seizure threshold Vascular - BP lowering not characterized in autonomic section Lungs, Thorax, or Respiration - other changes]
Intravenous. - Rabbit LDLo: 41 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Intravenous. - Guinea pig LDLo: 65 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Intravenous. - Mouse LD50: 39.4 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Intravenous. - Rat LD50: 18 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Intravenous. - Rat TDLo: 5 mg/kg [Vascular - BP lowering not characterized in autonomic section]
Intravenous. - Rat TDLo: 2343 ug/kg/5M [Cardiac - change in rate]
Intravenous. - Rat TDLo: 4688 ug/kg/5M [Vascular - BP lowering not characterized in autonomic section]
Intravenous. - Rabbit TDLo: 3 mg/kg [Cardiac - change in rate Cardiac - cardiac output Vascular - BP lowering not characterized in autonomic section]
Subcutaneous - Rat LD50: 335 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Subcutaneous - Mouse LD50: 238 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Subcutaneous - Guinea pig LD50: 120 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Subcutaneous - Human TDLo: 33.3 ug/kg [Behavioral - analgesia]
Subcutaneous - Mouse TDLo: 50 mg/kg [Peripheral Nerve and Sensation - local anesthetic]
Subcutaneous - Mouse TDLo: 150 mg/kg [Behavioral - convulsions or effect on seizure threshold]
Intraperitoneal. - Rat LD50: 133 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes]
Intraperitoneal. - Mouse LD50: 102 mg/kg [Peripheral Nerve and Sensation - local anesthetic Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia]
Intraperitoneal. - Rat TDLo: 2 mg/kg [Blood - other changes]

Prilocaine :

RTECS Number: UG5760000

Other Toxicological Information: Intravenous. - Mouse LD50: 59900 ug/kg [Details of toxic effects not reported other than lethal dose value.]
Subcutaneous - Mouse LD50: 519 mg/kg [Behavioral - excitement Lungs, Thorax, or Respiration - dyspnea Skin and Appendages - hair]
Intraperitoneal. - Mouse LD50: 231 mg/kg [Details of toxic effects not reported other than lethal dose value.]

Polyoxyethylene Fatty Acid Esters :

RTECS Number: FI4162000

Other Toxicological Information: Intravenous. - Mouse LD50 : 8 gm/kg [Details of toxic effects not reported other than lethal dose value.]

Carboxypolymethylene :

RTECS Number: AT4683000

Ingestion: Oral - Rat LD50 : 4100 mg/kg [Details of toxic effects not reported other than lethal dose value.]
Oral - Mouse LD50 : 4550 mg/kg [Details of toxic effects not reported other than lethal dose value.]

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 - TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.
DOT UN Number: Not Regulated.

SECTION 15 - REGULATORY INFORMATION

Lidocaine :

TSCA Inventory Status: Listed
EINECS Number: 205-302-8
Canada DSL: Listed
EINECS Number: 211-957-0

Polyoxyethylene Fatty Acid Esters :

TSCA Inventory Status: Listed
EINECS Number: 500-147-5
Canada DSL: Listed

Carboxypolymethylene :

Canada DSL: Listed

Purified Water :

TSCA Inventory Status: Listed
Canada DSL: Listed

SECTION 16 - ADDITIONAL INFORMATION

HMIS Health Hazard: 2
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X
MSDS Revision Date: September 02, 2010

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