

EMLA® CREAM

PH1491/1



# MATERIAL SAFETY DATA SHEET

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Name****EMLA® CREAM****Alternative Names**

Lidocaine/Prilocaine cream

Lignocaine/Prilocaine cream

**Address / Phone Number** : AstraZeneca  
1004 Middlegate Road  
Mississauga, ONTARIO  
CANADA L4Y 1M4  
Tel : 1-800 668 6000

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No. : None assigned for the product  
Use : topical anesthetic

HAZARDOUS INGREDIENT(S)	%	CAS No.
Lidocaine		137-58-6
Prilocaine		721-50-6

## 3. HAZARDS IDENTIFICATION

Form : cream, soft  
Color : white

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.

## 4. FIRST AID MEASURES

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- Inhalation : Unlikely route of exposure. Remove patient from exposure. Obtain medical attention if ill effects occur.
- Skin Contact : Remove contaminated clothing. Wash skin with soap and water.
- Eye Contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain immediate medical attention. Continue irrigation until medical attention can be obtained.
- Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

**Note to Physicians**

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

**5. FIRE FIGHTING MEASURES**

If involved in a fire, it may emit noxious and toxic fumes.

- Extinguishing Media (suitable) : water spray, foam, dry chemical or CO<sub>2</sub>.
- Fire Fighting Protective Equipment : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

**6. ACCIDENTAL RELEASE MEASURES**

- Personal Precautions : Ensure suitable personal protection during removal of spillages.
- Clean Up Methods : Adsorb spillages onto sand, earth or any suitable absorbent material. Wash the spillage area clean with water and detergent.

**7. HANDLING AND STORAGE**

- Handling : No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes.
- Storage : Keep container tightly closed.
- Storage Temperature : < 86 °F

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

- Engineering Controls : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.

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**Occupational Exposure Limits****HAZARDOUS****INGREDIENT(S)****TWA****STEL/CEILING(C)**Lidocaine 1 mg/m<sup>3</sup> 5 mg/m<sup>3</sup> COMPrilocaine 1 mg/m<sup>3</sup> 5 mg/m<sup>3</sup> COM

Personal Precautions : Selection of personal protective equipment and procedures for use should be based on the workplace risk assessment and local requirements. Respiratory protective equipment and gloves etc. should be changed at appropriate intervals as specified in the workplace risk assessment and in accordance with manufacturers information. Factors that affect breakthrough time are: Concentration of the material and duration of exposure, permeability, contact temperature, etc

Respirators : NIOSH/MSHA approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

Protective Clothing : Impervious gloves and apron.

Eye Protection : Chemical tight goggles.

Other Protective Equipment : Eyewash station in work area.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Form : cream, soft  
 Color : white  
 pH : 9.0  
 Melting Point : 18.00 °C  
 Solubility (Water) : miscible  
 Specific Gravity : 1.00

**10. STABILITY AND REACTIVITY**

Stability : Stable under normal conditions.  
 Hazardous Reactions : Incompatible materials: Water reactive materials.  
 Hazardous Decomposition : None known.  
 Product(s)

**11. TOXICOLOGICAL INFORMATION**

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The following information refers to active ingredient:

- Inhalation : May cause tingling/numbness in exposed areas (paresthesia).  
High atmospheric concentrations may lead to anesthetic effects.  
May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.
- Skin Contact : May cause mild skin irritation.  
May cause numbness.  
Repeated and/or prolonged contact may cause skin sensitization in a small proportion of sensitive individuals.
- Eye Contact : May cause excessive watering of the eye (lacrimation). Risk of serious damage to eyes. May cause permanent damage if eye is not immediately irrigated.
- Ingestion : Lidocaine Oral Median Lethal Dose (rat) 317 mg/kg  
Harmful if swallowed.  
May produce numbness of the tongue and anaesthetic effects on the stomach.
- Long Term Exposure : Lidocaine, Repeated exposure of animals to high levels produces adverse effects on the, liver, and, central nervous system, There is no evidence of teratogenicity or embryotoxicity., The substance is not considered to be genotoxic.

## 12. ECOLOGICAL INFORMATION

The product is soluble in water. The following information refers to Prilocaine hydrochloride

- Ecotoxicity : EC50 green algae 72 h 154 mg/l  
EC50 Daphnia magna 48 h 61 mg/l  
Harmful to aquatic organisms. LC50 Zebra Fish 96 h 188 mg/l
- Degradability : May cause long-term adverse effects in the aquatic environment. Not readily biodegradable.
- Bioaccumulation : The substance has low potential for bioaccumulation.

## 13. DISPOSAL CONSIDERATIONS

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- Chemical Disposal : Disposal should be in accordance with local, state or national legislation.
- Contaminated Packaging : Empty container will retain product residue. Observe all hazard precautions.

## 14. TRANSPORT INFORMATION

Not Classified as Dangerous for Transport.

## 15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.

## 16. OTHER INFORMATION

The following sections contain revisions or new statements :  
2, 6

This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, as modified 1998.

### GLOSSARY

- COM : In-house occupational exposure limit
- TLV : Threshold Limit Value (ACGIH)
- TLV-C : Threshold Limit Value – Ceiling Limit (ACGIH)
- Sk : Can be absorbed through skin, thus contributing to systemic effects
- Sen : Capable of causing respiratory sensitisation

This Glossary is applicable to substances for which Occupational Exposure Limits are assigned

The information herein is given in good faith but no warranty, expressed or implied, is made.