SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

EMLA CREAM

Details of the supplier of the safety data sheet
ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names
Lidocaine/Prilocaine cream
Lignocaine/Prilocaine cream
Also valid for EMLA emulsion

CAS No. : Not applicable
Use : topical anaesthetic

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Classification UN GHS</th>
<th>Hazard class</th>
<th>Category</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye irritation</td>
<td>2A</td>
<td>H319</td>
<td># Refer to Section 16 'Other Information'</td>
</tr>
</tbody>
</table>

Label elements

Signal word
Warning

Hazard statements
H319 : Causes serious eye irritation.

Precautionary statements
P264 : Wash skin thoroughly after handling.
P280 : Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 : Dispose of contents/container to an approved incineration plant.

Other hazards
May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness. See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine</td>
<td>2.5</td>
<td>137-58-6</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazard class</th>
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<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>4</td>
<td>H302</td>
</tr>
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<thead>
<tr>
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<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prilocaine</td>
<td>2.5</td>
<td>721-50-6</td>
</tr>
</tbody>
</table>

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<td>4</td>
<td>H302</td>
</tr>
<tr>
<td>Serious eye damage</td>
<td>1</td>
<td>H318</td>
</tr>
<tr>
<td>Acute aquatic toxicity</td>
<td>3</td>
<td>H402</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>3</td>
<td>H412</td>
</tr>
</tbody>
</table>

# Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures
Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye Contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
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.

Most important symptoms and effects, both acute and delayed
Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable) : water spray, foam, dry powder or CO2.
Extinguishing Media (unsuitable) : -
Special hazards arising from the substance or mixture : If involved in a fire, it may emit noxious and toxic fumes.
Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES
Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. See Section 8.

Environmental Precautions: Prevent entry into drains, sewers or watercourses.

Methods and material for containment and cleaning up: Clear up spillages. Wash the spillage area with water.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed. Do not freeze.

Specific end use(s): Storage temperature: < 30 °C

Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSOInAL PROTECTION

Control parameters

Occupational Exposure Limit Value

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Control parameters</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine</td>
<td>1 mg/m3</td>
<td>LTEL 8hr TWA</td>
<td>COM</td>
</tr>
<tr>
<td>Lidocaine</td>
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Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Respiratory protection

Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.

Skin protection

Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Eye protection

Use goggles or visor to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : cream, emulsion
Colour : white
pH : 8.7 - 9.7
Solubility (Water) : miscible

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : None known.
Conditions to avoid : No conditions producing hazardous situations known.
Incompatible materials : None known.
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

This health hazard assessment is based on a consideration of the composition of this product.

Inhalation : May cause effects as described under single exposure (STOT)
Skin Contact : May cause mild skin irritation.
               May cause numbness.
Eye Contact : Causes serious eye irritation.
               May cause excessive watering of the eye (lachrymation).
Ingestion : Low acute oral toxicity.
Specific Target Organ Toxicity (STOT) : Single exposure
Exposure routes: Ingestion
May produce numbness of the tongue and anaesthetic effects on the stomach.
Exposure routes: Inhalation
High atmospheric concentrations may lead to anaesthetic effects., May cause tingling/numbness in exposed areas (paraesthesia), May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.
Repeated exposure
Repeated exposure of animals to high levels produces adverse effects on the liver and central nervous system.
Sensitisation : May cause skin sensitisation in rare cases.
Carcinogenicity : No information available.
Mutagenicity : This material is not considered to be genotoxic.
Reproductive toxicity : There is no evidence of teratogenicity or embryotoxicity.

### 12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient:

**Toxicity**

- Prilocaine hydrochloride
  - Harmful to aquatic life with long lasting effects.
  - EC50 green algae 72 H 154 mg/l
  - Lidocaine hydrochloride monohydrate
  - EC50 green algae 72 H 780 mg/l
  - Prilocaine hydrochloride
  - EC50 Daphnia magna 48 H 61 mg/l
  - Lidocaine hydrochloride monohydrate
  - EC50 Daphnia magna 48 H 112 mg/l
  - Prilocaine hydrochloride
  - LC50 Zebra Fish 96 H 188 mg/l
  - Lidocaine hydrochloride monohydrate
  - LC50 Zebra Fish 96 H 106 mg/l

**Effect on Effluent Treatment** : No information available.

**Persistence and degradability** : Not readily biodegradable.

**Bioaccumulative potential** : The substance has low potential for bioaccumulation.

**Mobility in soil** : No information available.

**Other adverse effects** : No information available.

### 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods** : Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.

**Contaminated Packaging** : Empty container will retain product residue. Observe all hazard precautions.

### 14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT
15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements

H302 : Harmful if swallowed.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H402 : Harmful to aquatic life.
H412 : Harmful to aquatic life with long lasting effects.

The following sections contain revisions or new statements:

Minor changes: 2, 3, 11, 12, 16

GLOSSARY

COM : In-house occupational exposure limit
LTEL : Long-term exposure limit (8 hour TWA (time-weighted average))
 STEL : Short-term exposure limit (15-minute TWA (time-weighted average))
TLV : Threshold Limit Value (ACGIH)
TLV-C : Threshold Limit Value - Ceiling limit (ACGIH)
HYG : An in-house analytical method for occupational exposure monitoring is available
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 Hazardous Ingredients/Occupational Exposure Limits are assigned.