SAFETY DATA SHEET

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

Product identifier

XYLOCAINE SOLUTION FOR ORAL PUMP SPRAY

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
Xylocaine oral pump spray
Lidocaine spray
Lignocaine spray
Xylocaine spray

CAS No. : Not applicable
Use : topical anaesthetic

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Classification UN GHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard class</td>
</tr>
<tr>
<td>Flammable liquids</td>
</tr>
<tr>
<td>Acute toxicity</td>
</tr>
</tbody>
</table>

# Refer to Section 16 'Other Information'

Label elements

Signal word
Warning

Hazard statements

H226 : Flammable liquid and vapour.
H303 : May be harmful if swallowed.
Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P312 : Call a POISON CENTER or doctor/physician if you feel unwell.
P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

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. May cause eye irritation.

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>10</td>
<td>137-58-6</td>
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</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>24</td>
<td>64-17-5</td>
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Hazard class # | Category | Hazard statements #
Acute toxicity | 4 | H302

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure. Obtain medical attention.
Skin Contact : Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye Contact : 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) : foam, CO2 or dry powder. Water spray should be used to cool containers.
Extinguishing Media (unsuitable) : Do NOT use water jet.
Special hazards arising from the substance or mixture : Flammable liquid and vapour. If involved in a fire, it will burn and 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 : Eliminate all ignition sources if safe to do so. 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 : Contain and adsorb spillages onto an inert non-combustible adsorbent carrier. Do not adsorb onto sawdust or other combustible materials. Ventilate area. Transfer to a container for disposal. Wash the spillage area clean with water and detergent.

7. HANDLING AND STORAGE

Precautions for safe handling : Avoid contact with skin and eyes. Avoid inhalation of vapour/mist. Take precautionary measures against static discharges. Keep away from heat and sources of ignition.
Conditions for safe storage, including any incompatibilities : Keep container tightly closed, in a cool, well ventilated place.
Specific end use(s) : Not applicable, refer to Section 1
8. EXPOSURE CONTROLS/PERSEROAL 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>
<td>5 mg/m³</td>
<td>STEL 15min</td>
<td>COM</td>
</tr>
<tr>
<td>Ethanol</td>
<td>1000 ppm 1 880 mg/m³</td>
<td>LTEL 8hr TWA</td>
<td>TLV</td>
</tr>
</tbody>
</table>

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.

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 A if the risk assessment does not support the selection of other protection.

**Skin protection**
Avoid contact with skin. 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 safety glasses 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       | liquid         |
| Colour     | almost colourless to pale yellow |
| Odour      | fruit-like     |
| Flash Point| 27 - 32 °C     |
| Density    | 1,004 g/cm³ 20 °C |
| Solubility (Water) | soluble |

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 : Reacts vigorously with oxidising agents. Reacts with strong acids.
Conditions to avoid : No conditions producing hazardous situations known.
Incompatible materials : Strong acids and oxidizing agents
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 : No information available on acute toxicity.
May cause effects as described under single exposure.(STOT)

Skin Contact : May cause numbness.
Repeated or prolonged contact may cause defatting of the skin resulting in dryness, cracking and dermatitis.

Eye Contact : The vapour and liquid are irritant.
Permanent damage is unlikely.
May cause strong stinging and burning sensation.

Ingestion : May be harmful if swallowed.

Specific Target Organ Toxicity (STOT) : Single exposure
Exposure routes: Inhalation
May cause tingling/numbness in exposed areas (paraesthesia)., High atmospheric concentrations may lead to anaesthetic effects., May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

Exposure routes: Ingestion
May produce numbness of the tongue and anaesthetic effects on the stomach.

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 : The material is not considered to be a reproductive risk to human.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to Lidocaine hydrochloride monohydrate

Toxicity : EC50 green algae 72 H 780 mg/l
EC50 Daphnia magna 48 H 112 mg/l
LC50 Zebra Fish 96 H 106 mg/l
EC50 (microtox test) 15 MIN > 1 000 mg/l
Effect on Effluent Treatment : No information available.

Persistence and degradability : Not rapidly degradable.

Bioaccumulative potential : The substance has low potential for bioaccumulation.

Mobility in soil : The substance is essentially insoluble in water.

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

RESTRICTED FOR TRANSPORT

ICAO/IATA
UN No. : 1170
Proper Shipping Name : Ethanol solution
Class : 3
Packing Group : III

IMO/IMDG
UN No. : 1170
Proper Shipping Name : ETHANOL SOLUTION
Class : 3
Packing Group : III
Marine pollutant : Not classified as a Marine Pollutant

ADR
UN No. : 1170
Proper Shipping Name : ETHANOL SOLUTION
Class : 3
Label(s) : 3
Packing Group : III

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION
Hazard statements

H225: Highly flammable liquid and vapour.
H226: Flammable liquid and vapour.
H302: Harmful if swallowed.
H303: May be harmful if swallowed.

The following sections contain revisions or new statements:

Minor changes: 2, 11, 13

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.