

**SAFETY DATA SHEET****XYLOCAINE INJECTION AMPOULES\_ lidocaine hydrochloride**

**Issue Date:** 24 November 2020  
**Sponsor:** Aspen Pharmacare Australia Pty Ltd  
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**1. IDENTIFICATION OF THE MATERIAL**

**Product Identifier:** XYLOCAINE lidocaine HCl- injection ampoules

**Other means of identification:** Lignocaine

**Aspen product code/s:**  
07664 - Xylocaine 1% 50x2mL PE PDF  
07668 - Xylocaine 1% 50x5mL PE PDF  
07594 - Xylocaine 1% 5x20mL PP PDF ATP  
07665 - Xylocaine 2% 50x2mL PE PDF  
07667 - Xylocaine 2% 50x5mL PE PDF  
07592 - Xylocaine 2% 5x20mL PP PDF ATP

**Recommended Use:** This safety data sheet is written to provide health, safety and environmental information for people handling this product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician.

**Emergency phone number:** +(61 2) 8436 8300

Poisons Information Centre: 131 126 from anywhere in Australia, (0800 764 766 in New Zealand)

**2. HAZARDS IDENTIFICATION/DATA**

**Hazard Classification:**



**Hazard Information:**

Signal word: **Warning**

H336 – May cause drowsiness or dizziness.  
May cause skin and/or eye irritation.

**Label Elements, including  
 precautionary statements:**

Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.

Avoid use in individuals with hypersensitivities to amide-type anaesthetics. Use with caution in individuals with diabetes and/or severe hypertension.

**Prevention**

P261 – Do not breathe mist/vapours/spray.

P271 – Use in a well ventilated area.

**Response**

P304 + P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 – Call a POISON CENTER or doctor/physician if you feel unwell.

**Storage**

P405 – Store locked up.

**Disposal**

P501 – Dispose of contents/container in accordance with local/provincial/federal regulations.

**Other hazards which do not  
 result in classification:**

None Known

### 3. COMPOSITION

Chemical Ingredient	CAS No.	%
Lidocaine Hydrochloride	73-89-9	Low
Excipients	Unassigned	Medium
<i>Concentration Guide: Low (below 10%)    Medium (10 to 60%)    High (above 60%)</i>		

### 4. FIRST AID MEASURES

**In case of Skin Contact:**

Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. Remove and launder clothing before re-use.

**In case of Eye:**

Flush victim's eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation develops or persists.

**In case of Ingestion:** If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Seek medical attention if symptoms occur.  
 If large quantities are ingested, call the Poisons Information Centre immediately.

**Inhalation:** Remove victim to fresh air. Get medical attention if symptoms of exposure occur.

**Symptoms caused by exposure:** Drowsiness, confusion, excitability, nervousness, reduced heart rate, drop in blood pressure, dizziness, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.

**Medical attention and special treatment:** Treat symptomatically.

**5. FIRE FIGHTING MEASURES**

**Suitable extinguishing media :** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Special hazards arising from the substance or mixture:** Product is not flammable. Thermal decomposition may yield chlorine, hydrogen chloride, or oxides of nitrogen.

**Advice for firefighters:** Fight fire from safe distance or protected location. Water may be ineffective unless used as a fine spray or fog. Use water to cool fire-exposed containers. Contain water used in firefighting from entering sewers or natural waterways.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures :** Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of vapours or mists.

**Environmental precautions:** Avoid discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up:** Clean up spills with normal procedures used for non-hazardous liquids. This can include: absorb spill with inert material, then place in a chemical waste container. Clean

surface thoroughly with water to remove residual contamination.

## 7. HANDLING AND STORAGE

<b>Precautions for safe handling :</b>	Caution should be used to prevent against ingestion and contact with eyes Handle with care to avoid breakage.
<b>Conditions for safe storage, including any incompatibilities :</b>	Store in original container in a cool, dry place out of direct sunlight. Store in a well-ventilated location away from incompatible materials.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Control parameters – Exposure standards, biological monitoring :</b>	No data available.
<b>Engineering controls :</b>	Ventilation rates should be matched to usage conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
<b><u>Personal protective equipment</u></b>	
<b>Eye protection:</b>	None required under normal conditions of use. Wear safety glasses when the possibility exists for eye contact due to splashing or spraying material e.g. spills and breakages.
<b>Hand protection:</b>	None required under normal conditions of use. Wear compatible chemical resistant gloves when the possibility exists for skin contact e.g. spill clean-up.
<b>Skin and body protection:</b>	Impervious clothing.

## 9. PHYSICAL & CHEMICAL PROPERTIES

<b>Description of appearance (physical form, colour, shape):</b>	Clear colourless liquid.
<b>Odour:</b>	Odourless
<b>Odour threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting point/range:</b>	Aqueous solution (0°C)

<b>Boiling point/range:</b>	Aqueous solution (100°C)
<b>Flash point:</b>	Not flammable.
<b>Evaporation rate:</b>	No data available.
<b>Flammability:</b>	Not applicable.
<b>Upper/lower flammability or explosive limits:</b>	No data available.
<b>Vapour pressure:</b>	No data available.
<b>Vapour density:</b>	No data available.
<b>Relative density:</b>	No data available.
<b>Solubility (ies):</b>	Miscible.
<b>Partition coefficient: n-octanol/ water:</b>	No data available.
<b>Auto-ignition temperature:</b>	Not applicable.
<b>Decomposition temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Specific heat value:</b>	No data available.
<b>Particle size:</b>	Not applicable.
<b>Volatile organic compounds content:</b>	No data available.
<b>% Volatile:</b>	No data available.
<b>Saturated vapour concentration:</b>	No data available.
<b>Release of invisible flammable vapour and gases:</b>	No data available.

## 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No dangerous reactions known.
<b>Chemical stability:</b>	Material is stable under normal conditions of handling.
<b>Conditions to avoid:</b>	No dangerous reaction known under conditions of normal use.
<b>Incompatible material and possible hazardous reactions:</b>	Incompatible with compounds which react violently with water.
<b>Hazardous decomposition products:</b>	None known.

## 11. TOXICOLOGICAL INFORMATION

<b>Information on routes of exposure:</b>	<p><b>Ingestion:</b> May cause gastrointestinal irritation.</p> <p><b>Inhalation:</b> May cause slight respiratory tract irritation with coughing and anaesthetic effects.</p> <p><b>Skin contact:</b> May cause slight irritation and numbness.</p> <p><b>Eye contact:</b> Liquid can cause slight irritation with tears and blurred vision experienced. May cause numbness of sensation.</p>
<b>Symptoms related to exposure:</b>	Allergic and anaphylactic reactions associated with lidocaine can occur in a small amount of the population.
<b>Numerical measures of toxicity:</b>	Not expected to be acutely toxic in humans. LD <sub>50</sub> for Lidocaine Hydrochloride: 317 mg/kg (oral; rat)
<b>Immediate, delayed and chronic health effects from exposure:</b>	Repeat or chronic exposure may cause hypersensitivity and the development of methemoglobinemia. No significant effects were observed on foetal development. However, animal studies have found that continuous exposure throughout pregnancy may decrease birth weight.
<b>Exposure levels:</b>	None of the components are listed as carcinogens. No data available.
<b>Interactive effects:</b>	No data available.
<b>Data limitations:</b>	No data available.

## 12. ECOLOGICAL INFORMATION

<b>Ecotoxicity:</b>	<p>No information for this formulation. The following information refers to the active ingredient only; Lidocaine Hydrochloride.</p> <p>EC<sub>50</sub> green algae 72 H 780 mg/l</p> <p>EC<sub>50</sub> Daphnia magna 48 H 112 mg/l</p> <p>LC<sub>50</sub> Zebra Fish 96 H 106 mg/l</p> <p>EC<sub>50</sub> (microtox test) 15 MIN &gt; 1 000 mg/l</p>
<b>Persistence , degradability &amp; Persistence:</b>	Not rapidly degradable.
<b>Bioaccumulative potential:</b>	Low potential for bioaccumulation.
<b>Mobility in Soil:</b>	No data available.

**Other adverse effects :** None known.

### 13. DISPOSAL CONSIDERATIONS

**Safe handling and disposal 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.

**Disposal of any contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**Environmental regulations:** No data available.

### 14. TRANSPORT INFORMATION

**UN number:** Not classified as hazardous for transport.

**UN Proper Shipping name:** No data available.

**Transport hazard class:** Not applicable.

**Packing Group:** No data available.

**Environmental hazards:** None known.

**Special precautions during transport:** None known.

**Hazchem code:** No data available.

### 15. REGULATORY INFORMATION

**Safety, health and environmental regulations specific for the product in question** No special regulatory condition noted.  
See public ARTG summary for more information.

**Poisons Schedule Number:** (S4) Prescription Only Medicine

### 16. OTHER INFORMATION

**Date of preparation or review** 26<sup>th</sup> November 2020

**Key abbreviations or acronyms used**

CAS No. = Chemical Abstracts Service Number

LD<sub>50</sub> = Lethal Dose (50% of the sample population)IC<sub>50</sub> = inhibitory concentrationEC<sub>50</sub> = Effective concentration**DISCLAIMER**

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