

**SAFETY DATA SHEET****XYLOCAINE\_ lidocaine (lignocaine) 10% pump spray**

**Issue Date:** 16<sup>th</sup> June 2021  
**Sponsor:** Aspen Pharmacare Australia Pty Ltd  
**Address:** 34-36 Chandos Street, St Leonards, NSW, 2065  
**Telephone:** +61 2 8436 8300

**1. IDENTIFICATION OF THE MATERIAL**

**Product Identifier:** XYLOCAINE 10% PUMP SPRAY lidocaine (lignocaine)  
10mg/100uL 50ml  
**Other means of identification:** N/A  
**Aspen product code/s:** 07598 – Xylocaine 10% Pump Spray Solution 50ml Bottle  
**Recommended Use:** Topical anaesthetic  
**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:** Flammable liquids- Category 3  
**Hazard Information:** H226: Flammable liquid and vapour.

**Label Elements, including  
precautionary statements:**



**Signal word:** Warning

**Prevention:**

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

- P233 Keep container tightly closed.
- P240 Ground/bond container and receiving equipment.
- P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

**Response:**

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

**Disposal:**

P501 Dispose of contents/ container to an approved incineration plant.

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.  
 May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.  
 May cause eye irritation.  
 See Section 11.

**3. COMPOSITION**

Chemical Ingredient	CAS No.	%
Lidocaine	137-58-6	10
Excipients	Proprietary	>60
<i>Concentration Guide:    Low (below 10%)    Medium (10 to 60%)    High (above 60%)</i>		

**4. FIRST AID MEASURES**

- 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.

**Inhalation:** Remove patient from exposure.  
 Obtain medical attention if ill effects occur.

**Symptoms caused by exposure:** Refer to sections 2 and 11

**Medical attention and special treatment:** Symptomatic treatment and supportive therapy as indicated.  
 For further detail consult the prescribing information.

**5. FIRE FIGHTING MEASURES**

**Suitable extinguishing media:** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). Do NOT use a 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.

**Advice for firefighters:** 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.

**Environmental precautions:** Prevent entry into drains, sewers or watercourses.

**Methods and materials 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

<b>Precautions for safe handling:</b>	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.
<b>Conditions for safe storage, including any incompatibilities:</b>	Keep container tightly closed, in a cool, well-ventilated place. Store at the recommended storage conditions on the packaging.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Control parameters – Exposure standards, biological monitoring:</b>	Occupational Exposure Limit for Lidocaine hydrochloride monohydrate: TWA (Time weighted average) – 0.05mg/m <sup>3</sup>
<b>Engineering controls:</b>	The specific controls will depend on local circumstances and should be based on a 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.
<b>Personal protective equipment</b>	
<b>Eye protection:</b>	Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
<b>Respiratory protection:</b>	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.
<b>Skin and body protection:</b>	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.
<b>Protective Measures:</b>	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.

All the information above 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.

## 9. PHYSICAL & CHEMICAL PROPERTIES

<b>Description of appearance (physical form, colour, shape):</b>	Clear or almost clear slightly coloured liquid in a glass bottle closed by a spray head and pump assembly.
<b>Odour:</b>	Fruit like
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Melting point/range:</b>	No data available
<b>Boiling point/range:</b>	No data available
<b>Flash point:</b>	27 - 32 °C
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<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>Density:</b>	1.004 g/cm <sup>3</sup> (20 °C)
<b>Solubility (ies):</b>	No data available
<b>Partition coefficient: n-octanol/ water:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<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>	No data available
<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 known reactivity hazard under normal conditions.
<b>Chemical stability:</b>	Stable under normal conditions.
<b>Conditions to avoid:</b>	No conditions producing hazardous situations known.
<b>Incompatible material and possible hazardous reactions:</b>	Reacts vigorously with oxidising agents. Reacts with strong acids.
<b>Hazardous decomposition products:</b>	No hazardous decomposition products are known.

## 11. TOXICOLOGICAL INFORMATION

<b><u>Routes of exposure:</u></b>	<b>Ingestion:</b> Low acute oral toxicity.
	<b>Inhalation:</b> 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.
	<b>Eye contact:</b> May cause eye irritation. May cause excessive watering of the eye (lachrymation).
	<b>Skin Contact:</b> Repeated, excessive and/or prolonged contact may cause skin sensitisation in a small proportion of sensitive individuals.
<b>Symptoms related to exposure:</b>	May cause tingling/numbness in exposed areas (paraesthesia). Oral-May produce numbness of the tongue and anaesthetic effects on the stomach.

**Sensitisation:** Allergic reactions are rare, but may occur in individuals hypersensitive to lidocaine, other amide-type local anaesthetics, the preservatives, methyl- or propylparaben, or to other ingredients in the formulation. Allergic reactions are characterized by skin lesions, hives, oedema, or anaphylactoid reactions

**Numerical measures of toxicity:**

Species	Route	Type	Dose
Rat	Oral	LD <sub>50</sub>	317 mg/kg
Mouse 2	Oral	LD <sub>50</sub>	20,292 mg/kg
Mouse	Intravenous	LD <sub>50</sub>	22 mg/kg
Mouse	Intramuscular	LD <sub>50</sub>	260 mg/kg
Mouse	Intraperitoneal	LD <sub>50</sub>	119 mg/kg
Rat	Subcutaneous	LD <sub>50</sub>	570 mg/kg
Mouse	Subcutaneous	LD <sub>50</sub>	285 mg/kg

**Immediate, delayed and chronic health effects from exposure:**

**Germ cell mutagenicity:** The substance is not considered to be genotoxic.

**Reproductive toxicity:** Not classified based on available information.

**Carcinogenicity:** There is no evidence of teratogenicity or embryotoxicity.

**Exposure levels:**

Inhalation; 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.

Oral: May produce numbness of the tongue and anaesthetic effects on the stomach.

**Interactive effects:**

No data available

**Data limitations:**

No data available

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity:**

This product has no known ecotoxicological effects.

**Lidocaine hydrochloride monohydrate:**

Toxicity to fish

-LC50 (Danio rerio (zebra fish)): 106 mg/l

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 112 mg/l  
 Exposure time: 48 H  
 Method: OECD Test Guideline 202

Toxicity to algae

EC50 (green algae): 780 mg/l  
 Exposure time: 72 H  
 Method: OECD Test Guideline 201

**Persistence, degradability & Persistence:**

Biodegradability - Not rapidly degradable.  
 This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher

**Bioaccumulative potential:**

The substance is essentially insoluble in water. The substance has low potential for bioaccumulation.

**Mobility in Soil:**

No information available on this substance.

**Other adverse effects:**

No data available.

**13. DISPOSAL CONSIDERATIONS**

**Safe handling and disposal methods:**

Dispose substance in accordance with prevailing country, federal, state and local regulations.

This material and its container must be disposed of as hazardous waste.

**Disposal of any contaminated packaging:**

Waste, even small quantities, should never be poured down drains, sewers or water courses.  
 Solvent residues must not be allowed to enter drains, sewers or watercourses or to contaminate the ground.  
 Dispose of contents/ container to an approved incineration plant.

**Environmental regulations:**

No data available.

**14. TRANSPORT INFORMATION**

**UN number:** Not classified as dangerous in the meaning of transport regulations.

**15. REGULATORY INFORMATION**

**Safety, health and environmental regulations specific for the product in question** No safety, health and environmental regulations

**Poisons Schedule Number:** (S2) Pharmacy Medicine

**16. OTHER INFORMATION**

**Date of preparation or review:** 15<sup>th</sup> June 2021

**Key abbreviations or acronyms used** CAS No. = Chemical Abstracts Service Number  
LD= Lethal Dose  
EC50= Effective concentration  
TWA= time-weighted average

**DISCLAIMER**

The information contained herein forms no part of any contract between Aspen and any other party. The information is supplied by Aspen in good faith and is believed by Aspen to be correct, but Aspen makes no representations or warranties as to its correctness or completeness, or to the degree of care or skill used in its creation and compilation. Persons using the information will have to make their own decisions, prior to using the information, as to its suitability for their purposes. Aspen accepts no legal liability for the reliance on the information.

Aspen Pharmacare Australia Pty Ltd  
ABN: 51 096 236 985  
34-35 Chandos Street, St Leonards NSW 2065  
Phone (61 2)84368300 ~ Fax: (61 2) 9437 0081  
Email: [aspen@aspenpharmacare.com.au](mailto:aspen@aspenpharmacare.com.au)  
Web: [www.aspenpharma.com.au](http://www.aspenpharma.com.au)