Aspen Pharmacare Australia Pty Ltd
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SAFETY DATA SHEET

XYLOCAINE Injections with ADRENALINE

Issue Date:	May 2021
Sponsor:	Aspen Pharmacare Australia Pty Ltd
Address:	34-36 Chandos street, St Leonards, NSW, 2065
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1. IDENTIFICATION OF THE MATERIAL

Product Identifier: XYLOCAINE lidocaine with adrenaline

Other means of identification: Lignocaine

Aspen product code/s:

AS-07670	XYLOCAINE 2% ADRENALINE 1:200K 5X20ML
AS-07591	XYLOCAINE 2% ADRENALINE 1:80K 10X5ML
AS-07590	XYLOCAINE 1% ADRENALINE 1:100K 10X5ML
AS-07671	XYLOCAINE 1% ADRENALINE 1:200K 5X20ML
AS-07674	XYLOCAINE 0.5% ADRENALINE 1:200K 5X20ML

Recommended Use: Local anaesthetic solution for use in infiltration anaesthesia, intravenous regional anaesthesia and nerve blocks.

NOTE: 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/consumers 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: Not classified as a hazardous substance or mixture

Label Elements, including precautionary statements: Not a hazardous substance or mixture

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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.

3. COMPOSITION

Chemical Ingredient	CAS No.	%
Lidocaine hydrochloride monohydrate	6108-05-0	Low
Adrenaline acid tartrate	51-42-3	Low
Excipients	Unassigned	High

Concentration Guide: Low (below 10%) Medium (10 to 60%) High (above 60%)

4. FIRST AID MEASURES

In case of Skin Contact: Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.

In case of Eye: Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.

In case of 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: May cause reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

Medical attention and special treatment: Provide general supportive measures and treat symptomatically. Symptoms may be delayed. No specific antidotes are recommended. Treat according to locally accepted protocols.

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5. FIRE FIGHTING MEASURES

Suitable extinguishing media : Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Special hazards arising from the substance or mixture: If involved in a fire, product may emit noxious and toxic fumes.

Advice for firefighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Move containers from fire area if you can do so without risk.

Consider accelerants and the risk of other materials involved in the fire.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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. Ensure adequate ventilation during clean-up activities.

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

Methods and materials for containment and cleaning up: Stop the flow of material, if this is without. Contain the spill area and collect spill material in an appropriate container. Prevent entry into waterways, sewer, basements or confined areas.

Following product recovery, wash the spill area with soap and water.

7. HANDLING AND STORAGE

Precautions for safe handling : Avoid contact with skin and eyes. Avoid inhalation of vapour/mist. Ensure adequate ventilation during usage. Wear personal protective equipment appropriate for the handling activity. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities :	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Do not freeze. Store away from incompatible materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters – Exposure standards, biological monitoring :	No biological exposure limits established for the mixture.
Engineering 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.
Personal protective equipment	
Eye protection:	None required for general handling. Wear safety glasses during spill clean-up or if risk of direct eye contact is present.
Hand protection:	None required for general handling. Wear suitable chemical resistant gloves during spill clean-up or if risk of direct skin contact is present.
Skin and body protection:	Impervious clothing and enclosed footwear must be work at all times when handling the product.

9. PHYSICAL & CHEMICAL PROPERTIES

Description of appearance (physical form, colour, shape):	Colourless aqueous solution
Odour:	No data available.
Odour threshold:	No data available.
pH:	3.3 – 5.0
Melting point/range:	No data available.
Boiling point/range:	No data available.
Flash point:	Not applicable.
Evaporation rate:	No data available.
Flammability:	Not applicable.
Upper/lower flammability or explosive limits:	Not applicable.

Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	No data available.
Solubility (ies):	Water miscible – product form is aqueous solution.
Partition coefficient: n-octanol/ water:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Specific heat value:	No data available.
Particle size:	Not applicable.
Volatile organic compounds content:	No data available.
% Volatile:	No data available.
Saturated vapour concentration:	No data available.
Release of invisible flammable vapour and gases:	Not applicable.

10. STABILITY AND REACTIVITY

Reactivity:	No known reactivity hazard under normal conditions.
Chemical stability:	Material is stable under normal conditions.
Conditions to avoid:	No dangerous reaction known under conditions of normal use.
Incompatible material and possible hazardous reactions:	None known at the time of writing.
Hazardous decomposition products:	No hazardous decomposition product are known.

11. TOXICOLOGICAL INFORMATION

Information on routes of exposure:	**Ingestion:** Remarks: Low acute oral toxicity. **Inhalation:** Remarks: May cause effects as described under single exposure. **Skin contact:** No empirical data available. **Eye contact:** Direct contact with eyes may cause temporary irritation.

Symptoms related to exposure:	May cause reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness. May cause tingling/numbness in exposed areas (paraesthesia).
Numerical measures of toxicity:	**Acute toxicity:** Active Ingredient: Lidocaine hydrochloride LD50 Oral (Rat): 159 - 773 mg/kg
Immediate, delayed and chronic health effects from exposure:	May cause excessive watering of the eye (lachrymation). May cause numbness at exposure site. Repeated and/or prolonged contact may cause skin sensitisation in a small proportion of sensitive individuals.
Exposure levels:	No data available.
Interactive effects:	No data available.
Data limitations:	No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:	This product has no known ecotoxicological effects.
Persistence , degradability & Persistence:	Not rapidly degradable.
Bioaccumulative potential:	The substance has low potential for bioaccumulation. 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.
Mobility in Soil:	No data available.
Other adverse effects :	No data available.

13. DISPOSAL CONSIDERATIONS

Safe handling and disposal methods:	Spill clean-up and expired stock should be collected in appropriate waste containers and disposed of at an appropriate chemical waste disposal plant.
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:	None known.

14. TRANSPORT INFORMATION

UN number:	Not classified as dangerous in the meaning of transport regulations.
UN Proper Shipping name:	Unknown.
Transport hazard class:	Not applicable.
Packing Group:	Not applicable.
Environmental hazards:	Not considered hazardous to the environment.
Special precautions during transport:	Not applicable.
Hazchem code:	Not applicable.

15. REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product in question	None at the time of writing.
Poisons Schedule Number:	(S4) Prescription Only Medicine

16. OTHER INFORMATION

Date of preparation or review	May 2021
Key abbreviations or acronyms used	CAS No. = Chemical Abstracts Service Number LD= Lethal Dose

DISCLAIMER

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