Aspen Pharmacare Australia Pty Ltd
ABN: 51 096 236 985
34-36 Chandos Street, St Leonards NSW 2065
Phone: (61 2) 8436 8300 ~ Fax: (61 2) 9437 0081
Email: aspen@aspenpharmacare.com.au
Web: www.aspenpharma.com.au

SAFETY DATA SHEET

XYLOCAINE VISCOUS lidocaine (lignocaine) hydrochloride 2% oral liquid bottle

Issue Date:	18th November 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 VISCOUS 2% Oral Liquid
Other means of identification:	N/A
Aspen product code/s:	07666 – XYLOCAINE 2% VISCOUS SOLUTION 200ML BOTTLE
Recommended Use:	Indicated for the relief of pain & discomfort associated with: - irritated or inflamed mucous membranes of the mouth, - pharynx and upper gastrointestinal tract, e.g. post-tonsillectomy sore throat, dumping syndrome; - introduction of instruments and catheters into the respiratory and gastrointestinal tract.
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 a hazardous substance or mixture
Hazard Information:	Not a hazardous substance or mixture
Label Elements, including precautionary statements:	Not a hazardous substance or mixture P210 - Keep away from flames and hot surfaces. No smoking. P280 - Wear protective gloves/eye protection/ face protection.

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P370 + P378 - In case of fire: Use water, carbon dioxide, dry + chemical or foam as necessary to extinguish.

P403 + P235 - Store in a well-ventilated place. Keep cool.

P501 - Dispose of contents/container in accordance with local/regional/national/ international regulations

Other hazards which do not result in classification: May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness. (See Section 11.)

3. COMPOSITION

Chemical Ingredient	CAS No.	%
Lidocaine hydrochloride monohydrate	6108-05-0	Low
Excipients	Proprietary	Low

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

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. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that

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	medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves. Obtain medical attention if ill effects occur.
Symptoms caused by exposure:	Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions. WARNING: Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in the package insert. OVERDOSAGE: Acute emergencies from local anaesthetics are generally related to high plasma levels encountered during therapeutic use of local anaesthetics. See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS. SHAKE WELL BEFORE USE.
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 (CO2).
Special hazards arising from the substance or mixture:	If involved in a fire, it may 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:	Ensure suitable personal protection during removal of spill. For personal protection see section 8.
Environmental precautions:	Prevent entry into drains, sewers or watercourses.
Methods and materials for containment and cleaning up:	Contain spill area if safe to do so. Wash the spill area clean with water and detergent.

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7. HANDLING AND STORAGE

Precautions for safe handling:

Avoid contact with skin and eyes.

Handle in accordance with product label and/or product insert information.

Handle in accordance with good industrial hygiene and safety practices.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed.

Store at the recommended storage conditions on the packaging.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters – Exposure standards, biological monitoring:

Occupational Exposure Limit for Lidocaine hydrochloride monohydrate:

TWA (Time weighted average) – 0.05mg/m^3

Engineering controls:

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.

Personal protective equipment

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.

Respiratory protection:

Where necessary, 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 and body 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.

Protective Measures:

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

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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

Description of appearance (physical form, colour, shape):	A clear, red, viscous liquid with an odour of cherries
Odour:	Cherries
pH:	6.2 – 6.6

10. STABILITY AND REACTIVITY

Reactivity:	No known reactivity hazard under normal conditions.
Chemical stability:	Stable under normal conditions.
Conditions to avoid:	No conditions producing hazardous situations known.
Incompatible material and possible hazardous reactions:	None known.
Hazardous decomposition products:	No hazardous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Information on routes of exposure:	**Ingestion:** No data available. **Inhalation:** Inhalation of mist may cause slight irritation and transient numbness to nose and throat, dizziness, and drowsiness. While unlikely with this formulation,

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overexposure may cause toxic effects on the central nervous system and cardiovascular system.

Eye contact: Local anaesthetics applied to the cornea may cause transient stinging, then numbness and loss of sensation. Local anaesthesia suppresses automatic blinking and allows abnormal drying of the cornea.

Skin Contact: No dermal LD50 value was available. Lidocaine can be absorbed through broken or diseased skin. Skin reactions after topical administration include transient blanching, paleness, redness, and dermal analgesia.

Symptoms related to exposure:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

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_{50}	317 mg/kg
Mouse 2	Oral	LD_{50}	20,292 mg/kg
Mouse	Intravenous	LD_{50}	22 mg/kg
Mouse	Intramuscular	LD_{50}	260 mg/kg
Mouse	Intraperitoneal	LD_{50}	119 mg/kg
Rat	Subcutaneous	LD_{50}	570 mg/kg
Mouse	Subcutaneous	LD_{50}	285 mg/kg

Immediate, delayed and chronic health effects from exposure:

Germ cell mutagenicity: Not classified based on available information.

Reproductive toxicity: Not classified based on available information.

Carcinogenicity: Not classified based on available information.

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.

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Interactive effects: No data available

Data limitations: No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity: This product formulation has not been extensively studied for ecotoxicological effects.

Lidocaine hydrochloride monohydrate:
Toxicity to fish - LC50 (Danio rerio (zebra fish)): 106 mg/l

Exposure time: 96 H
Method: OECD Test Guideline 203
Remarks: Low toxicity to aquatic organisms.

EC50 ((microtox test)): > 1,000 mg/l
Exposure time: 15 MIN

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.

Bioaccumulative potential: 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 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.

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Disposal of any contaminated packaging:	Empty container will retain product residue. Observe all hazard precautions.
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:	17th November 2021
Key abbreviations or acronyms used:	CAS No. = Chemical Abstracts Service Number LD= Lethal Dose EC50= Effective concentration TWA= time-weighted average OEL= Occupational Exposure Limits

DISCLAIMER

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