

SAFETY DATA SHEET**XYLOCAINE_ lidocaine (lignocaine) hydrochloride 2% Jelly**

Issue Date: 15th June 2021
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1. IDENTIFICATION OF THE MATERIAL

Product Identifier: XYLOCAINE 2% Jelly 30g Tube
Other means of identification: N/A
Aspen product code/s: 07593 – Xylocaine 2% Jelly 30g Tube
Recommended Use: Surface anaesthesia and lubrication:
- of the male and female urethra during cystoscopy, catheterisation, exploration by sound and other endourethral operations,
- of nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy,
- during proctoscopy and rectoscopy,
- during intubation
- for the relief of pain after circumcision in children.
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

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	0.2
Excipients	Proprietary	0.3
<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 ₂).
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.
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. Transfer to a container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling:	Avoid contact with skin and eyes.
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: 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 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):	Clear to almost clear, slightly coloured, highly viscous liquid gel.
Odour:	Odourless
Odour threshold:	No data available
pH:	6.2 – 6.8

Melting point/range:	No data available
Boiling point/range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Solubility (ies):	No data available
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:	No data available
Volatile organic compounds content:	No data available
% Volatile:	No data available
Saturated vapour concentration:	No data available
Release of invisible flammable vapour and gases:	No data available

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, 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.
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: <u>Toxicity to fish</u> - 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 <u>Toxicity to daphnia and other aquatic invertebrates</u> EC50 (Daphnia magna (Water flea)): 112 mg/l Exposure time: 48 H Method: OECD Test Guideline 202 <u>Toxicity to algae</u> EC50 (green algae): 780 mg/l Exposure time: 72 H Method: OECD Test Guideline 201 Biodegradability - Not rapidly degradable.
Persistence, degradability & Persistence:	
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.

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: 11th June 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

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