

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

XYLOCAINE SOLUTION FOR INJECTIONS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names

Lidocaine solution for injections

CAS No. : Not applicable
Use : Local anaesthetic solution for use in infiltration anaesthesia, intravenous regional anaesthesia and nerve blocks.

2. HAZARDS IDENTIFICATION

This mixture is not classified as hazardous for supply/use according to GHS v 4.0. May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
Lidocaine hydrochloride monohydrate	2	6108-05-0		
		Hazard class [#]	Category	Hazard statements [#]
		Acute toxicity	3	H301

[#] Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Wash skin with soap and water.
Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable)	:	water spray, foam, dry powder or CO ₂ .
Extinguishing Media (unsuitable)	:	-
Special hazards arising from the substance or mixture	:	If involved in a fire, it may emit noxious and toxic fumes.
Special protective actions for fire-fighters	:	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 spillages. See Section 8. Ensure adequate ventilation.
Environmental Precautions	:	Prevent entry into drains.
Methods and material for containment and cleaning up	:	Clear up spillages. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Avoid contact with skin and eyes. Avoid inhalation of vapour/mist.
Conditions for safe storage, including any incompatibilities	:	Keep container tightly closed. Protect from light. Do not freeze.
Specific end use(s)	:	Storage temperature : < 25 °C Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Lidocaine hydrochloride	1 mg/m ³	LTEL 8hr TWA	COM
Lidocaine hydrochloride	5 mg/m ³	STEL 15min	COM

Exposure 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.

Occupational exposure controls

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.

The information below 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.

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 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Form	:	liquid
Colour	:	clear aqueous solution
Odour	:	odourless
pH	:	6,5
Boiling Point	:	100 °C approx
Vapour Pressure	:	17 mmHg 20 °C
Solubility (Water)	:	soluble
Specific Gravity	:	1,00 approx
Vapour Density	:	0,600

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

The following information refers to Lidocaine hydrochloride: The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation	:	No information available on acute toxicity. May cause effects as described under single exposure.(STOT)
Skin Contact	:	May cause numbness.
Eye Contact	:	May cause excessive watering of the eye (lachrymation).
Ingestion	:	Harmful if swallowed. Oral Median Lethal Dose (rat) 159 - 324 mg/kg May cause effects as described under single exposure.(STOT)
Specific Target Organ Toxicity (STOT)	:	Single exposure Exposure routes: 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. Exposure routes: Oral

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

Repeated exposure

Repeated exposure of animals to high levels produces adverse effects on the liver and central nervous system.

- Sensitisation : Repeated and/or prolonged contact may cause skin sensitisation in a small proportion of sensitive individuals.
- Carcinogenicity : No information available on this substance.
- Mutagenicity : The substance is not considered to be genotoxic.
- Reproductive toxicity : There is no evidence of teratogenicity or embryotoxicity.

12. ECOLOGICAL INFORMATION

The following information refers to active ingredient:

- Toxicity : Low toxicity to aquatic organisms.
EC50 green algae 72 H 780 mg/l
EC50 Daphnia magna 48 H 112 mg/l
LC50 Zebra Fish 96 H 106 mg/l
LC50 (microtox test) 15 MIN > 1 000 mg/l
- Effect on Effluent Treatment : No information available.
- Persistence and degradability : Not rapidly degradable.
- Bioaccumulative potential : The substance has low potential for bioaccumulation.
- Mobility in soil : Water solubility ≥ 1 mg/l.
- Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

- Waste treatment methods : Disposal should be in accordance with local, state or national legislation.
- Contaminated Packaging : Empty container will retain residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements H301 : Toxic if swallowed.

The following sections contain revisions or new statements :

The Safety Data Sheet has been updated to adhere to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)., This update affects most Sections of the Safety Data Sheet.

GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.