

SAFETY DATA SHEET**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****Product identifier****XYLOCAINE SOLUTION FOR ORAL PUMP SPRAY**

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Alternative Names

Xylocaine oral pump spray
Lidocaine spray
Lignocaine spray
Xylocaine spray

CAS No. : Not applicable
Use : topical anaesthetic

2. HAZARDS IDENTIFICATION**Classification of the substance or mixture**

Classification UN GHS		
Hazard class	Category	Hazard statements
Flammable liquids	3	H226
Acute toxicity	5	H303
		# Refer to Section 16 'Other Information'

Label elements	
Signal word Warning	
Hazard statements	
H226	: Flammable liquid and vapour.
H303	: May be harmful if swallowed.

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233	Keep container tightly closed.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P312	: Call a POISON CENTER or doctor/ physician if you feel unwell.
P370 + P378	: In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
P501	: Dispose of contents/ container to an approved incineration plant.

Other hazards

May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness. May cause eye irritation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
Lidocaine	10	137-58-6		
		Hazard class #	Category	Hazard statements #
		Acute toxicity	4	H302
Component	%	CAS No.		
Ethanol	24	64-17-5		
		Hazard class #	Category	Hazard statements #
		Flammable liquids	2	H225

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

- Inhalation : Remove patient from exposure. Obtain medical attention.
- 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.

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) : foam, CO2 or dry powder. Water spray should be used to cool containers.
- Extinguishing Media (unsuitable) : Do NOT use 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.
- 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 : Eliminate all ignition sources if safe to do so. Ensure suitable personal protection during removal of spillages. See Section 8.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses.
- Methods and material 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

- Precautions for safe handling : 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.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed, in a cool, well ventilated place.
- Specific end use(s) : Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Lidocaine	1 mg/m ³	LTEL 8hr TWA	COM
Lidocaine	5 mg/m ³	STEL 15min	COM
Ethanol	1000 ppm 1 880 mg/m ³	LTEL 8hr TWA	TLV

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.

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	:	almost colourless to pale yellow
Odour	:	fruit-like
Flash Point	:	27 - 32 °C
Density	:	1,004 g/cm ³ 20 °C
Solubility (Water)	:	soluble

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	:	Reacts vigorously with oxidising agents. Reacts with strong acids.

- Conditions to avoid : No conditions producing hazardous situations known.
- Incompatible materials : Strong acids and oxidizing agents
- Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

This 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.
Repeated or prolonged contact may cause defatting of the skin resulting in dryness, cracking and dermatitis.
- Eye Contact : The vapour and liquid are irritant.
Permanent damage is unlikely.
May cause strong stinging and burning sensation.
- Ingestion : May be harmful if swallowed.
- Specific Target Organ Toxicity (STOT) : **Single exposure**
Exposure routes: Inhalation
May cause tingling/numbness in exposed areas (paraesthesia), 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: Ingestion
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 : May cause skin sensitisation in rare cases.
- Carcinogenicity : No information available.
- Mutagenicity : This material is not considered to be genotoxic.
- Reproductive toxicity : The material is not considered to be a reproductive risk to human.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to Lidocaine hydrochloride monohydrate

- Toxicity : EC50 green algae 72 H 780 mg/l
EC50 Daphnia magna 48 H 112 mg/l
LC50 Zebra Fish 96 H 106 mg/l
EC50 (microtoxtest) 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 : The substance is essentially insoluble in water.
- Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

- Waste treatment methods : Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.
- Contaminated Packaging : Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

ICAO/IATA

- UN No. : 1170
- Proper Shipping Name : Ethanol solution
- Class : 3
- Packing Group : III

IMO/MDG

- UN No. : 1170
- Proper Shipping Name : ETHANOL SOLUTION
- Class : 3
- Packing Group : III
- Marine pollutant : Not classified as a Marine Pollutant

ADR

- UN No. : 1170
- Proper Shipping Name : ETHANOL SOLUTION
- Class : 3
- Label(s) : 3
- Packing Group : III

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard statements H225 : Highly flammable liquid and vapour.
 H226 : Flammable liquid and vapour.
 H302 : Harmful if swallowed.
 H303 : May be harmful if swallowed.

The following sections contain revisions or new statements :

Minor changes: 2, 11, 13

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.