

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Lidocaine Hydrochloride Topical Solution 4%

1.2. Recommended use

Use of the substance/mixture : Drug (Local Anesthetic - Topical)

1.3. Details of the supplier of the safety data sheet

Xttrium Laboratories, Inc.
1200 East Business Center Drive
Mt. Prospect, IL 60056

1.4. Emergency telephone number

Emergency number : 773-268-5800

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Physical hazards :Not classified.
Health hazards :Not classified.
OSHA defined hazards :Not classified.

2.2. Label elements

GHS-US labeling Hazard

pictograms : None.
Signal word : None.
Hazard statement : The mixture does not meet the criteria for classification.
This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement
Prevention : Observe good industrial hygiene practices.
Response : Wash hands after handling.
Storage : Store away from incompatible materials.
Disposal : Dispose of waste and residues in accordance with local authority requirements.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Mixture

Active Ingredient : Lidocaine Hydrochloride 4%

3.2. Composition

Name	Product identifier	%	
Purified Water	(CAS No) 7732-18-5	Trade Secret	
Propylene Glycol	(CAS No) 57-55-6	Trade Secret	
Methyl Paraben	(CAS No) 99-76-3	Trade Secret	

It may also contain Sodium Hydrochloride for pH adjustment.

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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develops or persists.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists
Ingestion	Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation. Prolonged skin contact may cause temporary irritation.

If used as a drug:

Side Effects may include any of the following: rash, hives, swelling or abnormal sensation at the site of application.

Possible Adverse Effects: chest tightness, shortness of breath, wheezing, swelling of the eyelids, face or lips, stuffy nose, itching, rash.

Symptoms of Overdose: blurred or double vision, confusion, numb, twitching, vomiting, dizziness, trouble breathing, restlessness, tiredness.

4.3. Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	: Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk.

5.4. Advice for firefighters

Use standard firefighting procedures and consider the hazards of other involved materials. The product is not flammable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Applies only to the product when used in an industrial setting.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Observe good industrial hygiene practices. Use care in handling/storage. Do not use in areas without adequate ventilation. Avoid inhalation and contact with skin and eyes. Wash thoroughly after handling. Avoid release to the environment. Always follow the advice of your physician while using this drug.

7.2. Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in light resistant containers. Storage temperature: between 15 and 30°C. Protect from heat and direct sunlight. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

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SECTION 8: Exposure controls/personal protection

8.1. Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

8.2. Individual protection measures, such as personal protective equipment

Hand protection : No specific hand protection noted, but gloves may still be advisable.

Eye protection : None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended.

Skin and body protection : None required for consumer use.

Respiratory protection : None required for consumer use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless.
Odor	: Odorless
Odor threshold	: No data available
pH	: 5.00 - 7.00
Relative evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Specific gravity	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Material is stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

Contact with incompatible materials. Exposure to light. Excessive heat.

10.5. Incompatible materials

Strong oxidizing agents.

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10.6. Hazardous decomposition products

No hazardous decomposition product are known.

SECTION 11: Toxicological information

11.1. Information on likely routes of exposure

- Inhalation : Not expected to be hazardous in final pharmaceutical form.
- Skin contact : Contact will cause localized anesthesia.
- Eye contact : Direct eye contact with local anesthetics may reduce sensation in the eyes and increase the risk of injury due to foreign bodies. There may be drying of the cornea, a burning sensation, excessive tears, sensitivity to light, swelling and redness of the conjunctiva and increased blinking.
- Ingestion : Accidental ingestion of the material may be harmful. Systemic toxicity due to local anesthetics may be manifested by yawning, restlessness, excitement, ringing sound in the ear, nausea and vomiting. Early warning signs are numbness of the tongue and around the mouth region. However, ingestion is not likely to be a primary route of occupational exposure

11.2. Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Prolonged skin contact may cause temporary irritation.

If used as a drug:

Side Effects may include any of the following: rash, hives, swelling or abnormal sensation at the site of application.

Possible Adverse Effects: chest tightness, shortness of breath, wheezing, swelling of the eyelids, face or lips, stuffy nose, itching, rash.

Symptoms of Overdose: blurred or double vision, confusion, numb, twitching, vomiting, dizziness, trouble breathing, restlessness, tiredness.

11.3. Information on toxicological effects

- Acute toxicity : Not expected to be acutely toxic.
- Skin corrosion/irritation : Prolonged skin contact may cause temporary irritation.
- Serious eye damage/eye irritation : Direct contact with eyes may cause temporary irritation.
- Respiratory or skin sensitization
- Respiratory sensitization : Not a respiratory sensitizer.
- Skin sensitization : Not classified as a sensitizer.
- Germ cell mutagenicity : No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
- Carcinogenicity : This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

SECTION 12: Ecological information

12.1. Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2. Persistence and degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential

No data available on bioaccumulation.

12.4. Mobility in soil

This product is water soluble and may disperse in soil.

12.5. Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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SECTION 13: Disposal considerations

13.1. Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

13.2. Local disposal regulations

Dispose in accordance with all applicable regulations.

13.3. Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

SECTION 14: Transport information

DOT Not regulated as dangerous goods.

IMDG Not regulated as dangerous goods.

IATA Not regulated as dangerous goods.

SECTION 15: Regulatory information

15.1. US Federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

This product is exempt from the TSCA Inventory. It is regulated by the FDA.

OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

15.2. Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated.

15.3. US State regulations

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

SECTION 16: Other information

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.