SDS: Lidocaine Hydrochloride Oral Topical Solution, USP 2% (Viscous)

SAFETY DATA SHEET

1. Identification

Product Identifier:	Lidocaine Hydrochloride Oral Topical Solution, USP 2% (Viscous)
Synonyms:	Lignocaine
National Drug Code (NDC):	50383-775-04 50383-775-17
Recommended Use:	Pharmaceutical.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards:	Combustible liquid	Category 4
Health Hazards:	Not classifiable.	
Symbol(s):	None.	
Signal Word:	Warning.	
Hazard Statement(s):	H227	Combustible liquid.
Precautionary Statement(s):	P210	Keep away from flames and hot surfaces. No smoking.
	P280	Wear protective gloves/eye protection/ face protection.
	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.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	137-58-6-USP	Lignocaine	$C_{14}H_{22}N_2O$	234.34	2%

*The formula also contains Carboxymethylcellulose Sodium, Methylparaben, Natural Orange Flavor, Propylparaben, Purified Water, and Saccharin Sodium. The pH is adjusted to 5.0 – 7.0 by means of Hydrochloric Acid and/or Sodium Hydroxide.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of 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 medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.

Medical Conditions Aggravated by Exposure:	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 this package insert.
Other Health Warnings:	OVERDOSAGE: Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS. SHAKE WELL BEFORE USE.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or foam as necessary.
Unsuitable Extinguishing Media:	With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	None.
Other Specific Hazards:	Not determined.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Pick up in the most efficient manner. Soak up with sawdust, sand oil dry or other absorbent material.
Environmental Precautions:	No data available.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: 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 between 59°F – 86°F in a cool, dry, well-ventilated place. Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Lidocaine Hydrochloride	Not established.

Engineering Controls: Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Clear, viscous solution.
Odor: No data available.
Odor Threshold: No data available.
pH: 5.0 – 7.0.
Melting Point: No data available.
Freezing Point: No data available.

Boiling Point:	No data available.
Flash Point:	>150°F.
Evaporation Rate:	Same as water.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	>1.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	Will not occur.
Chemical Stability:	Stable under recommended storage conditions. Avoid sources of ignition.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizer.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	Harmful if swallowed.
Skin Contact:	No data available.
Eye Contact:	No data available.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.

Acute Toxicity – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	Not listed.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

California Proposition 65:	Not listed.

16. Other Information

NFPA Rating:

Health:	1
Flammability:	1
Reactivity:	0

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