

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Lidocaine Hydrochloride Jelly, USP 2%

Synonyms: Lignocaine

National Drug Code (NDC): 17478-711-10
17478-711-30

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: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	137-58-6	Lignocaine	C ₁₄ H ₂₂ N ₂ O•HCl	270.80	2%

*The formula also contains Methylparaben, Propylparaben, Hypromellose, and Sodium Hydroxide and/or Hydrochloric Acid to adjust pH between 6.0 – 7.0.

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:	Effects noted after toxic doses include lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, blurred or double vision, hearing disturbances, cardiovascular depression, and slow heart rate. Nausea, vomiting, and abdominal discomfort may occur after ingestion. Massive over dosage can cause convulsions or seizures, cardiovascular and respiratory collapse, and heart stoppage. Lidocaine and the paraben preservatives may cause allergic reactions in susceptible individuals. Lidocaine can cause methemoglobinemia in susceptible individuals. Since it is a local anesthetic, contact with the eyes or skin may cause temporary loss of feeling or sensation and transient blanching of the skin. Inhalation and ingestion of excessive amounts may result in toxic effects on the central and nervous system and cardiovascular system.

Medical Conditions Aggravated by Exposure:

Known hypersensitivity to lidocaine or local anesthetics of the amide-type, methyl- or Propylparaben, saccharin; impaired liver, kidney, or cardiovascular function; heart disease (congestive heart failure or heart block).

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

Oxides of carbon, nitrogen, and sulfur.

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:

Use caution when handling spilled material using appropriate protective equipment. Small spills may be absorbed with a disposable towel; larger spills may require use of an appropriate vacuum cleaner designed for drug disposal. Carefully collect and place in a suitable, properly labeled container for disposal. Clean area using soap and water.

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:

Do not get on eyes, skin and clothing. Do not smell or taste chemicals. Do not breathe mist. Do not eat, drink, or smoke in areas where chemicals are present. Wash thoroughly after handling. Contaminated clothing should be laundered before reuse. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

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Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizing agents and acids.

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: 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: Not required for the normal use of this product. 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: Not required for the normal use of this product. Chemically compatible gloves. 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: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Clear to opalescent, colorless to slightly colored, colloidal jelly.

Odor: No data available.

Odor Threshold: No data available.

pH: 6.0 – 7.0.

Melting Point: No data available.

Freezing Point: No data available.

Boiling Point: No data available.

Flash Point: No data available.

Evaporation Rate: No data available.

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:	No data available.
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:	Incompatible with water reactive materials.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	When heated to decomposition, product may emit oxides of carbon, nitrogen and sulfur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

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.
Ingestion:	No data available.
Skin Contact:	No dermal LD ₅₀ 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.
Eye Contact:	Local anesthetics applied to the cornea may cause transient stinging, then numbness and loss of sensation. Local anesthesia suppresses automatic blinking and allows abnormal drying of the cornea.
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.

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Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Lidocaine Hydrochloride	Rat	Oral	LD ₅₀	317 mg/kg
Lidocaine Hydrochloride	Mouse 2	Oral	LD ₅₀	20,292 mg/kg
Lidocaine Hydrochloride	Mouse	Intravenous	LD ₅₀	22 mg/kg
Lidocaine Hydrochloride	Mouse	Intramuscular	LD ₅₀	260 mg/kg
Lidocaine Hydrochloride	Mouse	Intraperitoneal	LD ₅₀	119 mg/kg
Lidocaine Hydrochloride	Rat	Subcutaneous	LD ₅₀	570 mg/kg
Lidocaine Hydrochloride	Mouse	Subcutaneous	LD ₅₀	285 mg/kg

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:

Allergic reactions are rare, but may occur in individuals hypersensitive to lidocaine, other amide-type local anesthetics, the preservatives, methyl- or propylparaben, or to other ingredients in the formulation. Allergic reactions are characterized by skin lesions, hives, edema, or anaphylactoid reactions.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Reproductive Effects:

Pregnancy Category B. Studies to evaluate the effects on fertility in humans have not been conducted. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well controlled studies in pregnant women. Animal reproductive studies are not always predictive of human response. Lidocaine is not contraindicated in labor and delivery. Lidocaine rapidly crosses the placenta in animal models and high doses may affect fetal heart rate. Lidocaine is distributed into human milk.

Carcinogenicity:

No long term studies in animals have been conducted to evaluate the carcinogenic potential of lidocaine. Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals. Rats, in a two-year oral toxicity study with 2,6-xylidine (lidocaine metabolite) at 15, 50, and 150 mg/kg/day developed carcinomas, adenomas, and rhabdomyosarcomas, in the nasal cavity, subcutaneous fibromas and/or fibrosarcomas, and neoplastic nodules of the liver at the high dose level.

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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: Studies to evaluate the mutagenic potential of lidocaine base have not been performed. Lidocaine hydrochloride tested negative in the Ames, human lymphocyte chromosomal aberration, and in vivo mouse micronucleus assays. Mixed results have been noted in mutagenicity studies with the metabolite, 2, 6-xylidine.

Aspiration Hazard: Based on available data, the classification criteria are not met.

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**

Not made with natural rubber latex.

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