

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078948724

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078357610



# SAFETY DATA SHEET

## Lidocaine Hydrochloride Jelly, USP 2%

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Lidocaine Hydrochloride Jelly, USP 2%
<b>Synonyms:</b>	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride
<b>National Drug Code (NDC):</b>	17478-711-10 17478-711-30 17478-711-31
<b>Recommended Use:</b>	Lidocaine Hydrochloride Jelly, USP 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classified.
<b>Health Hazards:</b>	Not classified.
<b>Symbol(s):</b>	None.
<b>Signal Word:</b>	None.
<b>Hazard Statement(s):</b>	None.
<b>Precautionary Statement(s):</b>	None.
<b>Hazards Not Otherwise Classified:</b>	None.
<b>Supplementary Information:</b>	While this material is not classifiable as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200), 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.

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#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride	6108-05-0	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> 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 to 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:**

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. Systemic absorption can

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produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

#### Medical Conditions Aggravated by Exposure:

As with all pharmaceuticals, hypersensitivity is possible.

#### Notes to Physician:

Treat supportively and symptomatically. 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 the package insert. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs.

## 5. FIREFIGHTING MEASURES

#### Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or foam as necessary.

#### Unsuitable Extinguishing Media:

Not determined.

#### Specific Hazards Arising from the Chemical

#### Hazardous Combustion Products:

Oxides of carbon, nitrogen, and sulfur.

#### Other Specific Hazards: Special Protective Equipment and Precautions for Firefighters:

Not determined.

Wear self-contained breathing apparatus and full and protective gear.

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
<b>Environmental Precautions:</b>	Contain material and prevent release to basements, confined spaces, waterways or soil.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature.
<b>Specific End Use:</b>	Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Occupational Exposure Guidelines:

<b>Ingredient</b>	<b>Type</b>	<b>Value</b>
Lidocaine Hydrochloride	Not established	Not established

<b>Engineering Controls:</b>	None required for the normal use of this product.
<b>Respiratory Protection:</b>	None required for the normal use of this product.
<b>Eyes Protection:</b>	None required for the normal use of this product.
<b>Hand Protection:</b>	None required for the normal use of this product.
<b>Skin Protection:</b>	None required for the normal use of this product.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Clear to opalescent, colorless to slightly colored, colloidal jelly.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	6.0 to 7.0.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

#### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Contact with incompatible materials.
<b>Incompatible Materials:</b>	No data available.
<b>Hazardous Decomposition Products:</b>	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

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### 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:** 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.

**Delayed and Immediate Effects of Exposure:** No data available.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Lidocaine Hydrochloride	Mouse	Oral	LD <sub>50</sub>	292 mg/kg
	Rat	Oral	LD <sub>50</sub>	159-324 mg/kg

#### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

#### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

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### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Lidocaine Hydrochloride	Ames Test	S. typhimurium and E. coli	Negative
	Chromosomal aberration assay	Human lymphocytes	Negative
	<i>In Vivo</i> micronucleus assay	Mouse	Negative

<b>Aspiration Hazard:</b>	None anticipated from normal handling of this product.
<b>Toxicokinetics/Metabolism:</b>	See package insert for more information.
<b>Target Organ Effects:</b>	Based on clinical use, possible target organs include the nervous system and cardiovascular system.
<b>Reproductive Effects:</b>	Pregnancy Category B. 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.
<b>Carcinogenicity:</b>	Studies of Lidocaine in animals to evaluate the carcinogenic potential have not been conducted.
<b>National Toxicology Program (NTP):</b>	Not considered to be a carcinogen.
<b>International Agency for Research on Cancer (IARC):</b>	Not considered to be a carcinogen.
<b>Occupational Safety and Health Administration (OSHA):</b>	Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Lidocaine Hydrochloride	Daphnia magna	EC <sub>50</sub>	112 mg/l	48 hours
	Zebra danio (Danio rerio)	LC <sub>50</sub>	106 mg/l	96 hours

<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.





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**Other Adverse Effects:** No data available.

#### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

#### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

#### 15. REGULATORY INFORMATION

##### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Lidocaine Hydrochloride	No

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

##### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Lidocaine Hydrochloride	Listed	Listed	Not Listed

**California Proposition 65:** This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.



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#### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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