MSDS: Lidocaine HCl Jelly, 2%

Manufacturer: Akorn
1925 W. Field Court Suite 300
Lake Forest, IL 60045

Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

Common/Trade Name: Lidocaine Hydrochloride Jelly, USP 2%
Chemical Names: Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride
Chemical Formula: C_{14}H_{22}N_{2}O\cdot HCl
Category: Prescription Only.

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: Inhalation and skin and eye contact. Lidocaine is well absorbed through mucous membranes, from the gastrointestinal tract, and through damaged skin.

Carcinogenicity:
- NTP: No
- IARC: No
- OSHA Regulated: No

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS#</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>137-58-6</td>
<td>2%</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>1 N Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>pH adjustment</td>
</tr>
<tr>
<td>1 N Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>pH adjustment</td>
</tr>
</tbody>
</table>
Section 4 – FIRST AID MEASURES

Eyes: First check victim for contact lenses and remove if present. Flush victim’s eyes with large quantities of water for at least 15 minutes and contact a physician. Cover eye until normal sensation returns.

Skin: Wash affected areas of skin thoroughly with soap and water, while removing all contaminated clothing. If rash or irritation develops, contact a physician.

Inhalation: Immediately leave the contaminated area and take deep breaths of fresh air. Contact a physician.

Ingestion: If victim is conscious and not convulsing, treatment should be initiated with activated charcoal and cathartics within the first several hours post ingestion. Do not give anything by mouth if victim is convulsing or unconscious. Immediately contact a physician and transport the victim to a hospital.

Section 5 – FIRE FIGHTING MEASURES

Flash Point: NA

Auto ignition: NA

Lower Explosion Limit: NA

Upper Explosion Limit: NA

General Hazard: NA

Fire Fighting Instructions: Firefighters should use self-contained breathing equipment with full face piece operated in pressure-demand or positive-pressure mode and protective clothing.

Fire Fighting Equipment: Use extinguishing media suitable for surrounding materials.

Hazardous Combustion Products: Oxides of carbon, nitrogen, and sulfur

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-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.
Section 7 – HANDLING AND STORAGE

Precautions: NA

General 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.


Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE

Engineering Controls: Good general ventilation should be sufficient for most conditions.

Personal Protective Equipment

Eye Protection: Chemical safety goggles. Emergency eyewash fountains should be available.

Hand Protection: Rubber gloves

Respiratory Protection: If exposure to mist is possible, wear a NIOSH-approved half-face respirator equipped with a dust/mist filter. Respiratory protection should be adjunct to and not a substitute for engineering controls.

Skin Protection: A laboratory coat or apron appropriate for the work situation. Emergency shower should be available.

Exposure Limits: NA

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form/ Appearance: Clear to opalescent, colorless to slightly colored, colloidal jelly.

Boiling Point/Boiling Range: NA

Melting Point/Melting Range: NA

Freezing Point: NA

Vapor Pressure: NA

Relative Vapor Density: NA

Percent Volatiles: NA

pH: 6.0 to 7.0
Molecular Weight: 270.80
Solvent Solubility: Soluble in water
Latex Free: Yes

Section 10 – STABILITY AND REACTIVITY

Reactivity: Incompatible with water reactive materials.
Chemical Stability: Stable from a safety point of view.
Possibility of Hazardous Products: When heated to decomposition, product may emit oxides of carbon, nitrogen, and sulfur.
Conditions to Avoid: Extreme heat or cold.
Hazardous Polymerization: Will not occur.

Section 11 – TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure & Overexposure:
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 Accidental 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).
**Acute Toxicity:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Oral</td>
<td>Rat</td>
<td>317 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Subcutaneous</td>
<td>Mouse</td>
<td>285 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Oral</td>
<td>Mouse 2</td>
<td>20, 292 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Subcutaneous</td>
<td>Rat</td>
<td>570 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Intramuscular</td>
<td>Mouse</td>
<td>260 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Intravenous</td>
<td>Mouse</td>
<td>22 mg/kg</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>Mouse</td>
<td>119 mg/kg</td>
</tr>
</tbody>
</table>

**Chronic Effects on Humans:**

**Inhalation Toxicity:** 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.

**Eye:** 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.

**Skin:** No dermal LD50 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.

**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.

**Chronic/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.

**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.

**Reproductive/Developmental 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.

**Drug Interactions:** B-adrenergic blocking agents, succinylcholine, other antiarrhythmic drugs, cimetidine. See package insert for additional information.
Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity: NA
Biodegradable: NA

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of all waste in accordance with Federal, State and local regulations.

Section 14 – TRANSPORT INFORMATION

UN/NA Number: NA
U.S. DOT Hazard Class: NA
Proper Shipping Name: NA
Shipping Label: NA

Section 15 – REGULATORY INFORMATION

FDA (Food & Drug Administration): NA
TSCA (Toxic Substance Control Act): NA
HMIS (Hazardous Materials Information System (USA)): NA
WHMIS (Workplace Hazardous Materials): NA

FDA Designations: Prescription only medication.
NDC No. 17478-711-30 (30 ml aluminum tube)
NDC No. 17478-711-10 (5 ml aluminum tube)

Section 16 – OTHER INFORMATION

Date of preparation or last revision: 12-14

Key to Abbreviations:
NA = Not Available
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