Section 1 - IDENTIFICATION

TRADE NAME: Lidocaine Hydrochloride Jelly USP, 2%
NDC# 17478-711-10 (5 mL)
NDC # 17478-711-30 (30 mL)

Description: Clear to opalescent, colorless to slightly colored, colloidal jelly.

<table>
<thead>
<tr>
<th>Composition</th>
<th>CAS#</th>
<th>TLV (mg/m³)</th>
<th>PEL (mg/m³)</th>
<th>%Content</th>
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</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>137-58-6</td>
<td>NE</td>
<td>NE</td>
<td>2</td>
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<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>NE</td>
<td>NE</td>
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</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>NE</td>
<td>NE</td>
<td>&lt;1</td>
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<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>NE</td>
<td>NE</td>
<td>&lt;3</td>
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<tr>
<td>1 N Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>NE</td>
<td>NE</td>
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<tr>
<td>1 N Sodium Hydroxide</td>
<td>1310-73-2</td>
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<tr>
<td>DI Water</td>
<td>7732-18-5</td>
<td>NE</td>
<td>NE</td>
<td>Diluent</td>
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</tbody>
</table>

Common name of active ingredients: Lidocaine Hydrochloride

Chemical Formula: C₁₄H₂₂N₂O HCl

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Lidocaine Hydrochloride

% Threshold Limit Value: NE

Carcinogenicity: NE

NTP- No

IARC- No

OSHA- No

NE= Not established

<= Greater Than

>= Less Than

Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State: Viscous Jelly

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

Odor: Odorless

Boiling Point: NE

Vapor Density (air = 1): NE

Vapor Pressure (mm Hg): NE

Viscosity: NE

Solubility in Water: Soluble

Specific Gravity: 1.02

Volatile: NE

Evaporation Rate: NE

Reactivity in Water: NE

pH: 6.2 – 6.8

Melting Point: NE

Latex Free: Yes

NE=Not established
Section 4 – FIRE AND EXPLOSION HAZARD DATA

**Extinguisher Media:** Use extinguishing media suitable for surrounding materials

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

**Explosion:** None

**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.

Section 5 – REACTIVITY DATA

**Stability:** Stable from a safety point of view.

**Incompatibility:** Water reactive materials

**Hazardous Decomposition Products:** When heated to decomposition, product may emit oxides of carbon, nitrogen, and sulfur

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** Extreme heat or cold.

Section 6 – HEALTH HAZARDS

Lidocaine Hydrochloride 2% viscous jelly is a mixture of lidocaine hydrochloride, a local anesthetic, and preservatives, and suspending agents in water. It is intended for use as a topical anesthetic for irritated or inflamed mucous membranes of the mouth and pharynx and to reduce gagging during the taking of x-rays and dental impressions. Potential routes of occupational exposure include inhalation and skin and eye contact. Lidocaine is well absorbed through mucous membranes, from the gastrointestinal tract, and through damaged skin.

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.

**Chemical Listed as Carcinogen or Potential Carcinogen:**

**National Toxicology Program:** No

**I.A.R.C Monographs:** No

**OSHA:** No

**OSHA Permissible Exposure Limit:** NE

**ACGIH Threshold Limit Value:** NE

NE= Not established
Emergency and First Aid Procedures:

1. **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.
2. **Skin:** Wash affected areas of skin thoroughly with soap and water, while removing all contaminated clothing. If rash or irritation develops, contact a physician.
3. **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.
4. **Inhalation:** Immediately leave the contaminated area and take deep breaths of fresh air. Contact a physician.

**Note to Physician:** In case of accidental overexposure in a worker, ascertain airway breathing, and ensure oxygenation and ventilation. Equipment for emergency resuscitation and oxygen administration should be readily available. Be prepared to transport victim to hospital.

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**Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES**

**Storage:** Store at controlled room temperature, 20° - 25°C (68° - 77°F).

**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.

**Neutralizing Chemical Agent:** Not relevant

**Steps to be taken in case material is released or spilled:** 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.

**Waste Disposal Methods:** Dispose of material on-site in a licensed chemical incinerator, if allowed by the incinerator license or permit. If no on-site incinerator is available, dispose of material in a licensed commercial chemical incinerator. Disposal should be conducted in accordance with local, state and federal environmental regulations.

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**Section 8 – PROTECTION INFORMATION**

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

**Airborne Exposure Limits:** NE

**Ventilation:** Recommended

**Skin Protection:** Rubber gloves

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

**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.

**Other:** A laboratory coat or apron appropriate for the work situation. Emergency shower should be available.
Section 9 – TOXICOLOGY INFORMATION

Oral Toxicity: Lidocaine is well absorbed from the gastrointestinal tract but only about one third of the dose reaches the general circulation because of first pass liver metabolism. Symptoms noted after ingestion of high doses include nausea, vomiting, and abdominal discomfort. Oral doses greater than 5 to 10 mg/kg may result in seizures. Other 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. Massive over dosage can cause convulsions, cardiovascular and respiratory collapse, and heart stoppage. In case reports, inadvertent ingestion of 38.7 mg/kg resulted in acute delirium and sinus tachycardia; two 21.2 mg/kg doses of a viscous lidocaine solution 4 hours apart resulted in generalized tonic-clonic seizures.

LD50 (Acute oral toxicity of): Lidocaine Hydrochloride
LD50  rat, oral = 317 mg/kg,
LD50 Subcutaneous mice: 285mg/kg
LD50 mouse, oral: 220, 292 mg/kg.
LD50 rat, Subcutaneous = 570mg/Kg
LD50 mice, intramuscular = 260mg/Kg
LD50 mice, intravenous = 22mg/Kg
LD50 mice, intraperitoneal= 119 mg/Kg

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.

Medical Conditions Enhancing Toxicity: 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).

<table>
<thead>
<tr>
<th>Section 10 – ECOLOGICAL INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecotoxicity:</td>
</tr>
<tr>
<td>BOD₅ and COD:</td>
</tr>
<tr>
<td>Environmental fate information:</td>
</tr>
<tr>
<td>Chemical Fate:</td>
</tr>
<tr>
<td>Other Precautions:</td>
</tr>
</tbody>
</table>

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