MSDS: Akten® (Lidocaine Hydrochloride Ophthalmic Gel) 3.5%

Material Safety Data Sheet
Manufacturer: Akorn Incorporated
72-6 Veronica Avenue
Somerset, NJ 08873
Telephone: (732) 846-8066
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

Trade Name: Akten®
Description: Akten® is a local anesthetic indicated for ocular surface anesthesia during ophthalmologic procedures.

Akten® Ophthalmic Gel, 3.5% is supplied for single use in 5mL/10cc plastic dropper bottles.

<table>
<thead>
<tr>
<th>Composition</th>
<th>CAS#</th>
<th>TLV (mg/m³)</th>
<th>PEL (mg/m³)</th>
<th>% Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride, USP</td>
<td>73-78-9</td>
<td>NE</td>
<td>NE</td>
<td>3.5</td>
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<tr>
<td>Hypromellose, USP</td>
<td>009004-65-3</td>
<td>NE</td>
<td>NE</td>
<td>QS</td>
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<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>NE</td>
<td>NE</td>
<td>QS</td>
</tr>
<tr>
<td>Purified Water</td>
<td>7732-18-5</td>
<td>NE</td>
<td>NE</td>
<td>QS</td>
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</table>

Hydrochloric acid, NF and/or Sodium hydroxide, NF may be used to adjust pH.

Common name of active ingredient: Lidocaine hydrochloride
Molecular Formula: C14H22N2O ∙ HCl
Molecular Weight: 270.80 g/mole (anhydrous)
Legal Category: Prescription Only

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Lidocaine Hydrochloride
% Threshold Limit Value: Not Established
Carcinogenicity: Not Established
National Toxicology Program: No
I.A.R.C Monographs: No
OSHA: No
OSHA Permissible Exposure Limit: Not Established
ACGIH Threshold Limit Value: Not Established
Poisons Schedule: S2
Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance: Clear, colorless viscous gel  
Boiling Point: Not available  
Vapor Density (air = 1): Not available  
Vapor Pressure (mm Hg): Not available  
Viscosity: 4000 to 9000 cps  
Solubility in Water: Miscible  
Specific Gravity: 1.00 to 1.04  
Volatile Component: Not available  
Evaporation Rate: Not available  
Reactivity in Water: Not available  
pH: 5.5 to 7.5  
Latex Free: Yes

Section 4 – FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media: Use extinguishing media suitable for surrounding materials  
Hazardous Products: Oxides of carbon, nitrogen  
Explosion: None  
Fire Fighting Instructions: Firefighters should use self-contained breathing equipment with full-facepiece operated in pressure-demand or positive-pressure mode and protective clothing.

Section 5 – REACTIVITY DATA

Stability: Stable  
Incompatibility: Water reactive materials  
Hazardous Decomposition Products: When heated to decomposition, product may emit oxides of carbon and nitrogen.  
Hazardous Polymerization: Will not occur  
Conditions to Avoid: Keep container closed and protected from light in the original carton until used.

Section 6 – HEALTH HAZARDS

Lidocaine Hydrochloride Ophthalmic Gel 3.5% is a mixture of lidocaine hydrochloride, a local anesthetic, and suspending agents in water. It is intended for ocular surface anesthesia during ophthalmologic procedures.

Lidocaine is well absorbed through mucous membranes, from the gastrointestinal tract, and through damaged skin. Abdominal discomfort may occur after ingestion. Lidocaine may cause allergic reactions 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.

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

**Emergency and First Aid Procedures:**
In case of accidental overexposure, ascertain airway and breathing are sufficient to ensure oxygenation and ventilation. Equipment for emergency resuscitation and oxygen administration should be readily available. Be prepared to transport victim to hospital. Treat symptomatically.

1. **Eyes:** Remove contact lenses if present. Flush eyes with large quantities of water for at least 15 minutes and contact a physician. Cover eyes until normal sensation returns.
2. **Skin:** Wash affected areas 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. 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.

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

**Handling:** Do not get on eyes, skin and clothing. Do not breathe mist.
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 appropriate protective equipment. Carefully collect waste and place in a suitable, properly labeled container for disposal. Clean the area using soap and water.

**Waste Disposal Methods:** Disposal should be conducted in accordance with local, state and federal environmental regulations.

### Section 8 – PROTECTION INFORMATION

**Engineering Controls:** Provide good general ventilation

**Airborne Exposure Limits:** Not Established

**Skin Protection:** Rubber gloves, lab coat or apron, Emergency shower should be available.

**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.

**Contaminated Equipment:** Wash thoroughly with soap and water
Section 9 — TOXICOLOGY INFORMATION

LD<sub>50</sub> rat, oral = 317 mg/kg
   Non-fasted females = 459 mg/kg
   Fasted females = 214 mg/kg
LD<sub>50</sub> rat, intraperitoneal = 133 mg/kg
LD<sub>50</sub> mouse, oral = 220 to 292 mg/kg
LD<sub>50</sub> mouse, subcutaneous = 335 mg/kg

Although no systemic exposure is expected with administration of Akten®, the following information is offered for consideration:

**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 overdosage can cause convulsions, cardiovascular and respiratory collapse, and heart stoppage.

**Chronic Effects on Humans:** Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss.

**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.

**Skin:** 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.

**Carcinogenesis/Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Akten®. The effect of a non-ophthalmic formulation of lidocaine on fertility was examined in the rat model. Administration of 30mg/kg, subcutaneous (180 mg/m<sup>2</sup>) to the mating pair did not produce alterations in fertility or general reproductive performance of rats. There are no studies that examine the effect of lidocaine on sperm parameters.

The mutagenic potential of lidocaine has been tested in the Ames Salmonella reverse mutation assay, an in vitro chromosome aberrations assay in human lymphocytes and in an in vitro mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.
Reproductive/Developmental Effects: Pregnancy Category B. Reproduction studies of lidocaine 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. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproductive studies are not always predictive of human response. Lidocaine rapidly crosses the placenta in animal models and high doses may affect fetal heart rate. Lidocaine is not contraindicated in labor and delivery. Lidocaine is distributed into human milk. General consideration should be given before administering Akten® to women of childbearing potential.

Medical Conditions Enhancing Toxicity: Known hypersensitivity to lidocaine.

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