SAFETY DATA SHEETS

This SDS packet was issued with item:

078908052

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

078905755

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

Manufacturer: Akorn Incorporated
72-6 Veronica Avenue
Somerset, NJ 08873
Telephone: 1-732-846-8066
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.

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

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

Common name of active ingredient: Lidocaine hydrochloride
Molecular Formula: $C_{14}H_{22}N_2O \cdot HCl$
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_{50} rat, oral	=	317 mg/kg
Non-fasted females		459 mg/kg
Fasted females		214 mg/kg
LD_{50} rat, intraperitoneal	=	133 mg/kg
LD_{50} mouse, oral	=	220 to 292 mg/kg
LD_{50} 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^2) 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.

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity:	Not established
BOD_5 and COD:	Not available
Environmental fate information:	Not established
Other Precautions:	None

SDS: Akten®
(lidocaine hydrochloride ophthalmic gel) 3.5%

SAFETY DATA SHEET

1. Identification

Product Identifier: Akten® (lidocaine hydrochloride ophthalmic gel) 3.5%

Synonyms: Akten®; Lidocaine Hydrochloride Ophthalmic Gel; Lidocaine Hydrochloride; Lidocaine; Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-hydrochloride; 2-Diethylamino-N-(2,6-dimethylphenyl) acetamide hydrochloride; Lignocaine; Xylocaine.

National Drug Code (NDC): 17478-792-01

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: Specific target organ toxicity – single exposure (narcotic effects) Category 3

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H336 May cause drowsiness or dizziness.

Precautionary Statement(s):

P261 Do not breathe mist/vapours/spray.

P271 Use in a well ventilated area.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: May be harmful if swallowed, in contact with the skin or inhaled. Lidocaine is well absorbed through mucous membranes, the gastrointestinal tract and damaged skin. Abdominal discomfort may occur after ingestion. Because Akten® is a local anesthetic, contact with the eyes or skin may cause temporary loss of feeling or sensation. May cause general hypotension, bradycardia, central nervous system depression, dizziness, blurred vision, tremors, drowsiness, convulsions, and/or unconsciousness See product label and/or product insert for additional information.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride	73-78-9	Lidocaine Hydrochloride; 2-Diethylamino-N-(2,6-dimethylphenyl)acetamide hydrochloride; Lidocaine; Lignocaine; Xylocaine	$C_{14}H_{22}N_2O$• HCl	270.8	3.5%

*The formula also contains Hypromellose, Sodium Chloride, and Purified Water. The pH may be adjusted to 5.5 to 7.5 with Sodium Hydroxide and/or Hydrochloric Acid.

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:	Abdominal discomfort if ingested; eye irritation, skin irritation, loss of feeling/sensation; respiratory irritation if inhaled. May cause hypersensitivity.
Medical Conditions Aggravated by Exposure:	Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system, Cardiovascular or hepatic ailments.
Notes to Physician:	None.

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:	These products include carbon oxides, nitrogen oxides and hydrogen chloride.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, bases and water reactive materials.

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: 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: 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: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Semi-solid/Clear.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	5.5 to 7.5.
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):	Miscible 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:	Reactive 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):	No data available.
Incompatible Materials:	Oxidizers, acids, bases and water reactive materials.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through the skin. May cause skin irritation.
Eye Contact:	May cause eye irritation.

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:

Compound	Species	Route	Test Type	Dose
Lidocaine Hydrochloride	Mouse	Oral	LD_{50}	220 – 292 mg/kg
Lidocaine Hydrochloride	Rat	Oral	LD_{50}	317 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: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

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: No data available.
Aspiration Hazard: No data available.

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):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Lidocaine hydrochloride.
Pennsylvania:	Lidocaine hydrochloride.
California Proposition 65:	Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:

Health:	2
Flammability:	0
Reactivity:	0

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Revision Number: 1