


SAFETY DATA SHEET

Pilocarpine Hydrochloride Ophthalmic Solution, USP 1%, 2% and 4%

1. IDENTIFICATION

Product Identifier:	Pilocarpine Hydrochloride Ophthalmic Solution, USP 1%, 2% and 4%	
Synonyms:	2(3 <i>H</i>)-furanone,3-ethylidihydro-4-[(1-methyl-1 <i>H</i> -imidazol-5-yl)-methyl]-monohydrochloride, (3 <i>S</i> - <i>cis</i>)-	
National Drug Code (NDC):	17478-223-12 17478-224-12 17478-226-12	
Recommended Use:	Pilocarpine hydrochloride ophthalmic solution is a muscarinic cholinergic agonist indicated for the: reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension; management of acute angle-closure glaucoma; prevention of postoperative elevated IOP associated with laser surgery; induction of miosis.	
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:	Reproductive Toxicity	Category 2
Environmental Hazard:	Hazardous to the Aquatic Environment, Acute Hazard	Category 3
	Hazardous to the Aquatic Environment, Long Term Hazard	Category 3
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H361 Suspected of damaging fertility or the unborn child.	
	H402 Harmful to aquatic life	

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Precautionary Statement(s):	P202 Do not handle until all safety precautions have been read and understood.
	P308 IF exposed or concerned: Get medical advice/attention. + P313
	P273 Avoid release to the environment
	P501 Dispose of contents/container in accordance with all local and national regulations.
Hazards Not Otherwise Classified:	None.
Supplementary Information:	None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Pilocarpine Hydrochloride	2(3 <i>H</i>)-furanone,3-ethylidihydro-4-[(1-methyl-1 <i>H</i> -imidazol-5-yl)-methyl]-monohydrochloride, (3 <i>S</i> - <i>cis</i>)-	54-71-7	$C_{11}H_{16}N_2O_2 \cdot HCl$	244.72	1%, 2% and 4%

The formula also contains Hypromellose (2910) 5 mg (0.5%), Boric Acid, Sodium Citrate, Sodium Chloride (present in 1% only), Sodium Hydroxide and/or Hydrochloric Acid to adjust pH (3.5 to 5.5) and Water for Injection.

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.

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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:	Headache/browache, accommodative change, eye irritation, eye pain, blurred vision, visual impairment.
Medical Conditions Aggravated by Exposure:	No data available.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and 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: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Hazardous to aquatic environment. 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.

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7. HANDLING AND STORAGE

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

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from freezing. Keep tightly closed.

Specific End Use: Pharmaceuticals drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Pilocarpine Hydrochloride	Not established	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: Not required for the normal use of this product. 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: Not required for the normal use of this product. Chemically compatible gloves should be worn when working with large quantities. 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: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations: 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

Physical State/Color:	Clear, colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	3.5 to 5.5.
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):	No data available.
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:	The product is stable and non-reactive under normal conditions of use, storage and transport.
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:	Strong oxidizing agents.
Hazardous Decomposition Products:	NO _x , HCl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	Not expected to be hazardous in final pharmaceutical form.
Ingestion:	May be harmful if swallowed.
Skin Contact:	Not expected to be hazardous in final pharmaceutical form.
Eye Contact:	May cause eye irritation.

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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
Pilocarpine Hydrochloride	Mouse	Oral	LD ₅₀	200 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

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
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Systemic Effects:

No data available.

Reproductive Effects:

Pregnancy Category C. Suspected of damaging fertility or the unborn child. Impaired fertility was seen in animal studies with a related material. There are no adequate and well-controlled studies in pregnant women.

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.

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Occupational Safety and Health
Administration (OSHA):

Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Pilocarpine Hydrochloride	Crustacea (Daphnia magna)	EC ₅₀	13.1 mg/l	48 hours
	Activated sludge, industrial	EC ₅₀	>1,000 mg/l	3 hours

Terrestrial Toxicity: No data available.
Persistence and Degradability: Not readily biodegradable.
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

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
No applicable	No applicable	No applicable	No applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Pilocarpine Hydrochloride	Yes



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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
Pilocarpine 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.

16. OTHER INFORMATION

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

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