

**SDS: Cyclopentolate Hydrochloride Ophthalmic Solution,
USP 0.5%**

SAFETY DATA SHEET

1. Identification

Product Identifier: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5%

Synonyms: Cyclopentolate Hydrochloride; 2-(Dimethylamino)ethyl 1-hydroxy- α -phenylcyclopentaneacetate hydrochloride; Cyclopentolate HCl.

National Drug Code (NDC): 17478-096-15

Recommended Use: For Topical Ophthalmic Use Only. Not for Injection. Cyclopentolate hydrochloride ophthalmic solution is used to produce mydriasis and cycloplegia.

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 Category 2

Symbol(s): 

Signal Word: Warning.

Hazard Statement(s): H370 May cause CNS disturbance.

Precautionary Statement(s):

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P308 IF exposed or concerned: Get medical advice/attention.
+
P313

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

SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5%

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
2-(Dimethylamino)ethyl 1-hydroxy- α -phenylcyclopentaneacetate hydrochloride	5870-29-1	Cyclopentolate Hydrochloride;	$C_{17}H_{25}NO_3 \cdot HCl$	327.85	0.5%

*The formula also contains Benzalkonium Chloride, 0.01% as a preservative, Boric Acid, Edetate Disodium; Potassium Chloride, Sodium Carbonate and/or Hydrochloric Acid; may be added to adjust pH (3.0 – 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.

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).



SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5%

Signs and Symptoms: Increased intraocular pressure; burning eyes; photophobia; blurred vision; irritation of eyes; Hyperemia; conjunctivitis; blepharoconjunctivitis; punctate keratitis; synechiae; ataxia; incoherent speech; restlessness; hallucinations; hyperactivity; seizures; disorientation as to time and place; failure to recognize people; skin rash; unusual drowsiness; tachycardia; hyperpyrexia; vasodilation; urinary retention; diminished gastrointestinal motility; decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages; severe manifestations of toxicity include coma, medullary paralysis and death.

Medical Conditions Aggravated by Exposure: Heart disease; hiatal hernia or other gastrointestinal tract disorders; bleeding disorders; glaucoma; myasthenia gravis; prostate enlargement or other urinary obstruction; kidney or liver impairment; hyperthyroidism; hypertension; Down's syndrome; hypersensitivity to any of the components of the product.

Notes to Physician: Treat supportively and symptomatically.

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.



SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5%

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 and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Cyclopentolate Hydrochloride	No data available.
Boric Acid	ACGIH TLV: 2 mg/m ³ * TWA; 6 mg/m ³ * STEL

* Inhalable fraction; TLV listed under Borate compounds, Inorganic.

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: Protective laboratory coat, apron, or disposable garment.

9. **Physical and Chemical Properties**

Physical State/Color:	Liquid/Colorless.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	3.0 – 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):	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:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold. Do not freeze.
Incompatible Materials:	Oxidizers, acids, bases, alkali metals, alkali hydrides and silver preparations.
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 irritation.
Eye Contact:	May cause eye irritation.

SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5%

**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
Cyclopentolate Hydrochloride	Mouse	Oral	LD ₅₀	960 mg/kg
Boric Acid	Rat	Oral	LD ₅₀	2,660 mg/kg
Edetate Disodium	Rat	Oral	LD ₅₀	2,000 mg/kg
Benzalkonium Chloride	Mouse	Oral	LD ₅₀	960 mg/kg

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:

Pregnancy Category C. Animal reproduction studies have not been conducted with Cyclopentolate.

Carcinogenicity:

Studies in animals or humans have not been conducted to evaluate the carcinogenic potential of Cyclopentolate Hydrochloride Ophthalmic Solution, USP.

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.



**SDS: Cyclopentolate Hydrochloride Ophthalmic Solution,
USP 0.5%**

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

Chemical Name	UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Benzalkonium Chloride	Corrosive solids, toxic, n.o.s. (Benzalkonium Chloride)	2923	8 (6.1)	III

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

Chemical Name	Massachusetts	New Jersey	Pennsylvania
Cyclopentolate Hydrochloride	Not listed	Listed	Listed
Boric Acid	Not listed	Listed	Listed
Benzalkonium Chloride	Not listed	Listed	Listed
Potassium Chloride	Not listed	Listed	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

Revision Date: 12/10/2015

Revision Number: 0

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.