

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078914098

N/A



## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

### Material Safety Data Sheet

**Manufacturer:** Akorn  
150 S. Wyckles Road  
Decatur, IL 62522  
**Contact Telephone:** 1-800-932-5676  
**Email:** customer.service@akorn.com

#### Section 1 - IDENTIFICATION

**Common/Trade Name:** Cyclopentolate Hydrochloride Ophthalmic Solution, USP

**Description:** Anti-cholinergic: Ciliary muscle paralysis agent in a borate buffered topical ophthalmic solution.

**Common name of active ingredients:** Cyclopentolate Hydrochloride

**Chemical Formula:**  $C_{17}H_{25}NO_3 \cdot HCl$

**Legal Category:** Prescription only medication, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

**NE:** Not established

#### Section 2 – HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<b>Composition</b>	<b>CAS#</b>	<b>TLV (mg/m<sup>3</sup>)</b>	<b>PEL (mg/m<sup>3</sup>)</b>	<b>%Content</b>
Cyclopentolate HCl	5870-29-1	NE	NE	1%, 2%
Boric Acid	10043-35-3	10	15	≥ 1

Ingredients: <1%- Edetate Disodium, Potassium Chloride (except 2% strength), Benzalkonium Chloride

#### Section 3 – HEALTH HAZARD DATA

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##### EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless and odorless, aqueous solution. For eyes only. Do not engage in hazardous activity while under the influence. May cause temporary light sensitivity. Avoid mouth and skin contact.

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**Principal Hazardous Ingredients:** Cyclopentolate Hydrochloride

**% Threshold Limit Value:** NE

**Carcinogenicity:**

**NTP-** No

**IARC-** No

## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

OSHA-  
NE= Not established

No

**Eye:** This is an ophthalmic solution. May cause adverse reactions including intraocular pressure, burning sensation, blurred vision, irritation, increased blood inflow (hyperemia), inflammation (conjunctivitis), inflammation of the eyelid (blepharoconjunctivitis), cellular deposits on the back of the cornea (punctate keratopathy) and adhesion of parts (synechiae). This preparation may cause central nervous system disturbances. CNS disturbances are more likely in young, premature or small infants. Do not use concentrations higher than 0.5% in very small children. Children with spastic paralysis or brain damage are more susceptible to cyclopentolate. Patients should not drive or engage in other hazardous activity while pupils are dilated. Patients may experience sensitivity to light (photophobia) and should protect eyes in bright illumination during dilation. Complete recovery of accommodation takes 6 to 24 hours. Complete recovery from mydriasis in some individuals may take several days.

**Skin:** May cause irritation and repeated or prolonged contact can induce hypersensitivity in some individuals. Toxic systemic effects may be induced by skin contact.

**Ingestion:** This is not an oral solution. Toxic by ingestion. See chronic effects. Ophthalmic administration of this drug may cause feeding intolerance in neonates. It is recommended that feeding be withheld for four (4) hours after examination.

**Inhalation:** Aspiration of solution may cause irritation of the respiratory tract and induce systemic effects. Vapor inhalation poses little hazard as this is an aqueous solution.

**Chronic Effects:** Systemic toxicity effects include psychotic reactions and behavioral disturbances. These reactions include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place and failure to recognize people. This drug produces reactions similar to other anticholinergic drugs, but the central nervous system manifestations are more common. Other toxic manifestations of anticholinergic drugs are skin rash, abdominal distention in infants, unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastric motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis and death.

**Target Organs:** Eyes, central nervous system, heart, digestive tract and vascular system.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to cyclopentolate or any component of the preparation.

### Section 4 – FIRST AID MEASURES

**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and drink plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

### **Note to Physicians:**

- Cyclopentolate may interfere with the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
- Cyclopentolate is contraindicated in case of narrow angle glaucoma or anatomical narrow angles are present.
- Cyclopentolate may interfere with the antiglaucoma action of carbachol or pilocarpine; also concurrent use of these medications may antagonize the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
- It is not known whether this drug is excreted in the milk of nursing mothers, so caution should be exercised when prescribing cyclopentolate hydrochloride.
- CNS disturbances are more likely in young, premature or small infants. Children with spastic paralysis or brain damage are more susceptible to cyclopentolate.

## **Section 5 – FIRE FIGHTING MEASURES**

<b>Extinguisher Media:</b>	Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.
<b>Flash Point:</b>	NE
<b>Special Firefighting Procedures:</b>	Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.
<b>Hazardous Products:</b>	Toxic Fumes, carbon oxides, and nitrogen oxides
<b>Hazardous Decomposition Products:</b>	Emits toxic fumes.
<b>Hazardous Polymerization:</b>	Should not occur
<b>NE: Not established</b>	

## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

### Section 6 – ACCIDENTAL RELEASE MEASURES

**Large/Small Spills:** Use personal protective equipment. Contain the spill to prevent drainage into Sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

### Section 7 – HANDLING AND STORAGE

**Precautions to be taken in handling and storage:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product at a controlled room temperature 20° to 25° C (68° to 77° F). Keep tightly closed. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

**Steps to be taken in case material is released or spilled:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

**Waste Disposal Methods:** Dispose of waste in accordance with all applicable Federal, State and Local regulations. The method typically used in incineration.

### Section 8 – EXPOSURE CONTROLS/PERSONAL PROTECTIVE

**Mechanical/Engineering Controls:** In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

**Skin Protection:** Thick impermeable gloves and protective clothing.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials. Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.

**Local Exhaust:** NA

**Contaminated Equipment:** Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local Regulations.

## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

**Other:** None

**Ventilation:** Recommended

**Contaminated Equipment:** Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

### Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

<b>Appearance:</b>	Clear, colorless and odorless solution
<b>Boiling Point:</b>	NE
<b>Vapor Density:</b>	NE
<b>Vapor Pressure (mm Hg):</b>	NE
<b>Viscosity:</b>	NE
<b>Solubility in Water:</b>	Miscible
<b>Specific Gravity:</b>	1.0
<b>Volatile:</b>	<1
<b>Evaporation Rate:</b>	NE
<b>Reactivity in Water:</b>	None
<b>Latex Free:</b>	Yes
<b>NE=Not established</b>	

### Section 10 – STABILITY AND RECTIVITY

**Chemical Stability:** Stable

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

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:** Emits toxic fumes.

**Hazardous Polymerization:** Should not occur.

### Section 11– TOXICOLOGICAL INFORMATION

**Summary of risks:** Toxicology information refers to raw material of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

#### 5870-29-1 Cyclopentolate HCl

May cause eye, skin and respiratory tract irritation. May also cause a burning sensation in the eye. Induces paralysis of the ciliary muscle of the eye preventing the adjustment of the eye to light (cycloplegia) and dilates the pupil of the eye

## MSDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%, 2%

(mydriasis). Cyclopentolate is an anti-cholinergic agent which affects the nervous system. Hypersensitivity (anaphylactic) may be observed in some individuals. Toxicity induces clumsiness, weakness, drowsiness, confusion, hallucinations, slurred speech, rapid heartbeat, drug fever and flushed face. Oral-mouse LD<sub>50</sub> 960 mg/kg, IV-mouse LD<sub>50</sub> 84 mg/kg.

### 10043-35-3

#### Boric Acid

May cause irritation to the eyes, skin, respiratory tract and digestive system. Inhalation may cause coughing and chest discomfort. Dusts may irritate the skin. Harmful quantities may be absorbed through broken skin but is unlikely with intact skin. Ingestion may cause upset stomach and vomiting; large quantities may be fatal. Repeated or prolonged contact may cause hypersensitization (anaphylactic) in some individuals, central nervous system stimulation and erythematous flush (diffuse red skin rash). Oral-rat LD<sub>50</sub>: 2660 mg/kg.

## Section 12 – TRANSPORTATION INFORMATION

Not classified as hazardous by DOT regulations.

## Section 13 – DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

## Section 14 – ENVIRONMENTAL IMPACT INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment

## Section 15 – OTHER REGULATORY INFORMATION

**FDA Designations:** Prescription only medication.

**CALIFORNIA PROPOSITION 65:** Not Listed

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SDS: Cyclopentolate Hydrochloride Ophthalmic Solution,  
USP 1% and 2%

SAFETY DATA SHEET

1. **Identification**

**Product Identifier:** Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1%; Cyclopentolate Hydrochloride Ophthalmic Solution, USP 2%

**Synonyms:** Cyclopentolate Hydrochloride; 2-(Dimethylamino)ethyl 1-hydroxy- $\alpha$ -phenylcyclopentaneacetate hydrochloride; Cyclopentolate HCl.

**National Drug Code (NDC):** 17478-100-02  
17478-100-10  
17478-100-12  
17478-097-02  
17478-097-10  
17478-097-12

**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:** Reproductive toxicity Category 2



**Symbol(s):**

**Signal Word:** Warning.

**Hazard Statement(s):** H361 Suspected of damaging fertility or the unborn child.

**Precautionary Statement(s):** P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

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



## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

P405 Store locked up.

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

**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- $\alpha$ -phenylcyclopentaneacetate hydrochloride	5870-29-1	Cyclopentolate Hydrochloride; Cyclopentolate HCl	C <sub>17</sub> H <sub>25</sub> NO <sub>3</sub> •HCl	327.85	1% and 2%

\*The formula also contains Benzalkonium Chloride, 0.01% as a preservative, Boric Acid, 1.2%; Edetate Disodium; Potassium Chloride (except 2% strength); Sodium Carbonate and/or Hydrochloric Acid; may be added to adjust pH (3.0 – 5.5) and Purified Water.

### 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



## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

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:**

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.



## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

**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 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 <sup>3</sup> * TWA; 6 mg/m <sup>3</sup> * 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.



## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

**Skin Protection:** Protective laboratory coat, apron, or disposable garment.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Liquid/Colorless.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	3.0 – 5.5.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Miscible in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	No data available.
<b>Incompatible Materials:</b>	Oxidizers, acids, bases, alkali metals, alkali hydrides and silver preparations.
<b>Hazardous Decomposition Products:</b>	No data available.

### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

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

## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

### 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 <sub>50</sub>	960 mg/kg
Cyclopentolate Hydrochloride	Mouse	Subcutaneous	LD <sub>50</sub>	292 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:

Suspected of damaging fertility or the unborn child (Boric Acid).

### 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.



## SDS: Cyclopentolate Hydrochloride Ophthalmic Solution, USP 1% and 2%

### 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:	Cyclopentolate Hydrochloride; Boric Acid.
Pennsylvania:	Cyclopentolate Hydrochloride; Boric Acid.
California Proposition 65:	Not listed.

### 16. Other Information

Not made with natural rubber latex.

<b>NFPA Rating:</b>		<b>HMIS Classification:</b>	
Health:	2	Health:	2
Flammability:	0	Flammability:	0
Reactivity:	0	Physical Hazard:	0

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**Revision Number:** 2

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