BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/25/01		Manager EHS
Revision:	01	Core No. 049	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cyclopentolate Hydrochloride Ophthalmic Solution USP, 1.0%
Generic Name: Same
NDC No. 24208-735-01 (2 ml, box of 12)
24208-735-06 (15 ml)

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

Drug Composition: Anti-cholinergic: Ciliary muscle paralysis agent (cycloplegic; mydriatic) in a borate buffered topical ophthalmic solution.

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637
Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m^3)	PEL(mg/m^3)	% Content
Cyclopentolate HCL	5870-29-1	NE	NE	1.0
Boric Acid	10043-35-3	NE	NE	$\geq$1

Ingredients <1% - Potassium Chloride, Edetate Disodium, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Plastic bottle packed in a cardboard box. Clear, colorless, odorless 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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POTENTIAL HEALTH HAZARDS

Carcinogenicity: **(NTP)** No **(IARC)** No **(OSHA)** 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 (punctuate carotids) 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. Sever 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.

4. FIRST AID MEASURES

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

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.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Toxic fumes, carbon oxides, nitrogen oxides.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water fog and foam for

surrounding materials. Water spray will froth if sprayed into the burning material.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

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.

7. HANDLING AND STORAGE

Handling: 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 upright in original containers with the cap tightly closed at a controlled room temperature 15^0-30^0 C (59^0- 86^0 F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

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.

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.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Clear, colorless, odorless solution		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Soluble	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

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.

11. TOXICOLOGY INFORMATION

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

CAS #

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 (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_{50} 960 mg/kg, IV-mouse LD_{50} 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 produce 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_{50}2660 mg/kg.

12. ECOLOGICAL INFORMATION

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

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

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-735-01 (2 ml, box of 12)
NDC No. 24208-735-06 (15 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established
< - Less Than
> - Greater Than