

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Cyclopentolate Hydrochloride 1% Ophthalmic Solution**
- Product Code** • AB04903; AB04911; Core No. 049; NDC 24208-0735-01; NDC 24208-0735-06

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; Cyclopentolate hydrochloride ophthalmic solution is used to produce mydriasis (pupil dilation) and cycloplegia (paralysis of the ciliary muscle of the eye, resulting in a loss of accommodation).
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
- Telephone (General)** • 1-800-553-5340

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Specific Target Organ Toxicity Single Exposure 2

Label elements

UN GHS

WARNING



- Hazard statements** • May cause CNS disturbance.

Precautionary statements

Prevention ● Wear eye/face protection , .
Wash thoroughly after handling.

Response ● IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Storage/Disposal ● Keep tightly closed and store in upright position.
Store product refrigerated at 2-8°C (36-46°F).
Protect from light.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride (50%) Solution	CAS:139-07-1 EINECS:205-351-5	0.01%	UN GHS: NDA
Boric acid	CAS:10043-35-3 EINECS:233-139-2	1% TO 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Cyclopentolate Hydrochloride	CAS:5870-29-1 EINECS:227-521-8	1%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 1%	UN GHS: NDA
Potassium chloride	CAS:7447-40-7 EINECS:231-211-8	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT RE 1
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- Eye anesthetic.

Indication of any immediate medical attention and special treatment needed**Notes to Physician**

- When administration of the drug product is discontinued, the patient usually recovers spontaneously. In case of severe manifestations of toxicity the antidote of choice is physostigmine salicylate. Additional details are available on the product package insert or the Physicians Desk Reference.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures**Extinguishing media**

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage**Precautions for safe handling**

Handling • No special handling is required. Refer to Section 8. Use only in accordance with

product literature.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store between 2-8°C (36-46°F), to maintain product integrity. use before expiration date marked on carton and/or container. Protect from light.
- Incompatible Materials or Ignition Sources**
- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines		
	Result	ACGIH
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)

Exposure Control Notations

ACGIH

- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves. Wear protective gloves .

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Not relevant
Odor	Not relevant	Taste	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3 to 5.5
Specific Gravity/Relative Density	= 1.0028	Water Solubility	Water soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Heat of Combustion (ΔH_c)	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze. Protect from light and heat.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Cyclopentolate Hydrochloride (1%)	5870-29-1	Acute Toxicity: Eye-Child TDLo • 50 µg/kg-Intermittent; <i>Behavioral:</i> Hallucinations, distorted perceptions; Behavioral:Toxic psychosis ; Ingestion/Oral-Mouse LD50 • 960 mg/kg
Boric acid (1% TO 5%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; <i>Behavioral:</i> Convulsions or effect on seizure threshold; Behavioral:Ataxia
Potassium chloride (< 1%)	7447-40-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2600 mg/kg

Edetate Disodium Dihydrate (< 1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Benzalkonium Chloride (50%) Solution (0.01%)	139-07-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 400 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 2
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - Not expected to cause skin irritation.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause irritation. Allergic contact dermatitis has been reported following use of this product.

Eye

- Acute (Immediate)**
 - Increased intraocular pressure, burning, photophobia, blurred vision, irritation, hyperemia, conjunctivitis, blepharoconjunctivitis, punctate keratitis, synechiae. Results in increased sensitivity to light.
- Chronic (Delayed)**
 - Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
 - No data available.

Other

- Chronic (Delayed)**
 - Systemic: Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances, usually in pediatric patients, especially with a 2% concentration. These disturbances 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 those of other anticholinergic drugs, but the central nervous system manifestations as noted above are more common. Other toxic manifestations of anticholinergic drugs are skin rash, abdominal distention in infants, unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis and death.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Benzalkonium Chloride (50%)	139-07-1	Yes	Yes	Yes

Solution				
Boric acid	10043-35-3	Yes	Yes	Yes
Cyclopentolate Hydrochloride	5870-29-1	Yes	Yes	No
Potassium chloride	7447-40-7	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria (including 23.8%)
• Boric acid	10043-35-3	D2A
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	1 %
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Edetate Disodium Dihydrate	139-33-3	Not Listed
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• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	S:53-45
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed

• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride (50%) Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Cyclopentolate Hydrochloride	5870-29-1	Not Listed

Section 16 - Other Information

Last Revision Date

- 04/May/2015

Preparation Date

- 04/May/2015

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