

## SAFETY DATA SHEETS

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

078058940

N/A

## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • **Tetracaine Hydrochloride Ophthalmic Solution, 0.5%**  
**Product Code** • AB09111; Core No. 091; NDC 24208-920-64

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

- Recommended use** • Finished Pharmaceutical Product; For procedures in which a rapid and short-acting topical ophthalmic anesthetic is indicated such as in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, suture removal from the cornea, other short corneal and conjunctival procedures.
- 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** • No data available

#### Label elements

**UN GHS**

#### WARNING



- Hazard statements** • Anesthetic effect on eyes  
May cause eye irritation

May cause serious eye damage

## Precautionary statements

**Prevention** ● Use personal protective equipment as required.  
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. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

## 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
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
Chlorobutanol	CAS:57-15-8 EINECS:200-317-6	0.4%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	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
Tetracaine Hydrochloride	CAS:136-47-0 EINECS:205-248-5	0.5%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

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

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

#### Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

#### Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of

**Ingestion**

- water for at least 15 minutes. Get medical attention if eye irritation persists.
- 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**

- A rare, severe, immediate allergic corneal reaction has been reported, characterized by acute diffuse filament formation and/or sloughing of large areas of dead skin, swelling and inflammation of the iris.

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

- May cause temporary stinging, burning, and conjunctival redness. After installation, the eye may be scratched without pain, so should not be rubbed. May cause hypersensitivity.

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

**Suitable Extinguishing Media** • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**Unsuitable Extinguishing Media** • No data available

**Special hazards arising from the substance or mixture**

**Unusual Fire and Explosion Hazards** • None known - product is not flammable or combustible.

**Hazardous Combustion Products** • No data available

**Advice for firefighters**

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

**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. Refer to Section 8.

**Emergency Procedures** • No emergency procedures are expected to be necessary when used in accordance with product literature.

**Environmental precautions**

- No data available

**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.

**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 at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

## 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

- No respiratory protection required during normal handling.

##### Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn. Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

##### Hands

- Gloves are not required under normal handling conditions.

##### Skin/Body

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

#### Environmental Exposure Controls

- No data available

## Section 9 - Physical and Chemical Properties

### Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Colorless to slightly yellow.
Odor	Camphor-like	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3.7 to 6
Specific Gravity/Relative Density	= 1.008	Water Solubility	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	Autoignition	Not relevant

**Environmental**

Octanol/Water Partition coefficient	No data available		
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**Section 10: Stability and Reactivity****Reactivity**

- No dangerous reactions known.

**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.

**Incompatible materials**

- None.

**Hazardous decomposition products**

- None expected.

**Section 11 - Toxicological Information****Information on toxicological effects****Other Material Information**

- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Tetracaine Hydrochloride (0.5%)	136-47-0	<b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 160 mg/kg; <i>Behavioral:</i> <b>Muscle weakness; Lungs, Thorax, or Respiration:Respiratory depression; Lungs, Thorax, or Respiration:Other changes</b>
Boric acid (1% TO 5%)	10043-35-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2500 mg/kg; <i>Behavioral:</i> <b>Convulsions or effect on seizure threshold; Behavioral:Ataxia</b>
Potassium chloride (< 1%)	7447-40-7	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2600 mg/kg
Edetate Disodium Dihydrate (< 0.1%)	139-33-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2 g/kg
Chlorobutanol (0.4%)	57-15-8	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 510 mg/kg

GHS Properties	Classification
<b>Acute toxicity</b>	UN GHS • Classification criteria not met
<b>Aspiration Hazard</b>	UN GHS • Classification criteria not met
<b>Carcinogenicity</b>	UN GHS • Classification criteria not met
<b>Germ Cell Mutagenicity</b>	UN GHS • Classification criteria not met
<b>Skin corrosion/Irritation</b>	UN GHS • Classification criteria not met

<b>Skin sensitization</b>	UN GHS • Classification criteria not met
<b>STOT-RE</b>	UN GHS • Classification criteria not met
<b>STOT-SE</b>	UN GHS • Classification criteria not met
<b>Toxicity for Reproduction</b>	UN GHS • Classification criteria not met
<b>Respiratory sensitization</b>	UN GHS • Classification criteria not met
<b>Serious eye damage/Irritation</b>	UN GHS • Eye Irritation 2A

## Potential Health Effects

### Inhalation

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

### Skin

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

### Eye

- Acute (Immediate)** • Transient symptoms (signs) such as stinging, burning and conjunctival redness may occur.
- Chronic (Delayed)** • Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently creating a "vicious circle". Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur.

### Ingestion

- Acute (Immediate)** • Small amounts (less than a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Chronic (Delayed)** • No data available.

Carcinogenic Effects		
	CAS	NTP
Boric acid	10043-35-3	Evidence of Carcinogenicity

## 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
Chlorobutanol	57-15-8	Yes	Yes	Yes
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Tetracaine Hydrochloride	136-47-0	Yes	Yes	No
Boric acid	10043-35-3	Yes	Yes	Yes
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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS



## classification criteria

**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 %
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	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
• Tetracaine Hydrochloride	136-47-0	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

## Section 16 - Other Information

### Last Revision Date

- 13/May/2015

### Preparation Date

- 13/May/2015

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