Safety Data Sheet

Section 1: Identification

Product identifier

Product Name | **Tetracaine Hydrochloride Ophthalmic Solution, 0.5%**

Product Code | NDC 69292-0317-15

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

Recommended use | Finshed 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 | Amici Pharmaceuticals LLC

425 Broadhollow Road Suite 115
Melville, NY 11747
United States

Telephone (General) | 631 – 396 - 0111

Emergency telephone number

Manufacturer | 631 – 396 - 0111

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 15-25ºC (59-77ºF), 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

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

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

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 15-25ºC (59-77ºF), 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		

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	**Acute Toxicity:** Ingestion/Oral-Mouse LD50 • 160 mg/kg; *Behavioral*:**Muscle weakness**; *Lungs, Thorax, or Respiration*:**Respiratory depression**; *Lungs, Thorax, or Respiration*:**Other changes**
Boric acid (1% TO 5%)	10043-35-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2500 mg/kg; *Behavioral*:**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 (< 0.1%)	139-33-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2 g/kg
Chlorobutanol (0.4%)	57-15-8	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 510 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** • Classification criteria not met
Toxicity for Reproduction	**UN GHS** • Classification criteria not met
Respiratory sensitization	**UN GHS** • Classification criteria not met
Serious eye damage/Irritation	**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 20/February/2018

Preparation Date 20/February/2018

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