

# SAFETY DATA SHEET

**PRODUCT: EPINASTINE HCL OPHTHALMIC SOLUTION 0.5 Mg/ mL**

## Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village,  
Nelamangala,  
Bangalore, India-562123.

**PRODUCT NAME: EPINASTINE HCL OPHTHALMIC SOLUTION 0.5 Mg/ mL**

## Section 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance/Odor	Clear solution, the solution is clear when compared with a portion of water for injection
Classification of the substance mixture	Acute toxicity: oral, category 3
Label elements	GHS signal word: Danger
GHS hazard phrases	H301: Toxic if swallowed
GHS precaution phrases	P264: wash( hands) thoroughly after handling
GHS response phrases	P301+310: IF SWALLOWED: immediately call a poison centre or doctor/physician P330: Rinse mouth
GHS storage and disposal phrases	Please refer to section no. 7 for storage and section 13 for disposal information.
Adverse human health effects and symptoms	Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation or skin absorption. May cause eye, skin or respiratory system irritation. Toxic if swallowed To the best of our knowledge, the toxicological properties have not been thoroughly investigated
<i>Potential Health Effects: See Section 11 for more information</i>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	

**Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS**

Component	CAS Number
Epinastine Hydrochloride	108929-04-0
Benzalkonium Chloride NF	8001-54-5
Monobasic sodium phosphate USP Monohydrate	10049-21-5
Edetate disodium USP	6381-92-6
Sodium Chloride	7647-14-5
Sodium Hydroxide	1310-73-2
Hydrochloric Acid	7647-01-0
Water for Injection	7732-18-5

**Section 4: FIRST AID MEASURES**

In case of inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention
In case of skin contact	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
In case of eye contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
In case of ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do not induce vomiting unless directed to do so by medical personnel.

**Section 5: FIRE FIGHTING MEASURES**

Suitable extinguishing media	Use alcohol – resistant foam, carbon dioxide, water or dry chemical spray. Use water spray to cool fire-exposed containers
Unsuitable extinguishing media	A solid water stream may be inefficient
Flammable properties and hazards	No data available
Explosive limits	No data available
Protection for Firefighters: As in any fire, wear self- contained breathing apparatus pressure- demand (NOISH approved or equivalent) and full protective gear to prevent contact with skin and eyes.	

## Section 6: ACCIDENTAL RELEASE MEASURES

Suitable precautions Protective equipment and emergency procedures	Avoid raising and breathing and provide adequate ventilation. As conditions warrant, wear NOISH approved self-contained breathing apparatus or respirator and appropriate personal protection ( rubber boots, safety goggles and heavy rubber gloves)
Environmental precautions	Take steps to avoid release into the environment, if safe to do so.
Methods and material for containment and cleaning up	Contain spill and collect as appropriate. Transfer to a chemical waste container of disposal in accordance with local regulations.

## Section 7: HANDLING AND STORAGE

<p><b>Handling:</b> avoid breathing dust/fume/gas/mist/vapours/spray</p> <p><b>Storing:</b> Keep container tightly closed. Store in accordance with information listed on the product insert.</p>
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## Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure controls	Description
Engineering controls (Ventilation etc.)	Use process enclosures, local exhaust ventilation or other engineering controls to control airborne levels below recommended exposure limit.

Personal Protective Equipment	Description
Eye protection	Safety glass
Protective gloves	Compatible chemical – resistant gloves
Other protective clothing	Lab coat
Respiratory equipment	NOISH approved respirator as conditions warrant.
Work/Hygienic/Maintenance practices	Do Not take internally. Facilities storing or utilizing this material should be equipped with an eye wash and a safety shower. Wash thoroughly after handling No data available

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear solution
Clarity of the solution	The solution is clear when compared with a portion of water for injection.
Colour of the solution	Not darker than B9
pH	Between 6.7 and 7.3
Foreign matter	Free from particles of foreign matter that can be observed on visual inspection
Osmolality	Between 250 and 310 mOsmol/Kg
Assay of Epinastine Hydrochloride ( label claim: 0.5 mg/ml)	Not less than 95.0% and not more than 105.0% of label claim of Epinastine Hydrochloride ( C <sub>16</sub> H <sub>15</sub> N <sub>3</sub> .HCL)
Assay of Benzalkonium chloride ( label claim: 0.1 mg/ml)	Not less than 90.0% and not more than 110.0% of label claim
Assay of Edetate disodium ( label claim: 0.475 mg/ml)	Not less than 90.0% and not more than 110.0% of label claim
Related substances	a. 13,14 dehydro Epinastine: NMT 0.3% b. Single largest unknown impurity: NMT 0.2% c. Total impurities: NMT 1.2%
Residual solvents	Should meet the requirements of residual solvent USP <467> as per option 1

## Section 10: STABILITY AND REACTIVITY

Stability	Stable.
Conditions to Avoid	No data available
Incompatibility – materials to avoid	Reactive with strong oxidising agents
Hazardous Decomposition by-products	Carbon Monoxide, Carbon Dioxide, hydrogen chloride gas and nitrogen gas
Stability note(s)	Stable if stored in accordance with information listed on the product insert.

## Section 11: TOXICOLOGY INFORMATION

information on toxicological effects	The toxicological effects of this product have not been thoroughly studied Epinastine ( Hydrochloride) Toxicity data: oral LD <sub>50</sub> ( rat):192 mg/kg, Oral TDLO(rat):30 mg/kg
Chronic toxicological effects	Epinastine (Hydrochloride) - investigated as a reproductive effector. Only select Registry Of Toxic Effects Of Chemical Substances (RTCES) data is presented here. See actual entry in RTCES for complete information. Epinastine ( Hydrochloride) RTCES Number : HO4360000

## Section 12: ECOLOGICAL INFORMATION

Toxicity	Avoid release into the environment Runoff from fire control or dilution water may cause pollution
Persistence and degradability	No data available
Bio accumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	No data available
Other adverse effects	No data available

## Section 13: DISPOSAL CONDITIONS

Disposal do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

## Section 14: TRANSPORTATION INFORMATION

<b>14.1 LAND TRANSPORT ( US DOT)</b>	
<b>DOT proper shipping name</b>	<b>Toxic solids, organic, n.o.s ( Epinastine Hydrochloride)</b>
DOT Hazard class	6.1 POISION
UN/NA Number	2811 packing group: III
Additional transport information	Transport in accordance with local, state, and federal regulations. When sold in quantities of less than or equal to 1 ml or 1 g with an expected quantity code of E1, E2, E4 or E5 this item meets the de Minimis quantities exemption per iATA 2.6.10. Therefore packing does not have to be labelled as dangerous Goods/ Expected quantity.

## Section 15: REGULATORY INFORMATION

Regulatory information statement	This safety data sheet (SDS) prepared in accordance with 29 CFR 1910.1200 and regulation (EC) No. 1272/2008
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## Section 16: OTHER INFORMATION

This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty or merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.