

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 046

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Naphazoline Hydrochloride Ophthalmic Solution USP, 0.1%
Generic Name: Same
NDC No. 24208-725-06 (15 ml)

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

Drug Composition: Imidazoline (Vasoconstrictor)

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
Naphazoline HCL	550-99-2	NE	NE	0.1
Boric Acid	10043-35-3	NE	NE	≥1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% Sodium Chloride, Edetate Disodium, Sodium Carbonate, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless and odorless, aqueous solution. Do not engage in hazardous activity while under the influence. May be toxic by ingestion.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No **(IARC)** No **(OSHA)** No

Eye: This is an ophthalmic preparation that may cause irritation and cause hypersensitivity (anaphylactic) in some individuals. Can induce pupillary dilation, increase interior eyeball (intraocular) pressure, light sensitivity (photophobia) from dilation of the pupil (mydriasis), brow ache, eye (ocular) pain and headache. Systemic effects due to absorption are high blood pressure (hypertension), heart (cardiac) irregularities, and high blood sugar (hyperglycemia). Adverse effects, after congestion, include renewed contraction of the pupil (rebound myosis) after the adrenergic effects wear off, floating shady spots (opacities), scleroconjunctival and corneal fluid collection (chemosis). In narrow angle glaucoma, mydriasis may close the angle sufficiently to increase intraocular pressure.

Skin: May cause irritation and hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Ingestion of large doses may cause headache, drowsiness, weakness, tremors, light headedness, insomnia, and heart palpitations. Systemic effects due to absorption are hypertension, cardiac irregularities and hyperglycemia.

Inhalation: May cause irritation and hypersensitivity (anaphylactic) in some individuals. This is not likely with a liquid preparation.

Chronic Effects: Adverse effects include rebound myosis after the adrenergic effects wear off, floating opacities, scleroconjunctival and corneal chemosis. May cause irritation and hypersensitivity (anaphylactic) in some individuals.

Target Organs: Blood vessels and central nervous system.

Medical Conditions Aggravated by Long Term Exposure:

- Naphazoline Hydrochloric Ophthalmic Solution is contraindicated for persons with narrow angle glaucoma.

- Hypersensitivity to any of the components of the product is contraindicated.
- Use with caution in the presence of hypertension, cardiac irregularities, hyperglycemia (diabetes), hyperthyroidism and when other medications are being used.
- It is not known whether naphazoline can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to pregnant women only when clearly needed.
- Use in infants and children may result in CNS depression leading to coma and marked reduction in body temperature.

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: Patients taking monoamine oxidase inhibitors (MAOI) may experience a severe hypertensive crisis if given a sympathomimetic drug. Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes.

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 15⁰-30⁰ C (59⁰- 86⁰ 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 to slightly yellow odorless aqueous solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Complete	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers 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 #

550-99-2 **Naphazoline HCL**

May cause irritation to the eyes, skin and respiratory tract. Can cause irritation and congestion of the mucous membranes and hypersensitivity (anaphylactic) in some individuals by inhalation, ingestion or skin contact. May induce headaches, drowsiness, weakness, tremors, light headedness, insomnia, or palpitations. Oral-rat LD₅₀ 1232 mg/kg, Oral-rabbit LD₅₀ 50 mg/kg.

10043-35-3 **Boric Acid**

May cause irritation to the eyes, skin, respiratory and digestive tract. Inhalation may cause coughing and chest discomfort. Prolonged skin contact can cause burns and sensitization. Ingestion may cause nausea and vomiting and swallowing large quantities can be fatal. Chronic exposure may cause central nervous system

stimulation and skin redness or rash. Oral-rat LD₅₀ 2660 mg/kg, Inhalation-rat LC₅₀ >16 mg/L.

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. 24208-725-06 (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