SDS: Naphazoline Hydrochloride Ophthalmic Solution, USP 0.1%

SAFETY DATA SHEET

1. Identification

Product Identifier: Naphazoline Hydrochloride Ophthalmic Solution, USP 0.1%

Synonyms: 4,5-Dihydro-2-(1-naphthalenylmethyl)-1Himidazole

National Drug Code (NDC): 17478-216-12

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Naphazoline Hydrochloride	550-99-2	4,5-Dihydro-2-(1-naphthalenylmethyl)-1Himidazole	$C_{14}H_{14}N_2HCl$	246.74	0.1 %

*The formula also contains Benzalkonium Chloride, 0.1 mg (0.01%) as a preservative; Boric Acid, Edetate Disodium, Sodium Carbonate, Sodium Chloride, and Hydrochloric Acid may be added to adjust pH (6.5 – 7.0), and Purified Water.

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Solution is not considered hazardous under normal conditions.
Medical Conditions Aggravated by 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.
Notes to Physician:	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. Firefighting Measures

Suitable Extinguishing Media:	Dry chemical, carbon dioxide, halon, water fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	Emits toxic fumes.
Other Specific Hazards:	Not determined.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.
Fire Fighting Instructions:	Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	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.
Environmental Precautions:	Product administered to patients presents a negligible impact on the environment.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product and use caution to prevent puncturing containers. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°C - 30°C (59°F - 86°F). Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Naphazoline Hydrochloride	0.5 mg/m^3 TWA

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.
WARNING: Do not use air purifying respirators in oxygen depleted environments.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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. Physical and Chemical Properties

Physical State/Color:	Clear, colorless to slightly yellow aqueous solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.0.
% Volatile by Volume:	<1.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold.
Incompatible Materials:	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. Toxicological Information

Information on the Likely Routes of Exposure:

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

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.

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

Eye Contact: 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.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Naphazoline HCl	Rat	Oral	LD_{50}	1,232 mg/kg
Naphazoline HCl	Rabbit	Oral	LD_{50}	50 mg/kg
Boric Acid	Rat	Oral	LD_{50}	2,660 mg/kg
Boric Acid	Rat	Inhalation	LC_{50}	>16 mg/L

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.
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.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	Blood vessels and central nervous system.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.
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.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	Not listed.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Not listed.
Pennsylvania:	Not listed.
California Proposition 65:	Not listed.

16. Other Information

Revision Date: 05/14/2015

Revision Number: 0