



Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 01/11/2016

Version: 2.0

Section 1: Identification Of The Substance/ Mixture

Product Identifier

Product name:	Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%
Synonyms:	None
NDC Number:	2.5%: 4270210215 10% : 4270210305
Intended Use Of The Product :	Pharmaceutical
Company Name & Address:	Paragon BioTeck, Inc. 4640 SW Macadam Ave, Suite 80 Portland, OR 97239
Contact Telephone:	(888) 424-1192
E mail:	info@paragonbioteck.com
Emergency Phone Number :	(888) 424-1192

Section 2: Hazards(s) Identification

Classification of the Substance/ Mixture

GHS-US Classification:	None
Physical Hazards:	Not Classifiable
Health Hazards:	Not Classifiable
Hazard Pictograms:	None
Signal Word:	None
Hazard Statement(s):	None
Precautionary Statement(s)	P235 – Keep cool (2°C to 8°C (36°F to 46°F)) P501 – Dispose of contents/ container



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	according to local, regional, national, and international regulations.
Hazards Not Otherwise Classified:	None known
Unknown Acute Toxicity (GHS US):	No data available
Supplementary Information:	
Clear, colorless to slightly yellow, aqueous solution. Do not use if solution is brown color or contains a precipitate. Patients with insulin-dependent diabetes, hypertension, hyper-thyroidism, generalized arteriosclerosis, cardiac disease, asthma and the elderly may be more susceptible to systemic effects. For eyes only. Presents little or no hazards if spilled and no unusual hazard if involved in fire.	

Section 3: Composition/Information on Ingredients

Ingredients:

Name	CAS#	% by Weight
Phenylephrine Hydrochloride	61-76-7	2.5 and 10
Sodium Phosphate Monobasic	7558-80-7	---
Sodium Phosphate Dibasic	7558-79-4	---
Boric Acid	10043-35-3	---
Benzalkonium chloride	63449-41-2	---
Hydrochloric Acid	7647-01-0	As needed to adjust pH (4.0-7.5)
Sodium Hydroxide	1310-73-2	As needed to adjust pH (4.0-7.5)

*The formula also contains water for Injection.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Section 4: First Aid Measures



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Description of the First Aid Measures

Eyes Contact:

Rinse immediately with water for at least 20 minutes. If irritation persists or signs of toxicity occur, contact physician immediately.

Inhalation:

Escort person outside for fresh air, and if breathing stops, use artificial respiration. Contact physician.

Skin Contact:

Remove all contaminated clothing and wash skin with water for at least 20 minutes. Contact a physician if skin becomes irritated.

Ingestion:

Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. For all cases, contact a physician.

Note to Physicians:

Phenylephrine is a sympathomimetic drug related to epinephrine and ephedrine; although it is rare, it may produce such reactions as tremor, pallor, perspiration, abnormal palpitation, or collapse. Additional details are available on the package insert.

Pregnancy:

Animal reproduction studies have not been conducted with topical phenylephrine. It is also not known whether phenylephrine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Phenylephrine Hydrochloride should be given to a pregnant woman only if clearly needed. Refer to package insert for a full description of the information.

Nursing Mothers:

It is not known whether this drug is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10% is administered to a nursing woman.



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Section 5: Fire-Fighting Measures

Extinguishing Media

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

Advice for Firefighters

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.

Protection during Firefighting:

Firefighters should wear full protective gear. Do not enter fire area without protective equipment, including respiratory protection.

Section 6: Accidental Release Measures

Personal Precautions, protective equipment and emergency procedures

Personal Precaution:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Protective equipment:



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Use appropriate personal protection equipment (PPE).

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.

Environmental Precautions:

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Reference to other sections:

See heading 8, Exposure Controls and Personal Protection.

Section 7: Handling and Storage

Precautions for Safe Handling

Precautions for Safe Handling:

Handle in accordance with product label and/ or product insert information. 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.

Hygiene Measures:

Handle in accordance with good industrial hygiene and safety procedures.

Conditions for Safe Storage, including any Incompatibilities

Storage Conditions:

Store product under refrigerated condition, at approximately 2°C to 8°C (36°F to 46°F). Do not Freeze.

Specific End Use(s): Pharmaceutical

KEEP THIS AND ALL OTHER DRUGS OUT OF THE REACH OF CHILDREN.

Section 8: Exposure Controls/Personal Protection



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Appropriate Engineering Controls:

Engineering controls should be used as the primary means to control exposures. 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.

Personal Protective Equipment:

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 Safety Data Sheets.

Eye Protection:

Recommend goggles or chemical safety glasses.

Skin Protection:

Thick impermeable gloves and protective clothing.

Respiratory Protection:

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: N/A

Ventilation: Recommended

Contaminated Equipment:

Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

Section 9: Physical and Chemical Properties



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Information on Basic Physical and Chemical Properties

Physical State:	Solution
Appearance and Color:	Clear, colorless to slightly yellow solution
Odour:	No data available
Odour Threshold:	No data available
pH:	4.0 – 7.5
Melting Point:	Not established
Freezing Point:	Not established
Boiling Point:	Not established
Flash Point:	Not established
Evaporation Rate:	Not established
Flammability (solid, gas):	Not established
Flammability Limit - Lower:	Not established
Flammability Limit - Upper:	Not established
Vapor Pressure:	Not established
Vapor Density:	Not established
Relative Density:	Not established
Solubility (ies):	Miscible in water
Partition Coefficient (n-octanol/water):	Not established
Auto-Ignition Temperature:	Not established
Decomposition Temperature:	Not established
Viscosity:	Not established
Specific Gravity:	1.0
Water Solubility:	Complete
Percent Volatile by Volume:	<1%

Section 10: Stability and Reactivity



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Reactivity:	No data available
Chemical Stability:	Stable
Possibility of Hazardous Reactions:	Under normal/indicated conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid:	Extreme heat or cold
Incompatibility:	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Hazardous Polymerization:	Should not occur

Section 11: Toxicological Information

Information on Toxicological Effects

Summary of Risks:

Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see SDS on chemical material.

Acute Toxicity:

Product/Ingredient Name	Species	Route	Test Type	Dose
Phenylephrine Hydrochloride	Rat	Oral	LD ₅₀	350 mg/kg

Skin Corrosion/ Irritation: No data available

Sensitization: No data available

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.



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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

Specific target organ toxicity

(single exposure): No data available

Specific target organ toxicity

(repeated exposure): No data available

Aspiration Hazard: No data available

Information on the Likely Routes of Exposure

Eye Contact: May cause irritation, a burning sensation and cause hypersensitivity (anaphylactic) in some individuals. May cause headache, irregular heart rate, increase in blood pressure and dizziness. Persons with cardiac diseases and asthma may be more susceptible to systemic side effects.

Skin Contact: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Ingestion: May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause headache, irregular heart rate, increase in blood pressure, tremor, perspiration, pallor, vomiting, dizziness and collapse.

Inhalation: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Inhalation of a liquid preparation is not likely. Evaporation is minimal at controlled room temperatures.

Ingestion: May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause headache, irregular heart rate, and increase in blood pressure, tremor, perspiration, pallor, vomiting, dizziness and collapse.

Chronic Effects: Repeated and prolonged exposure may cause hypersensitivity in some individuals.

Medical Conditions Aggravated by Long Term Exposure:

Hypersensitivity to any of the components of the product. Persons hypersensitive to other sympathomimetics (amphetamines, ephedrine, epinephrine, isoproterenol,



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metaproterenol, norepinephrine, phenylpropanolamine, pseudoephedrine, terbutaline) may be hypersensitive to phenylephrine hydrochloride. Any mydriatic is usually not indicated for patients with narrow angle glaucoma. There have been rare reports associating the use of phenylephrine hydrochloride 10 percent ophthalmic solutions with the development of serious cardiovascular reactions, including ventricular arrhythmias and myocardial infarctions. These episodes, some ending fatally, have usually occurred in elderly persons with preexisting cardiovascular diseases. A significant elevation in blood pressure is rare, but has been reported, following installation into the eye the recommended doses of phenylephrine hydrochloride 10 percent ophthalmic solutions. Caution should be exercised in administering the 10 percent solutions to children of low body weight, the elderly, and patients with insulin-dependent diabetes, hypertension, hyperthyroidism, generalized arteriosclerosis, or cardiovascular disease. Animal reproduction studies have not been done with phenylephrine hydrochloride. It is not known if phenylephrine hydrochloride ophthalmic solutions can cause fetal harm when given to a pregnant woman or if it is excreted in breast milk.

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.

Section 12: Ecological Information

Ecotoxicity:

Chemical Fate Information:	Product administered to patients presents a negligible impact on the environment.
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



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Other Adverse Effects:	No data available
Section 13: Disposal Consideration	
<p>Dispose of material according to Federal, State and Local regulations. The method typically used is incineration.</p> <p>EPA Designation - RCRA Hazardous Waste: Not Listed</p> <p>SARA Title III: Not Listed</p>	
Section 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 (DOT):	Not classified 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.
Section 15: Regulatory Information	
US Federal Regulations:	
Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.



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CERCLA Hazardous Substance and

Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed
EPA Designations:	RCRA Hazardous Waste (40 CFR 261.33) Not Listed
FDA Designations:	Prescription only medication. NDC No. 42702-102-15 (2.5%, 15mL), 42702-103-05 (10%, 5mL)
OSHA Designations:	(29 CFR 1910.1000, Table Z) Not Listed under Section 313 of Toxic Release Reporting.
<u>State Regulations:</u>	
CALIFORNIA PROPOSITION 65:	Not Listed

Section 16: Other Information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication (11JAN2016). The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.