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

Section 1: Identification

Substance/Mixture Identifying Information

Product Identifier:	Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%
National Drug Code (NDC):	42702-102-15 (2.5%, 15 mL) 42702-102-10 (2.5%, 10 mL) 42702-103-05 (10%, 5 mL)
Synonyms:	None
Chemical Name:	(R)-3-hydroxy-α-[(methylamino)methyl] benzenemethanol hydrochloride
Restricted Use:	Pharmaceutical
Manufacturer:	Paragon BioTeck, Inc. 4640 S Macadam Ave, Suite 80 Portland, OR 97239
Contact Phone:	+1 (888) 424-1192
Contact Email:	info@paragonbioteck.com
Emergency Contact Phone:	+1 (888) 424-1192

IN CASES OF EMERGENCY CALL 911

For additional information about this SDS, contact the manufacturer directly.

Section 2: Hazard Identification(s)

Substance/Mixture Hazard Classification

GHS-US Hazard Classification:	None
Physical Hazards:	Not classifiable
Health Hazards:	Not classifiable
Hazard Statements(s):	None
Hazard Pictograms(s):	None
Signal Word(s):	None
Precautionary Statement(s):	P233 – Keep container tightly closed. P235 – Keep cool (2°C to 8°C (36°F to 46°F)). P501 – Dispose of contents/container according to local, regional, national, and international regulations.

Section 2: Hazard Identification(s), Continued

Hazards Not Otherwise Classified: Not classifiable

Unknown Acute Toxicity (GHS US): No data available

Supplemental Information:

- Not for injection. Topical ophthalmic use only.
- Physical Description: Clear, odorless, colorless to slightly yellow, aqueous solution. Do not use if solution is brown in color or contains a precipitate.
- Pediatric patients <1 year old and individuals with a history of pre-existing cardiovascular and/or endocrine disease, hypertension, thyrotoxicosis, and/or hyperthyroidism may be more susceptible to systemic effects.
- Eye pain and/or stinging on instillation, temporary blurred vision and photophobia, and conjunctival sensitization may occur.
- **See Prescribing Information on package insert for comprehensive hazard identification(s).**

Section 3: Composition/Ingredients Information

Active and Inactive Ingredients*

Composition of Phenylephrine HCl Ophthalmic Solution, USP 2.5% & 10%

Chemical Name	CAS#	Concentration 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	0.01
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 mixture formula also contains Water for Injection (WFI).

Within the current knowledge of the supplier and in the concentrations applicable, there are no ingredients present that are classified as hazardous to health or the environment, or that require reporting in this section.

Section 4: First-Aid Measures

Description of First-Aid Measures

After Eye Contact:

Rinse immediately with water for at least 20 minutes. If irritation persists or signs of systemic toxicity occur, contact a physician immediately. Due to its vasoconstrictor and mydriatic action, mydriasis may occur within 20-90 minutes and persist for 3-8 hours.

After Inhalation:

Remove any physical breathing obstructions and escort affected individual outside for fresh air. If breathing stops, begin artificial respiration and contact emergency services.

After Skin Contact:

Remove all contaminated clothing and rinse affected area with water for at least 20 minutes. Contact a physician if skin shows signs of irritation (pain, redness, swelling).

After Ingestion:

Rinse mouth and drink large amounts of water and/or bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not administer any substance to an unconscious person. For all cases, contact a physician or emergency services.

Note to Physicians:

Phenylephrine is a sympathomimetic drug similar to epinephrine and ephedrine; in rare cases it may produce adverse reactions including hypertension, abnormal palpitations, myocardial infarction, tachycardia, arrhythmia, and subarachnoid hemorrhage. Refer to the drug prescribing information for a full description of potential drug interactions.

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 the drug prescribing information for a full description of use in specific populations.

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 is administered to a nursing woman.

Note:

This information is not intended to be used as a substitute to the Prescribing Information included on the package insert for Phenylephrine Hydrochloride USP, 2.5% and 10%. See the full Prescribing Information for comprehensive instructions for use.

Section 5: Fire-Fighting Measures

Extinguishing Media

Suitable Extinguishing Media:

Dry sand, dry chemical, and/or alcohol-resistant foam for extinction.

Unsuitable Extinguishing Media:

Not determined.

Hazardous Chemical Combustion Products:

Phenylephrine Hydrochloride emits carbon oxides upon combustion.

Advice for Firefighters

Fire Fighting Instructions:

Wear a 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 Precautions:

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

Product Spills:

Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains, municipal water systems, and/or bodies of water. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of spilled materials according to federal, state, and local regulations.

Environmental Precautions:

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

References to Other Sections:

See Section 8: Exposure Controls and Personal Protection
See Section 11: Toxicological Information
See Section 13: Disposal

Section 7: Handling and Storage

Precautions for Safe Handling

Precautions for Safe Handling:

Handle in accordance with product label and/or package insert prescribing information. Avoid contact with product and use caution to prevent puncturing containers.

Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10% should only be administered by a physician or other healthcare professional.

Conditions for Safe Storage

Storage Conditions:

Store product under refrigerated condition at 2°C to 8°C (36°F to 46°F). Do not freeze. After opening, product may be used up to the expiration date printed on the bottle.

Specific End Use:

Pharmaceutical

KEEP THIS AND ALL DRUG PRODUCTS OUT OF REACH OF CHILDREN.

Section 8: Exposure Controls/Personal Protection

Precautions for Exposure Control

Occupational Exposure Guidelines:

There is no Employee Exposure Limit data available for this product.

Appropriate Engineering Controls:

In the clinical environment, handle product consistent with labeling and information provided in the Prescribing Information on the package insert.

In the manufacturing environment, provide adequate ventilation for the raw material handling and compounding process to maintain dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof.

Personal Protective Equipment:

In the manufacturing environment, adequate personal protective equipment including but not limited to NIOSH-approved respirators, goggles or safety glasses, gloves, and protective coverings should be used per OSHA requirements. Ensure training in the handling of chemical materials and the use of current Safety Data Sheets.

Recommended Eye Protection:

Laboratory goggles or chemical safety glasses.

Recommended Hand and Skin Protection:

Thick impermeable gloves and protective outer clothing.

Section 8: Exposure Controls/Personal Protection, Continued

Respiratory Protection:

No specific respiratory protection is required in the clinical environment.

NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Contaminated Equipment:

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

Information on Basic Physical and Chemical Properties

Characteristic	Description
Physical State:	Solution
Appearance and Color:	Clear, colorless to slightly yellow solution
Odor:	Odorless
Odor Threshold:	No data available
pH	4.5 – 7.5
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:	Miscible 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
Percent Volatile by Volume:	< 1%

Section 10: Stability and Reactivity

Information on Chemical Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable at 2 – 8 °C storage conditions. Stable at 22 – 25 °C for up to 6 months.
Possibility of Hazardous Reactions:	Under normal/indicated conditions of storage and use, hazardous reactions will not occur.
Conditions to Avoid:	Extreme heat or cold; freezing.
Incompatible Materials:	This product has the incompatibilities of water solutions, 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 finished product dosage form.

Acute Toxicity:

Compound	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.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.

Section 11: Toxicological Information, Continued

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 Potential Routes of Exposure

Eye Contact:

May cause irritation, a burning sensation, temporarily blurred vision, and anaphylactic hypersensitivity in some individuals. Side effects may include headache, irregular heart rate, increase in blood pressure, and dizziness. Individuals with existing cardiac and/or endocrine disease may be more susceptible to systemic side effects.

Skin Contact:

May cause irritation and anaphylactic hypersensitivity in some individuals.

Inhalation:

May cause irritation and anaphylactic hypersensitivity in some individuals. Inhalation of a liquid can mechanically impede respiration. Evaporation of product is minimal at controlled room temperatures.

Ingestion:

May cause irritation and anaphylactic hypersensitivity in some individuals. May cause headache, irregular heart rate and increase in blood pressure, tremor, perspiration, pallor, vomiting, dizziness, and syncope.

Chronic Effects:

Repeated and prolonged exposure may cause hypersensitivity in some individuals.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

See Section 4. To the best of the manufacturer's knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated nor characterized.

Section 11: Toxicological Information, Continued

Medical Conditions Aggravated by Exposure:

Hypersensitivity to any of the components of the product. Individuals hypersensitive to other sympathomimetics (amphetamines, ephedrine, epinephrine, isoproterenol, 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% 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% ophthalmic solutions. Caution should be exercised in administering the 10% 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.

Section 12: Ecological Information

Ecotoxicity:

Chemical Fate Information:	Product administered to patients presents a negligible risk for 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
Other Adverse Effects:	No data available

Section 13: Disposal Considerations

Dispose of material according to Federal, State and Local regulations.

SARA Title III:	Not listed
EPA Designation – RCRA Hazardous Waste:	Not listed

Section 14: Transport Information

UN Number:	Not applicable
UN Proper Shipping Name:	Not applicable
Transport Hazard Class:	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 and State 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.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed
SARA 313:	Not listed
SARA 302:	Not listed
EPA Designation:	Not listed under RCRA Hazardous Waste (40 CFR 261.33).
FDA Designation:	Prescription only medication.
OSHA Designation:	Not Listed under Section 313 of Toxic Release Reporting (29 CFR 1910.1000, Table Z).
California Proposition 65:	Not listed

Section 16: Other Information

Disclaimer

The information provided in this Safety Data Sheet is complete and accurate to the best of the manufacturer's knowledge, information, and understanding at the date of its publication. The information provided is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a product 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 Prescribing Information on the package insert.

Refer to the Prescribing Information on the package insert for complete and comprehensive instructions for use.

Revision History

Document Version	Revision Date	Summary of Changes
3.0	11/10/2020	Content updated to recent product changes
2.0	01/11/2016	Update to GHS standard
1.0	04/22/2013	Original