



**SDS: Phenylephrine Hydrochloride Ophthalmic Solution,
USP 2.5% and 10.0%**

SAFETY DATA SHEET

1. Identification

Product Identifier: Phenylephrine Hydrochloride Ophthalmic Solution,
USP 2.5% and 10.0%

Synonyms: (R)-3-hydroxy- α [(methylamino)methyl]benzenemethanol
hydrochloride

National Drug Code (NDC): 17478-206-05
17478-201-02
17478-201-15

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): P501 Dispose of contents/container in accordance
with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: The product is filled in plastic bottle with dropper tip,
secured with screw cap in cardboard box. Clear
colorless to slight yellow 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. Not for intraocular use.
Presents little or no hazards if spilled and no unusual
hazard if involved in fire. It may be Toxic by ingestion.

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3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(R)-3-hydroxy-α[(methylamino)methyl]benzenemethanol hydrochloride	61-76-7	Phenylephrine Hydrochloride	C ₉ H ₁₃ NO ₂ •HCl	203.67	2.5% and 10%

*The formula also contains Benzalkonium Chloride, 0.01% as a preservative, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Sodium Hydroxide and/or Phosphoric acid may be added to adjust pH (4.0 – 7.5) and Water for Injection.

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:

Headache; irregular heart rate; dizziness; increase in blood pressure; perspiration; tremor; vomiting; pallor. May cause hypersensitivity.



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Medical Conditions Aggravated by Exposure:

Hypersensitivity to any of the components of the product. Persons 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 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.

Notes to Physician:

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 or in the Physicians' Desk Reference.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, phosphorous oxides and other hazardous products of combustion.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/ Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.



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6. Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
Environmental Precautions:	Contain material and prevent release to basements, confined spaces, waterways or soil.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:	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 according to label and/or product insert information. Store away from oxidizers, acids, and bases.
Specific End Use:	Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Phenylephrine Hydrochloride	No data available.

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



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Hand Protection:	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.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless to slightly yellow solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	4.0 – 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(ies):	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.

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 the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products:	Emits toxic fumes.
Hazardous Polymerization:	Should not occur

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11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be harmful if inhaled. Dust may cause respiratory tract irritation and may affect respiration (mechanically impede respiration).

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.

Skin Contact: May cause irritation.

Eye Contact: May cause eye irritation.

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
Phenylephrine Hydrochloride	Rat	Oral	LD ₅₀	350 mg/kg

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: No data available.

Reproductive Effects: This material may cause vasoconstriction of uterine blood vessels and the reduction of uterine blood flow, resulting in fetal hypoxia. Some case-controlled studies in humans suggest a small increase in unusual birth defects. Based on available data, the classification criteria are not met.

Nursing Mothers: It is not known if whether this drug is excreted in milk; many are. Caution should be exercised when phenylephrine hydrochloride ophthalmic solution is administered to a nursing woman.

Pregnancy: Animal reproduction studies have not been conducted with phenylephrine hydrochloride ophthalmic solutions. It is also not known whether phenylephrine hydrochloride ophthalmic solutions can cause fetal harm when administered to a pregnant woman or can affect



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reproduction capacity. Phenylephrine hydrochloride ophthalmic solutions should be given to a pregnant woman only if clearly needed.

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.

Compound	Study Type	Cell Type/Organism	Results
Phenylephrine Hydrochloride	Chromosomal aberration assay	Chinese hamster ovary cells	Negative
Phenylephrine Hydrochloride	Lymphoma test (without activation)	Mouse	Positive
Phenylephrine Hydrochloride	S. typhimurium assay (with and without activation)	Mouse	Negative
Phenylephrine Hydrochloride	Sister chromatid exchange assay	Chinese hamster ovary cells	Positive

Aspiration Hazard: No data available.

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.



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**International Maritime Dangerous
Good (IMDG):**

Not regulated as a dangerous good.

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.

**CERCLA Hazardous Substance
and Reportable Quantity:**

Not listed.

**SARA 313:
SARA 302:**

Not listed.
Not listed.

State Regulations

California Proposition 65:

Not listed.

16. Other Information

Not made with natural rubber latex.

Revision Date: 06/30/2015

Revision Number: 3

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