


SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

Section 1. Chemical Product and Company Information	
Product	Phenylephrine Hydrochloride Injection, USP, 10 mg/mL
Chemical Name(s):	phenylephrine hydrochloride/ 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1)
Product Form	Sterile Solution for Intravenous Injection
Product NDC#	1 mL: 61990-0211-0 5 mL: 61990-0212-0 10 mL: 61990-0213-0
Synonym	Phenylephrine Hydrochloride Injection
CAS Number	61-76-7
RTECS #	Not Available
Trade Name	VAZCULEP
Chemical Formula	<i>C₉H₁₃NO₂.HCl</i>
Contact Information	Apollo Pharmaceuticals USA Inc. 4400 PGA Blvd. Suite 102, Palm Beach Gardens, FL 33410, USA Tel.: (561) 469-9058, Fax: (561) 727 8943
Emergency Phone Number	National Poison Control 1-800-222-1222
Section 2: Hazards Identification	
<p>Hazard pictograms (GHS-US):</p> <div style="text-align: center;">  </div>	
<p>Potential Acute Health Effects: Hazardous in case of skin contact (irritant), of inhalation. May cause an allergic skin reaction.</p>	
<p>Potential Chronic Health Effects: Based on available data, the classification criteria are not met.</p>	
<p>Carcinogenic Effects: Based on available data, the classification criteria are not met.</p>	
<p>Mutagenic Effects: Based on available data, the classification criteria are not met.</p>	
<p>Teratogenic Effects: Based on available data, the classification criteria are not met.</p>	
<p>Developmental Toxicity: Based on available data, the classification criteria are not met.</p>	
<p>Adverse effects: Not available</p>	
<p>Hazard statements</p>	

SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

H317 - May cause an allergic skin reaction.

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

Section 3: Composition and Information on Ingredients

Chemical characterization

Adrenergic receptor agonist:

Active substance: phenylephrine hydrochloride/ 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1)

Sum formula: C₉H₁₃NO₂.HCl

Molecular weight: 167.21 g/mol

Hazardous components

EC No	Chemical Name	Quantity
200-517-3	phenylephrine hydrochloride/ 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1)	1%
CAS No	Classification according to Directive 67/548/EEC	
61-76-7	Xn - Harmful R22-43	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
N/A	Acute Tox. 4, Skin Sens. 1B, Aquatic Acute 2; H302 H317 H401	
REACH No		
01-2120047675-50		

Full text of R-, H- and EUH-phrases: see section 16.

Section 4. First Aid Measures



SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

General: Remove contaminated soaked clothing immediately and dispose of safely. Take away from danger area and lay down affected person. If you feel unwell, seek medical advice.

Inhalation: In case of inhalation of mist seek medical advice. Information on label instructions. Remove the casualty into fresh air and keep him immobile. Medical treatment.

Skin contact: Wash off immediately with soap and plenty of water. Consult a doctor if skin irritation persists.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

Ingestion: If swallowed, seek medical advice immediately and show this container or label. Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

Notes to physician: See product package insert for complete information. Treat symptoms.

Overdose Treatment: Not available.

Section 5. Fire-fighting Measures

Flammability of the product: Product does not burn.

Combustion Products: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

Unusual Fire and Explosion Hazards: Not Available.

Extinguishing Media and instruction:

Suitable extinguishing media: fire-extinguishing activities according to surrounding. Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.

Unsuitable extinguishing media: Do NOT use full water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Cool containers at risk with water spray jet. Collect contaminated firefighting water separately, must not be discharged into the drains. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

Special remarks on explosion hazard: Not available

Section 6. Accidental Release Measures



SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

Release to land:

Spill: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Contaminated objects and floor clean thoroughly by consideration of environment regulations. Wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area. For proper waste disposal, see section 13 of the SDS.

Release to air: Not available

Release to Water: Do not discharge into the drains/surface waters/ground water.

Protective equipment: Get unprotected persons to safety. Do not breathe vapours. Use personal protective clothing. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition. Observe protective instructions (see Sections 7 and 8).

Section 7. Handling and Storage

Handling: Avoid formation of aerosols. Allow for sucking off. Handle and open container with care. Use personal protective clothing.

No specific precautions required for protection against fire and explosion.

Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

Storage: Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place. Store in a cool and shaded area. Do not store together with oxidizing agents. Do not store with acids or alkalies. Keep away from food, drink and animal feeding stuffs.

Incompatibilities: Protect against direct sun radiation. Keep away from heat.

Section 8. Exposure Control / Personal Protection

Engineering Controls: Ensure adequate ventilation, especially in confined areas. Avoid formation of Aerosols. Provide emergency shower. Provide eye bath.

Personal Protection: Tightly fitting goggles (EN 166), Chemical-resistant gloves (EN 374). (Latex gloves.) Follow the recommendations of the glove manufacturer for breakthrough properties especially for workplace conditions involving mechanical stress and contact duration. Protective suit.

Respiratory Protection: No special protection is necessary when the product is handled inside a safety cabinet or an isolator. Not required, except in case of aerosol formation. Short term: filter apparatus, Filter P3

Exposure limit: Not available

Section 9. Physical and chemical properties



SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

<p>Physical appearance: Liquid Color: Colorless, clear Molecular Weight: 167.21 g/mol Taste: Not available Odor: Mild Odor Threshold: Not available pH: Not available Melting Point: Not available Freezing Point: Not available Boiling Point: Not available Flash Point: Not available Evaporation rate: Not available</p>	<p>Flammability: Not available Upper Flammable Limit: Not available Lower Flammable Limit: Not available Vapor Pressure: Not available Vapor Density: Not available Relative Density: Not available Partition Coefficient: Not available Auto-Ignition Temperature: Not available Decomposition Temperature: Not available Viscosity: Not available Dispersion Properties: Not available Solubility: Soluble at 20°C</p>
---	---

Section 10. Stability and reactivity

Reactivity: No decomposition if stored and applied as directed.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reaction: Stable under normal conditions.
Conditions to avoid: To avoid thermal decomposition, do not overheat.
Incompatible materials: Not known.
Hazardous decomposition products: No decomposition if stored and applied as directed.
Corrosivity: Not available.
Polymerization/Polymorphism: Will not occur.

Section 11. Toxicological information

Acute toxicity

Based on available data, the classification criteria are not met.

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (phenylephrine hydrochloride/ 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1))

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

SAFETY DATA SHEET**Phenylephrine Hydrochloride Injection, USP****Carcinogenic/mutagenic/toxic effects for reproduction**

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Section 12. Ecological information**Toxicity**

No information available.

Persistence and degradability

No information available.

Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

Results of PBT and vPvB assessment

No information available.

Other adverse effects

No information available.

Further information

Do not discharge into the drains/surface waters/ground water.

Section 13. Disposal Information

Waste classification: Not available

Advice on disposal

Waste disposal according to local regulations. Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Waste disposal number of waste from residues/unused products

SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

180108 - WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; cytotoxic and cytostatic medicines
Classified as hazardous waste.

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

Section 14. Transport Information

DOT Classification: Not a DOT controlled material (United States).
UN Number: Not available. No hazardous material as defined by the transport regulations.
UN Shipping name: Not available. No hazardous material as defined by the transport regulations.
Transport hazard class: Not available. No hazardous material as defined by the transport regulations.
Packing Group: Not available. No hazardous material as defined by the transport regulations.
Environmental hazard: Not available. No hazardous material as defined by the transport regulations.
Transport in bulk: Not available. No hazardous material as defined by the transport regulations.
Special precautions needed with transport: Not available. No hazardous material as defined by the transport regulations.

Section 15 Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Additional information

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for childbearing mothers and nursing.

Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

Section 16. Additional Information

Abbreviations and acronyms

ADR = Accord europeen relatif au transport international des marchandises Dangereuses par Route

SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

RID = Reglement concernant le transport international ferroviaire de marchandises dangereuses

AON = Accord europeen relatif au transport international des marchandises dangereuses par voie de navfgation interieure

IMDG = International Maritime Code for Dangerous Goods

IATNCAO = International Air Transport Association/ International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH= Registration, Evaluation, Authorization and Restriction of Chemicals CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization DIN= Deutsche Industrie Norm

PST= Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant R-phrases (Number and full text)

22 - Harmful if swallowed.

43 - May cause sensitisation by skin contact.

Relevant H- and EUH-phrases (Number and full text)

H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

H401 - Toxic to aquatic life.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.



SAFETY DATA SHEET

Phenylephrine Hydrochloride Injection, USP

(n.a. = not applicable; n.d. = not determined)

Created: Aug 05, 2020

Last Updated: Not applicable

Prepared & Approved by: Apollo Pharmaceuticals USA Inc.

The above information is believed to be accurate and represents the best information currently available to Apollo Pharmaceuticals USA Inc. The use of this product should be through or under the direction of a licenced physician or a registered healthcare practitioner. This SDS does not address therapeutic use of this product. Apollo Pharmaceuticals USA Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should Apollo Pharmaceuticals USA Inc. be liable for any claim, loss, or damage of any third party, even if Apollo Pharmaceuticals USA Inc. has been advised of the possibility of such damages to occur.