



Material Safety Data Sheet

Revision date: 2/8/2013
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Phenylephrine Hydrochloride Injection, USP
Product Codes: NDC 0641-6142-01, NDC 0641-6142-25
Synonyms: None
Chemical Family: Cardiovascular drug
Product Type: Regulated Prescription Drug
Container Information: 1 mL vial
Product Use: Pharmaceutical.

Supplier:
West-Ward Pharmaceuticals
Eatontown, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Phenylephrine Hydrochloride 61-76-7	1	None	Xn
Sodium Metabisulfate 7681-57-4	<0.5	None	Xn;R22 Xi;R41 R31 S:2-26-39-46
Sodium Citrate, dihydrate 6132-04-3	<0.5	None	None
Citric Acid Monohydrate 5949-29-1	<0.2	None	Xi
Sodium Chloride 7647-14-5	<0.5	None	Xi; R38
Water 7732-18-5	>97	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: WARNING! HARMFUL IF SWALLOWED. May cause allergic reaction.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

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3. HAZARDS IDENTIFICATION

Ingestion:	Harmful if swallowed. Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Nervous system effects (headache, dizziness, light headedness).
Skin contact:	May cause allergic reaction.
Eye contact:	May cause irritation and/or allergic reactions.

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Skin contact:	Wash contaminated skin with soap and water. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use alcohol foam, water spray or fog.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

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7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling. Do not ingest.

Storage:

Technical measures/Storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store between 15-30°C (59 to 86°F). Protect from light.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Phenylephrine Hydrochloride 61-76-7	None	None	None	None	None	None
Sodium Metabisulfate 7681-57-4	5 mg/m ³	None	None	5 mg/m ³	None	None
Sodium Citrate, dihydrate 6132-04-3	None	None	None	None	None	None
Citric Acid Monohydrate 5949-29-1	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 3.0 - 6.5

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9. PHYSICAL AND CHEMICAL PROPERTIES

Molecular weight:	Not applicable
Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Phenylephrine Hydrochloride 61-76-7	Oral LD50 Rat = 350 mg/kg Oral LD50 Mouse = 120 mg/kg Intravenous LD50 Rat = 440 µg/kg Intravenous LD50 Mouse = 1120 µg/kg Subcutaneous LD50 Rat = 27 mg/kg Subcutaneous LD50 Mouse = 22 mg/kg Intramuscular LD50 Rabbit = 7200 µg/kg Intravenous LD50 Rabbit = 500 µg/kg
Sodium Metabisulfate 7681-57-4	Oral LD50 Rat > 2 g/kg
Sodium Citrate, dihydrate 6132-04-3	None
Citric Acid Monohydrate 5949-29-1	None
Sodium Chloride 7647-14-5	Inhalation LC50 Rat >42 gm/m ³ /1H Oral LD50 Rat = 3 gm/kg Oral LD50 Mouse = 4 gm/kg Dermal LD50 Rabbit >10 gm/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

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Acute toxicity:	Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Nervous system effects (headache, dizziness, light headedness). May cause allergic reactions.
Chronic toxicity:	Target organs: heart.
Carcinogenic effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.
Mutagenic effects:	No data is available on the product itself.
Reproductive toxicity:	No data is available on the product itself.
FDA Pregnancy Category	C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Phenylephrine Hydrochloride 61-76-7	None.	None.	None.	None.
Sodium Metabisulfate 7681-57-4	89 mg/L EC50 24 h	32mg/LLC50Lepomis macrochirus96h	40 mg/L 96 h 48 mg/L 72 h	56mg/LEC50Pseudomonas putida17h
Sodium Citrate, dihydrate 6132-04-3	5600 mg/L EC50 48 h	18000mg/LLC50Poeilia reticulata96h	1800 - 3200 mg/L 96 h	1800 - 3200mg/LEC50Pseudomonas fluorescens8h
Citric Acid Monohydrate 5949-29-1	120 mg/L EC50 72 h	1516mg/LLC50Lepomis macrochirus96h 440mg/LLC50Leuciscus idus96h	None.	14mg/LEC50Photobacterium phosphoreum15min
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h	12946mg/LLC50Lepomis macrochirus96h 7650mg/LLC50Pimephales promelas96h 9675mg/LLC50Lepomis macrochirus96h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

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13. DISPOSAL CONSIDERATIONS

Waste from residues /
unused products:

Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None
DOT Packing Group: None
DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
TDG UN/NA Number: None
TDG Packing Group: None
TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN NUMBER: None
IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List -

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS)

This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Phenylephrine Hydrochloride	1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Metabisulfate	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate, dihydrate	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Monohydrate	<0.2	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Water	>97	Not Listed	Not Listed	Not Listed	Not Listed

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STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Phenylephrine Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Metabisulfate	Not Listed	Present	Not Listed	Toxic	Present	Present	sn 1708
Sodium Citrate, dihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Monohydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:
Not determined

Safety Phrases:
Not Determined

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Updated NDC codes.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet

Product name: Phenylephrine Hydrochloride Injection, USP