Section 1. Identification

GHS product identifier : Phenylephrine Hydrochloride Injection, USP
Synonyms : None.
Product code : NDC 0641-6142-01, NDC 0641-6142-25
Chemical family : Cardiovascular drug.
Product type : Regulated prescription drug.
Container information : 1 mL vial.

Identified uses
Pharmaceutical.

Supplier's details
West-Ward Pharmaceutical Corp.
465 Industrial Way West
Eatontown NJ 07724 USA

Emergency telephone number (with hours of operation)
24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture : SKIN SENSITIZATION - Category 1B

GHS label elements
Hazard pictograms :

Signal word : Warning
Hazard statements : May cause an allergic skin reaction.

Precautionary statements
General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
Prevention : Wear protective gloves. Avoid breathing vapor. Contaminated work clothing should not be allowed out of the workplace.
Response : IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.
Storage : Not applicable.
Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazard not otherwise classified : None known.
Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of identification : None.

CAS number/other identifiers
CAS number : Not applicable.
Product code : NDC 0641-6142-01, NDC 0641-6142-25

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>60 - 100</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>0.1 - 1</td>
<td>61-76-7</td>
</tr>
<tr>
<td>Sodium Metabisulphite</td>
<td>0.1 - 1</td>
<td>7681-57-4</td>
</tr>
<tr>
<td>Sodium Citrate, dihydrate</td>
<td>0.1 - 1</td>
<td>6132-04-3</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.1 - 1</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Citric Acid Monohydrate</td>
<td>0.1 - 1</td>
<td>5949-29-1</td>
</tr>
</tbody>
</table>

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact : May cause an allergic skin reaction.
Section 4. First aid measures

Ingestion: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact: No known significant effects or critical hazards.

Inhalation: No known significant effects or critical hazards.

Skin contact: Adverse symptoms may include the following:
- irritation
- redness

Ingestion: No known significant effects or critical hazards.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Notes to physician:

In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments: No specific treatment.

No known significant effects or critical hazards.

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: No specific fire or explosion hazard.

Hazardous thermal decomposition products: Decomposition products may include the following materials:
- carbon dioxide
- carbon monoxide
- nitrogen oxides
- halogenated compounds

Special protective actions for fire-fighters: No special measures are required.

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Section 6. Accidental release measures

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).

Methods and materials for containment and cleaning up

Spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for safe storage, including any incompatibilities: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits: None.

Appropriate engineering controls: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Section 8. Exposure controls/personal protection

Eye/face protection
Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection
Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection
Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection
Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection
Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state
Liquid. [Aqueous solution.]

Color
Colorless.

Odor
Not available.

Odor threshold
Not available.

pH
3 to 6.5

Melting point
Not available.

Boiling point
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not available.

Lower and upper explosive (flammable) limits
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility
Soluble in the following materials: cold water and hot water.

Partition coefficient: n-octanol/water
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.
Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>350 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure

Dermal contact. Eye contact. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.
Section 11. Toxicological information

Skin contact: Adverse symptoms may include the following:
- irritation
- redness

Ingestion: No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure
- Potential immediate effects: No known significant effects or critical hazards.
- Potential delayed effects: No known significant effects or critical hazards.

Long term exposure
- Potential immediate effects: No known significant effects or critical hazards.
- Potential delayed effects: No known significant effects or critical hazards.

Potential chronic health effects
- General: Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
- Carcinogenicity: No known significant effects or critical hazards.
- Mutagenicity: No known significant effects or critical hazards.
- Teratogenicity: No known significant effects or critical hazards.
- Developmental effects: No known significant effects or critical hazards.
- Fertility effects: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

<table>
<thead>
<tr>
<th>Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATE value</td>
<td>35000 mg/kg</td>
</tr>
</tbody>
</table>

Section 12. Ecological information

Toxicity
There is no data available.

Persistence and degradability
There is no data available.

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>LogP&lt;sub&gt;ow&lt;/sub&gt;</th>
<th>BCF</th>
<th>Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>-0.31</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

Mobility in soil

| Soil/water partition coefficient (K<sub>oc</sub>) | Not available. |

Other adverse effects
No known significant effects or critical hazards.
Section 13. Disposal considerations

**Phenylephrine Hydrochloride Injection, USP**

**Disposal methods**

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

<table>
<thead>
<tr>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>shipping name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>hazard class(es)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Environmental</td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td>hazards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**AERG** : Not applicable.

**Special precautions for user**

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

**U.S. Federal regulations**

- **Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)**: Not listed
- **Clean Air Act Section 602 Class I Substances** : Not listed
- **Clean Air Act Section 602 Class II Substances** : Not listed

**TSCA 8(a) PAIR**: Sodium Metabisulphite

**TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

**United States inventory (TSCA 8b)**: All components are listed or exempted.
Section 15. Regulatory information

DEA List I Chemicals (Precursor Chemicals) : Not listed
DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304
Composition/information on ingredients
No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312
Composition/information on ingredients

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
<th>Fire hazard</th>
<th>Sudden release of pressure</th>
<th>Reactive</th>
<th>Immediate (acute) health hazard</th>
<th>Delayed (chronic) health hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>0.1 - 1</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
</tbody>
</table>

State regulations
Massachusetts : None of the components are listed.
New York : None of the components are listed.
New Jersey : None of the components are listed.
Pennsylvania : None of the components are listed.
California Prop. 65
No products were found.

International regulations
International lists : Australia inventory (AICS): All components are listed or exempted.
                     China inventory (IECSC): Not determined.
                     Japan inventory: All components are listed or exempted.
                     Korea inventory: All components are listed or exempted.
                     Malaysia Inventory (EHS Register): Not determined.
                     New Zealand Inventory of Chemicals (NZIoC): Not determined.
                     Philippines inventory (PICCS): All components are listed or exempted.
                     Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed
Chemical Weapons Convention List Schedule II Chemicals : Not listed
Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History
Date of issue mm/dd/yyyy : 12/15/2013
Version : 1
Revised Section(s) : Not applicable.
Prepared by : KMK Regulatory Services Inc.
Section 16. Other information

Key to abbreviations:
- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- UN = United Nations

Notice to reader
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.