MATERIAL SAFETY DATA SHEET

Product Name: NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

Synonyms
(-)-m-Hydroxy-α-[(methylamino) methyl] benzyl alcohol hydrochloride; (1R)-1-(3-Hydroxyphenyl)-2-methylaminoethanol

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Phenylephrine Hydrochloride

Chemical Formula
C9H13NO2 • HCl

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, sodium citrate, citric acid monohydrate, and sodium metabisulfite.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>1</td>
<td>61-76-7</td>
<td>DO7525000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection) is a solution containing phenylephrine hydrochloride, a vasoconstrictor and pressor drug chemically related to epinephrine and ephedrine. Clinically, it is used to maintain blood pressure during spinal and inhalation anesthesia and for the treatment of vascular failure in shock, shock-like states, and drug-induced hypotension, or hypersensitivity. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potent drug. Based on clinical use, possible target organs include the central nervous system, cardiovascular system and eyes.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact. Since phenylephrine is absorbed through the mucosa, systemic effects may occur after application to the eyes or the nasal mucosa.
Product Name: NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

Signs and Symptoms
None known from occupational exposure. Phenylephrine constricts blood vessels, increases blood pressure and causes the pupils of the eyes to dilate. In clinical use, adverse effects may include headache, reflex bradycardia, excitability, restlessness, and rarely arrhythmias. Other effects may include dizziness, trembling, increased heart rate and blood pressure, nervousness, pallor, and cold sweats, ventricular extrasystoles and short paroxysms of ventricular tachycardia, a sensation of fullness in the head and tingling of the extremities.

Medical Conditions
Pre-existing hypersensitivity to this material; pre-existing central nervous system, cardiovascular system and ocular ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required for hazard control under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
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Special Precautions  No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, colorless liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>3.0 - 6.5</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Freely soluble in water and alcohol</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined.

Conditions to avoid Not determined.

Incompatibilities Not determined.

Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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</thead>
<tbody>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>350</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>120</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Phenylephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>0.44</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>1.12</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>0.5</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. Phenylephrine hydrochloride has rarely produced allergic contact dermatitis in patients when used eye drop preparations.

Reproductive Effects Animal reproduction studies have not been conducted with phenylephrine hydrochloride. However, it has been reported that phenylephrine given to pregnant rabbits during the last third of gestation produced fetal growth retardation and the onset of early labor.

Mutagenicity Phenylephrine hydrochloride was negative in the Ames assay; it produced increased sister-chromatid exchange in an assay in Chinese hamster ovary cells, but was generally negative or equivocal in other assays for genotoxicity.

Carcinogenicity Phenylephrine hydrochloride was not carcinogenic in two-year dietary studies in mice and rats at oral dosages up to 50 mg/kg/day and 270 mg/kg/day, respectively.

Target Organ Effects Based on clinical use, possible target organs include the cardiovascular system,
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central nervous system, and eyes.

### 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity**
Not determined for product.

**Persistence/Biodegradability**
Not determined for product.

**Bioaccumulation**
Not determined for product.

**Mobility in Soil**
Not determined for product.

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal**
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal**
Dispose of container and unused contents in accordance with federal, state and local regulations.

### 14. TRANSPORTATION INFORMATION

**DOT STATUS**
Not regulated

**IMDG STATUS:**
Not regulated

**ICAO/IATA STATUS:**
Not regulated

### 15. REGULATORY INFORMATION

#### USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Not Listed

**U.S. OSHA Classification**
Target Organ Toxin

**GHS Classification**
Possible Irritant

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class**
Not Applicable

**Hazard Category**
Not Applicable

**Signal Word**
Not Applicable
Product Name: NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

Symbol: Not Applicable


Hazard Statement: Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

**EU Classification**
Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Phenylephrine Hydrochloride.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: S23 - Do not breathe vapor.

Safety Phrases: S24 - Avoid contact with skin.

S25 - Avoid contact with eyes.

S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

<table>
<thead>
<tr>
<th>Notes:</th>
<th>ACGIH TLV</th>
<th>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td></td>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td></td>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td></td>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td></td>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td></td>
<td>NE</td>
<td>Not established</td>
</tr>
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<td></td>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td></td>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td></td>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td></td>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td></td>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
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<tr>
<td></td>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
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<tr>
<td></td>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
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<tr>
<td></td>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
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</tbody>
</table>

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/27/2011
Obsolete Date: 10/21/2008
Product Name: NEO-SYNEPHRINE® HYDROCHLORIDE (phenylephrine hydrochloride injection)

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