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
Epinephrine Injection, USP

Synonyms
4-[1-hydroxy-2-(methylamino) ethyl]1,2 benzenediol.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
L-Epinephrine

Chemical Formula
C₉H₁₃NO₃

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

<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>L-Epinephrine</td>
<td>≤0.1</td>
<td>51-43-4</td>
<td>DO2625000</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>L-Epinephrine</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Epinephrine Injection is a solution containing epinephrine, a vasoconstrictor agent. In clinical use, epinephrine is used to relieve respiratory distress due to bronchospasm, to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and to prolong the action of anesthetics. Its cardiac effects may be of use in restoring cardiac rhythm in cardiac arrest due to various causes. In the workplace, this material should be considered a potent drug and possibly irritating to the skin and eyes. Based on clinical use, possible target organs include the nervous system, cardiovascular system, eyes, and respiratory system.

Occupational Exposure Potential
Though not well absorbed, inhalation or topical application can produce systemic effects. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known form occupational exposure. In clinical use, serious adverse effects may include rapid and large increases in blood pressure, cerebral hemorrhage, pulmonary arterial hypertension resulting in edema, hyperglycemia, and cardiac arrhythmia with ventricular fibrillation. Other adverse effects may include fearfulness, anxiety, sweating, nervousness,
palpitations, tenseness, restlessness, headache, tremor, dizziness and lightheadedness, fever, chills, nausea, vomiting, respiratory difficulty, tachycardia, dilated pupils, blurred vision, cyanosis, ECG changes, disruption of cardiac rhythm, hypertension, metabolic acidosis, and injury to the heart. Locally, tissue necrosis can result at the injection site due to vasoconstriction. Ocular use has produced conjunctival irritation (burning, stinging, tearing and rebound redness).

Medical Conditions Aggravated by Exposure

Pre-existing nervous system, cardiovascular system, ocular, or respiratory system ailments. Pre-existing hypersensitivity to this material.

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 from this aqueous product.

Fire & Explosion Hazard
None anticipated from 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 fire fighting 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 any 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 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.

Special Precautions
No special precautions are required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Epinephrine</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>1</td>
<td>8 Hr TWA</td>
</tr>
<tr>
<td>L-Epinephrine</td>
<td>Hospira STEL</td>
<td>N/A</td>
<td>N/A</td>
<td>20</td>
<td></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>Not Determined</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
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<tr>
<td>pH:</td>
<td>3.3 (2.5 to 5.0)</td>
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<tr>
<td>Melting point/Freezing point</td>
<td>NA</td>
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<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>With acids, forms salts that are freely soluble in water</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>
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) and nitrogen oxides (NOx).

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>Epinephrine</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>150</td>
<td>mcg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>217</td>
<td>mcg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>mcg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
<td>mcg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Epinephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>62</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Epinephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>24</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Epinephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>140</td>
<td>mcg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Epinephrine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>4.7</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product. Inadvertent inhalation of small amounts of this product may produce irritation and possibly bronchial dilation.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, dilated pupils, and blurred vision.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
No teratogenic effect was noted in offspring of pregnant rats given continuous infusions of epinephrine at a dose about 8 times the normal human dose. An increase in the frequency of cleft palate was noted in the offspring of one strain
Product Name: Epinephrine Injection, USP

of mice treated during pregnancy with epinephrine at doses that were 40-80 times the normal human dose. An increase in the frequency of fetal loss was noted in pregnant mice and rabbits given epinephrine at doses that were 200 and 85 times, respectively, the human therapeutic dose. The frequency of malformations was not increased in offspring of hamsters treated during pregnancy with 25 times the human subcutaneous dose.

Mutagenicity

Salmonella gene mutation tests with L-epinephrine were negative in the TA100 strain in the presence of S9 metabolic activation, but equivocal in the absence of S9. No mutagenic activity was observed in strains TA98, TA1535, or TA1537 with or without S9. Results noted in a CHO cell assay for induction of sister chromatid exchanges were considered negative and equivocal in the presence and absence of S9 activation, respectively.

Carcinogenicity

No data found for epinephrine. By analogy, in a chronic aerosol inhalation studies in rats and mice, epinephrine hydrochloride did not significantly increase the incidence of tumors over controls in these animals. Increased incidences of supurative inflammation, dilatation of the nasal glands in rats and mice, and hyperplasia of the respiratory epithelium in rats only were noted in this study.

Target Organ Effects

Based on clinical use, possible target organs include the nervous system, cardiovascular system, eyes, and respiratory system.

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 wastes must be properly characterized by the waste generator. 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

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None
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>L-Epinephrine</td>
<td>Listed</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Epinephrine – Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts.

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

**GHS Classification**
*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

**Symbol**
Not Applicable

**Prevention**
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**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 L-Epinephrine.

**Classification(s):**
Not Applicable

**Symbol:**
Not Applicable

**Indication of Danger:**
Not Applicable

**Risk Phrases:**
R00 - Not Applicable

**Safety Phrases:**
S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37 - Wear suitable gloves.
S39 - Wear eye / face protection.
## 16. OTHER INFORMATION:

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

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**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** 09/19/2011  
**Obsolete Date:** 05/26/2009

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