# SAFETY DATA SHEET

**Product Name**: **Epinephrine Injection**

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

| | |
|---|---|
| **Manufacturer Name And Address** | Hospira, Inc.<br>275 North Field Drive<br>Lake Forest, Illinois 60045<br>USA |
| **Emergency Telephone** | CHEMTREC: North America: 800-424-9300;<br>International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418 |
| **Hospira, Inc., Non-emergency** | 224 212-2000 |
| **Product Name** | Epinephrine Injection |
| **Synonyms** | 4-[1-hydroxy-2-(methylamino) ethyl]-1,2 benzenediol |

## 2. HAZARD(S) IDENTIFICATION

**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.

**U.S. OSHA GHS Classification**

| **Physical Hazards** | **Hazard Class** | **Hazard Category** |
|---|---|---|
| | Not Classified | Not Classified |
| **Health Hazards** | **Hazard Class** | **Hazard Category** |
| | STOT – RE | 2 |

**Label Element(s)**

**Pictogram**

**Signal Word**: Warning

**Hazard Statement(s)**: May cause damage to organs through prolonged or repeated exposure

**Precautionary Statement(s)**

**Prevention**:
Do not breathe vapor or spray
Wash hands thoroughly after handling

**Response**:
Get medical attention if you feel unwell.

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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** L-Epinephrine
**Chemical Formula** $C_9H_{13}NO_3$

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|---|---|---|---|
| L-Epinephrine | ≤ 0.1 | 51-43-4 | DO2625000 |

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 (for pH adjustment).

## 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**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 control 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.

**Special Precautions** No special precautions required for hazard control.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines**

| | Exposure Limits | | | |
|---|---|---|---|---|
| **Component** | **OSHA-PEL** | **ACGIH-TLV** | **AIHA WEEL** | **Hospira EEL** |
| L-Epinephrine | 8 hr TWA: Not Established | 8 hr TWA: Not Established | 8 hr TWA: Not Established | 8 hr TWA: Not Established |

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

**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

| | |
|---|---|
| **Appearance/Physical State** | Epinephrine is a white, crystalline powder. Epinephrine Injection is a clear, colorless liquid. |
| **Odor** | Not determined. |
| **Odor Threshold** | NA |
| **pH** | 3.3 (2.2 to 5.0) |
| **Melting point/Freezing Point** | NA |
| **Initial Boiling Point/Boiling Point Range** | NA |
| **Flash Point** | NA |
| **Evaporation Rate** | NA |
| **Flammability (solid, gas)** | NA |
| **Upper/Lower Flammability or Explosive Limits** | NA |
| **Vapor Pressure** | NA |
| **Vapor Density (Air =1)** | NA |
| **Relative Density** | NA |
| **Solubility** | With acids, epinephrine forms salts that are freely soluble in water. |
| **Partition Coefficient: n-octanol/water** | NA |
| **Auto-ignition Temperature** | NA |
| **Decomposition Temperature** | NA |
| **Viscosity** | NA |

## 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 active ingredient is as follows:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|---|---|---|---|---|---|---|
| Epinephrine | 100 | LD50 | Intravenous | 150<br>217<br>50<br>100 | mcg/kg<br>mcg/kg<br>mcg/kg<br>mcg/kg | Rat<br>Mouse<br>Rabbit<br>Dog |
| Epinephrine | 100 | LD50 | Dermal | 62 | mg/kg | Rat |
| Epinephrine Hydrochloride | 100 | LD50 | Oral | 24 | mg/kg | Rat |
| Epinephrine Hydrochloride | 100 | LD50 | Intravenous | 140 | mcg/kg | Mouse |
| Epinephrine Hydrochloride | 100 | LD50 | Intraperitioneal | 4.7 | mg/kg | Mouse |

LD 50: Dosage that produces 50% mortality.

**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 anticipated from normal handling of this product. 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).

**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. However, this product contains sodium metabisulfite which may elicit allergic reactions in people sensitive to sulfites.

## 11. TOXICOLOGICAL INFORMATION: continued

| | |
|---|---|
| **Reproductive Effects** | None anticipated from normal handling of this product. 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 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. |
| **Carcinogen Lists** | **IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed |
| **Specific Target Organ Toxicity – Single Exposure** | NA |
| **Specific Target Organ Toxicity – Repeat Exposure** | Based on clinical use, possible target organs include the nervous system, cardiovascular system, eyes, and respiratory system. |

## 12. ECOLOGICAL INFORMATION

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|---|---|
| **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

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|---|---|
| **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

| | |
|---|---|
| **ADR/ADG/ DOT STATUS** | Not regulated |
| **Proper Shipping Name** | NA |
| **Hazard Class** | NA |
| **UN Number** | NA |
| **Packing Group** | NA |
| **Reportable Quantity** | NA |
| **ICAO/IATA STATUS** | Not regulated |
| **Proper Shipping Name** | NA |
| **Hazard Class** | NA |
| **UN Number** | NA |
| **Packing Group** | NA |
| **Reportable Quantity** | NA |
| **IMDG STATUS** | Not regulated |
| **Proper Shipping Name** | NA |
| **Hazard Class** | NA |
| **UN Number** | NA |
| **Packing Group** | NA |
| **Reportable Quantity** | NA |

Notes: DOT - US Department of Transportation Regulations

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **US TSCA Status** | Exempt |
| **US CERCLA Status** | Epinephrine – Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements. |
| **US SARA 302 Status** | Not listed |
| **US SARA 313 Status** | Not listed |
| **US RCRA Status** | Epinephrine – Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements. |
| **US PROP 65 (Calif.)** | Not listed |

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP 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 | Hazard Category | Pictogram | Signal Word | Hazard Statement |
|---|---|---|---|---|
| NA | NA | NA | NA | NA |

**Prevention**

Do not breathe vapor or spray
Wash hands thoroughly after handling

**Response**

Get medical attention if you feel unwell.

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.

## 15. REGULATORY INFORMATION: continued

| | |
|---|---|
| **EU Classification*** | *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. |
| **Classification(s)** | NA |
| **Symbol** | NA |
| **Indication of Danger** | NA |
| **Risk Phrases** | NA |
| **Safety Phrases** | S23: Do not breathe vapor/spray<br>S24: Avoid contact with the skin<br>S25: Avoid contact with eyes<br>S37/39 Wear suitable gloves and eye/face protection. |

## 16. OTHER INFORMATION

Notes:

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|---|---|
| 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 |
| $LD_{50}$ | 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 |
| STOT - SE | Specific Target Organ Toxicity – Single Exposure |
| STOT - RE | Specific Target Organ Toxicity – Repeated Exposure |
| TSCA | Toxic Substance Control Act |
| TWA | 8-hour Time Weighted Average |

| | |
|---|---|
| MSDS Coordinator: | Hospira GEHS |
| Date Prepared: | October 18, 2012 |
| Date Revised: | June 02, 2014 |

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