MATERIAL SAFETY DATA SHEET

Product Name: Ephedrine Sulfate Injection, USP

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 Ephedrine Sulfate Injection, USP

Synonyms α-[1-(methylamino) ethyl] benzenemethanol sulfate (2:1)(salt)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Ephedrine Sulfate

Chemical Formula (C_{10}H_{15}NO)_{2} • H_{2}SO_{4}

Preparation Non-hazardous ingredients include water.

<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>Ephedrine Sulfate</td>
<td>5</td>
<td>134-72-5</td>
<td>KB2625000</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>Ephedrine Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Ephedrine Sulfate Injection is a solution containing ephedrine sulfate, a sympathomimetic amine with direct and indirect effects on adrenergic receptors. Clinically, it is used to treat bronchial asthma and reversible bronchospasm; to treat shock by producing cardiac stimulation and vasoconstriction; and to treat hypotension, myasthenia gravis and enuresis. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the heart, lungs, cardiovascular system and central nervous system.

Occupational Exposure Potential Information on the absorption of this product via skin contact is not available. The active ingredient may be absorbed via ingestion or inhalation. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms No signs or symptoms from occupational exposure are known. In clinical use, adverse effects may include excitation, tremulousness, insomnia, nervousness, restlessness, anxiety, tremor, weakness, dizziness, confusion, pallor, nausea, hypertension, palpitations, tachycardia, precordial pain, arrhythmias, vertigo, dry nose and throat, headache, sweating and vomiting. Chronic use may produce modest weight loss.
Medical Conditions Aggravated by Exposure Hypersensitivity to ephedrine sulfate and/or similar materials; pre-existing central nervous system, cardiovascular system, respiratory system ailments; hypertension; diabetes, hyperthyroidism.

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 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 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 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

<table>
<thead>
<tr>
<th>Exposure limits</th>
</tr>
</thead>
</table>
Product Name: Ephedrine Sulfate Injection, USP

<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>Ephedrine Sulfate</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
<td>8 hr TWA</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

Appearance/Physical State: Liquid
Color: Ephedrine Sulfate Injection, USP is a sterile, nonpyrogenic Odor: Odorless
Odor Threshold: NA
pH: 5.3 (4.5 to 7.0)
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: 1 in 1.3 of water and 1 in 90 of alcohol
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity: Not determined
Product Name: Ephedrine Sulfate Injection, USP

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Strong oxidizers

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), sulfur oxides (SOx) and H2SO4.

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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<tbody>
<tr>
<td>Ephedrine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>404</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>812</td>
<td>mg/kg</td>
<td>Mouse</td>
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<td></td>
<td></td>
<td>825</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<tr>
<td>Ephedrine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>102</td>
<td>mg/kg</td>
<td>Rat</td>
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<td></td>
<td></td>
<td>73</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. However, 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.

Reproductive Effects
Animal reproduction studies have not been conducted with ephedrine sulfate.

Mutagenicity
Ephedrine sulfate was negative in Ames test in strains TA100, TA1535, TA97 and TA98 with and without activation. Did not induce sister-chromatid exchanges or chromosomal aberrations in Chinese hamster ovary cells with and without activation.

Carcinogenicity
In chronic feeding studies, there was no evidence of carcinogenicity for F344/N rats or B6C3Fi mice of either sex receiving 125 or 250 ppm ephedrine sulfate in the diet for 2 years.

Target Organ Effects
Based on clinical use, possible target organs include the heart, lungs, cardiovascular system and central nervous 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 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
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>
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RCRA Status  Not Listed
U.S. OSHA Classification  Target Organ Toxin
Classification  Possible Irritant

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
Signal Word  Not Applicable
Symbol  Not Applicable
Prevention  P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
Product Name: Ephedrine Sulfate Injection, USP

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 Ephedrine Sulfate.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapour.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and 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 Ac. Exempt, However, ephedrine sulfate is on the TSCA inventory.
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/19/2011
Obsolete Date: 10/21/2008
Product Name: Ephedrine Sulfate Injection, USP

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