Material Safety Data Sheet

Product Name: Dobutamine in 5% Dextrose 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
Dobutamine in 5% Dextrose Injection

Synonyms
(±)-4-[2-[(3-(p-hydroxyphenyl)-1-methylpropyl] amino]ethyl]-pyrocatechol hydrochloride

2. Composition/Information on Ingredients

Active Ingredient Name
Dobutamine Hydrochloride

Chemical Formula
C_{18}H_{23}NO_{3} • HCl

Preparation
Non-hazardous ingredients include Water for Injection and dextrose. Hazardous ingredients present at less than 1% include sodium metabisulfite and edetate disodium, dihydrate. Hydrochloric acid and/or sodium hydroxide are added to adjust the pH.

<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>Dobutamine Hydrochloride</td>
<td>0.4</td>
<td>49745-95-1</td>
<td>CZ9001000</td>
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</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>Dobutamine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Dobutamine in 5% Dextrose Injection is a solution containing dobutamine hydrochloride, a synthetic catecholamine that is a cardiac stimulant. Clinically, it is used to increase cardiac output in the short-term treatment of cardiac decompensation due to heart disease or surgery. 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 eyes and the cardiovascular system.

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.

Signs and Symptoms
None known from occupational exposures. In clinical use, dobutamine hydrochloride produces a marked increase in heart rate and blood pressure in up to 10% of patients. Premature ventricular beats have occurred during infusion in 5% of patients. Precipitous decreases in
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blood pressure have occasionally been described in association with dobutamine therapy. The most frequently reported adverse effects include nausea, headache, anginal pain, nonspecific chest pain, palpitations, and shortness of breath. Other adverse effects include hypersensitivity (rash, fever, eosinophilia and bronchospasms), nausea, vomiting, tingling sensation, paresthesia, dyspnea, headache, mild leg cramps, and pruritus of the scalp have been reported.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to this material; pre-existing sensitivity to sulfites; pre-existing cardiovascular 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 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
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<tbody>
<tr>
<td>Dobutamine Hydrochloride</td>
<td>Hospira STEL</td>
<td>N/A</td>
<td>N/A</td>
<td>500</td>
<td>15 Min STEL</td>
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</tbody>
</table>

**Exposure Guidelines**

**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**  Sterile, nonpyrogenic, prediluted solution

**Odor**  NA

**Odor Threshold:**  NA

**pH:**  3.0 (2.5 to 5.5)

**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:**  NA

**Partition coefficient: n-octanol/water:**  NA

**Auto-ignition temperature:**  NA

**Decomposition temperature:**  NA

10. STABILITY AND REACTIVITY
Product Name: Dobutamine in 5% Dextrose Injection

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions. Dobutamine is oxygen sensitive.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Dobutamine is incompatible with alkaline solutions such as sodium bicarbonate 5% and alkaline drugs.

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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<tbody>
<tr>
<td>Dobutamine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>2296</td>
<td>mg/kg</td>
<td>Rat</td>
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<td></td>
<td>1324</td>
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<td></td>
<td>&gt;40</td>
<td>mg/kg</td>
<td>Dog</td>
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<td></td>
<td>34.3</td>
<td>mg/kg</td>
<td>Mouse</td>
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</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Dobutamine hydrochloride was non corrosive/non-irritating in a skin irritation study in animals.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, dobutamine hydrochloride was severely irritating and corrosive in an eye irritation test in animals. Inadvertent contact of this product with eyes may produce severe irritation with redness and tearing.

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

Reproductive Effects
Studies to evaluate the potential to affect fertility have not been conducted. Reproduction studies performed in rats at doses up to the normal human dose (10 mcg/kg/min for 24 hours, total daily dose of 14.4 mg/kg) and in rabbits at doses up to 2 times the normal human dose have revealed no evidence of harm to the fetus due to dobutamine.

Mutagenicity
Studies to evaluate the mutagenic potential of dobutamine hydrochloride have not been conducted.
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Carcinogenicity  
Studies to evaluate the carcinogenic potential of dobutamine hydrochloride have not been conducted.

Target Organ Effects  
Based on clinical use, possible target organs include the eyes and the cardiovascular 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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<tr>
<td>U.S. OSHA Classification</td>
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<tr>
<td>GHS Classification</td>
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*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,
Product Name: Dobutamine in 5% Dextrose Injection

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/vapours/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 Dobutamine Hydrochloride.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapour.
S24/25 - Avoid contact with skin and 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 Act
Product Name: Dobutamine in 5% Dextrose Injection

TWA  8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/15/2011
Obsolete Date: 10/21/2008

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