# SAFETY DATA SHEET

## Product Name: Dobutamine Hydrochloride 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** | Dobutamine Hydrochloride Injection |
| **Synonyms** | 1,2-benzenediol, 4-[2-[[3-(4-hydro-xyphenyl)-1-methylpropyl]amino]ethyl]-hydrochloride, (±). |

## 2. HAZARD(S) IDENTIFICATION

**Emergency Overview**

Dobutamine Hydrochloride 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 cardiovascular system.

**U.S. OSHA GHS Classification**

| **Physical Hazards** | **Hazard Class** | **Hazard Category** |
|---|---|---|
| | Not Classified | Not Classified |
| **Health Hazards** | **Hazard Class** | **Hazard Category** |
| | Eye Damage/Irritation | 2A |
| | STOT - RE | 2 |

**Label Element(s)**

**Pictogram**

**Signal Word**

Warning

**Hazard Statement(s)**

Causes serious eye irritation
May cause damage to organs through prolonged or repeated exposure

**Precautionary Statement(s)**

**Prevention**

Do not breathe vapor or spray.
Wear eye protection/face protection.
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** Dobutamine Hydrochloride
**Chemical Formula** $C_{18}H_{23}NO_3 \bullet HCl$

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|---|---|---|---|
| Dobutamine Hydrochloride | 1.25 | 49745-95-1 | CZ9001000 |

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

## 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** |
| Dobutamine Hydrochloride | 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** | A clear, practically colorless, sterile, nonpyrogenic solution |
| **Odor** | NA |
| **Odor Threshold** | NA |
| **pH** | 2.5 to 5.5 |
| **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** | NA |
| **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. 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 active ingredient is as follows:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|---|---|---|---|---|---|---|
| Dobutamine Hydrochloride | 100 | LD50 | Oral | 2296<br>1324<br>>40 | mg/kg<br>mg/kg<br>mg/kg | Rat<br>Mouse<br>Dog |
| Dobutamine Hydrochloride | 100 | LD50 | Intravenous | 59.6<br>34.3 | mg/kg<br>mg/kg | Rat<br>Mouse |

LD 50: Dosage that produces 50% mortality.

**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 anticipated from normal handling of this product. 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 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

**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. This product contains sodium metabisulfite which can cause allergic-type reactions in people sensitive to sulfites.

**Reproductive Effects** None anticipated from normal handling of this product. 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.

## 11. TOXICOLOGICAL INFORMATION: continued

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

Notes:

## 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** | Not listed |
| **US SARA 302 Status** | Not listed |
| **US SARA 313 Status** | Not listed |
| **US RCRA Status** | Not listed |
| **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.
Wear eye protection/face protection.
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.

**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 17, 2012 |
| Date Revised: | June 02, 2014 |

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