



300 Northfield Road  
 Bedford, OH 44146  
 Telephone: (440) 232-3320  
 -or- (800) 562-4797

**MATERIAL SAFETY DATA SHEET**

**Section I - IDENTITY**

**Common/Trade Name:** Dobutamine Hydrochloride Injection (250mg/20ml)

**Chemical Names:** Dobutamine Hydrochloride

**Synonyms:** Dobutrex® Injection; Dobutamine HCl; Dobutrex® Solution

**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.

**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146

**Emergency Telephone Number:** Chemtrec: 1(800)424-9300

**Telephone Number for Info.:** (440)232-3320 or (800)562-4797

**Medical Emergency:** Professional Services 1(800)521-5169

**Date Prepared:** June 29, 1995

**Date Revised:** December 31, 2001

**Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION**

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Dobutamine HCl	1.25%	52663-81-7	NONE	NONE	0.5 mg/m3 (STEL)
Sodium Bisulfite	0.03%	7631-90-5	NONE	NONE	NONE
Water for Injection	98.7%	7732-18-5	NONE	NONE	NONE
Sodium Hydroxide and/or Hydrochloric Acid for pH adjustment					

Dobutamine is a sterile injectable liquid drug provided in a vial.

**Section III - HEALTH HAZARD DATA**

**Routes of Entry:** Dobutamine Hydrochloride may be absorbed through inhalation and skin contact. Exposure is not expected under normal use.

**Health Hazard (Acute & Chronic):** Dobutamine is a drug used in cardiac care. Excessive exposure may cause an elevated heart rate. Irritation to skin and eyes may occur. The target organ is the heart and cardiovascular system. Chronic allergic reactions may result in persons sensitive to bisulfites. Rashes and broncospasms may result in persons who have an allergic reaction.

**Carcinogenicity:** NTP? NO IARC Monographs? NONE  
 OSHA Regulated? NO

**Signs & Symptoms of Exposure:** Increased heart rate, skin/eye irritation, increased blood pressure.

**Medical Conditions Generally Aggravated by Exposure:** None known

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**Section IV - FIRST AID MEASURES**

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**Eye Exposure:** Flush eyes with large amounts of water for 15 minutes.

**Skin Exposure:** Wash skin with cool, soapy water for 15 minutes.

**Ingestion:** Do not induce vomiting. Seek medical attention from a physician immediately.

If available, administer activated charcoal (6-8 heaping teaspoons) with 2-3 glasses of water.

**Inhalation:** If difficulty breathing, administer oxygen. Seek medical attention immediately.

If necessary, provide artificial respiration.

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**Section V - FIRE AND EXPLOSION HAZARD DATA**

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**Flash Point (Method Used):** Not determined    **LEL:** NA    **UEL:** NA

**Flammable Limits:** Dobutamine Hydrochloride is not a flammable solution.

**Extinguishing Media:** Use water or type ABC aqueous-based multi-purpose extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:** None

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**Section VI - ACCIDENTAL RELEASE INFORMATION**

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**Release to land:** Absorb Dobutamine Hydrochloride with absorbent materials and dispose of according to local, state, and federal regulations.

**Release to air:** If aerosolized, avoid and reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

**Release to water:** Refer to local water authority; drain disposal is not recommended; however, refer to local, state, and federal guidelines.

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**Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

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**Steps to be taken in case material is released or spilled:** See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

**Waste Disposal Method:** Incineration in an approved/permitted incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store at controlled room temperature, 15 to 30°C (59 to 86°F).

**Other Precautions:** None

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**Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT**

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**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle product in a well-ventilated area.

**Protective Gloves:** Nitrile or latex

**Eye Protection:** Safety glasses

**Other Protective Clothing or Equipment:** Lab Coat

**Work/Hygienic Practices:** Wash hands following use; no eating, drinking, or smoking while handling product.

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## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

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**Physical State:** Liquid

**Specific Gravity:** Not available

**Appearance and Odor:** Clear, colorless to a faint straw color with no odor

**Melting Point:** Not applicable

**Boiling Point:** Not available

**Evaporation Rate:** Not available

**Vapor Pressure:** Not available

**Solubility in Water:** Soluble

**Vapor Density:** Not available

**pH:** 2.5-5.5

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## Section X - STABILITY AND REACTIVITY DATA

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**Stability:** Stable

**Incompatibility (Materials to Avoid):** May react with strong oxidizing agents.

**Hazardous Decomposition or Byproducts:** May emit toxic chloride fumes when heated to decomposition. As with any burning material, carbon monoxide and carbon dioxide or other toxic gases may be produced.

**Hazardous Polymerization:** Not known to occur

**Conditions to Avoid:** Storage with strong oxidizers or water reactive materials.

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## Section XI - TOXICOLOGICAL INFORMATION

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For the active ingredient Dobutamine Hydrochloride:

LD<sub>50</sub> oral, mouse = 1324 mg/kg

LD<sub>50</sub> intraperitoneal, mouse = 243 mg/kg

LD<sub>50</sub> intravenous, mouse = 34.3 mg/kg

LD<sub>50</sub> oral, rat = 2296 mg/kg

LD<sub>50</sub> intraperitoneal, rat = 260 mg/kg

LD<sub>50</sub> subcutaneous, rat = 368 mg/kg

LD<sub>50</sub> intravenous, rat = 60 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

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## Section XII - ENVIRONMENTAL IMPACT INFORMATION

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Information is currently not available on the environmental impact of Dobutamine. Handle in a manner to prevent spills or releases to the environment.

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**Section XIII - DISPOSAL INFORMATION**

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Dispose of by incineration at an approved/permitted incinerator.  
Review local, state, and federal regulations.

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**Section XIV - TRANSPORTATION INFORMATION**

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Dobutamine Hydrochloride Injection is not a DOT Hazardous Material.  
Dobutamine Hydrochloride is not a Marine Pollutant

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**Section XV - REGULATORY INFORMATION**

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SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO

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**Section XVI - OTHER DATA**

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1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.