



# Dobutamine Hydrochloride for Injection

Eli Lilly and Company  
Material Safety Data Sheet

Effective Date: 11-Mar-2000

## Section 1 - Chemical Product and Company

**Manufacturer:**  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

**Manufacturer's Emergency Phone:**  
1-317-276-2000  
**CHEMTREC:**  
1-800-424-9300 (North America)  
1-703-527-3887 (International)

**Common Name:** Dobutamine Hydrochloride for Injection

**Chemical Name:** 1,2-Benzenediol, 4-[2-[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]ethyl]-, hydrochloride

**Chemical Name 2:** 1,2-Benzenediol, 4-[2-[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]ethyl]-, hydrochloride, (+/-)-

**Synonym(s):** 081929 Hydrochloride Formulation; Dobutamine Hydrochloride; Dobutamine HCl; Dobutamine; 046236 Formulation

**Trademarks(s):** Docutrix; Inorex; Inotrex; Dobutrex

**Lilly Item Code(s):** AM7050; AM7051; AM7056; AM7175; CA1517; CA1518; VL7050; VL7051; VL7054; VL7226

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<b>Ingredient</b>	<b>CAS</b>	<b>Concentration %</b>
Dobutamine Hydrochloride	49745-95-1	52 - 73
Mannitol	69-65-8	27 - 48


Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

**Exposure Guidelines:** Dobutamine hydrochloride - LEG 2.2 mg/m<sup>3</sup> TWA for 12 hours.  
Mannitol - Exposure Guideline 10 mg/m<sup>3</sup> TWA for 8 or 12 hours.

## Section 3 - Hazards Identification

**Appearance:** White to off-white plug  
**Physical State:** Solid

**Odor:** Odorless



## Emergency Overview

**Emergency Overview Effective Date:** 11-Mar-2000

**Lilly Laboratory Labeling Codes:**  
**Health 3**                      **Fire 1**                      **Reactivity 0**

**Primary Physical and Health Hazards:** Corrosive (eyes). Heart Effects.

**Caution Statement:** Dobutamine Hydrochloride for Injection may cause burns or permanent tissue damage to the eyes. Effects of exposure may include increased blood pressure and change in heart rate.

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Eye irritation has been reported from occupational exposure to dobutamine hydrochloride. Based on animal data, dobutamine hydrochloride may cause burns or permanent tissue damage to the eyes.

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

**Carcinogenicity:**

Remaining ingredients - Not listed by IARC, NTP, ACGIH, or OSHA.

Mannitol - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year dietary studies demonstrated no evidence of carcinogenicity in mice and rats.

## Section 4 - First Aid Measures

**Eyes:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

**Hazardous Combustion Products:** May emit toxic chloride fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

## Section 7 - Handling and Storage

**Storage Conditions:** Store in a cool, dry, well-ventilated area.

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Chemical goggles and/or face shield.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

**Additional Exposure Precautions:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

## Section 9 - Physical and Chemical Properties

**Appearance:** White to off-white plug

**Odor:** Odorless

**Boiling Point:** Not applicable

**Melting Point:** Not applicable

**Specific Gravity:** Not applicable

**pH:** 2.5-5.0

**Evaporation Rate:** No applicable information found

**Water Solubility:** Soluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic chloride fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

Data for the active ingredient, dobutamine hydrochloride, are reported.

**Oral:** Dobutamine hydrochloride - Rat, 500 mg/kg, no deaths, reduced activity.

**Skin:** Dobutamine hydrochloride - Rabbit, 500 mg/kg, no deaths or toxicity.

**Inhalation:** Dobutamine hydrochloride - Rat, 83 mg/m<sup>3</sup> for 1 hour, no deaths or toxicity.  
Dog, 546 mg/m<sup>3</sup> for 4 hours, no deaths, increased heart rate.

**Intravenous:** Dobutamine hydrochloride - Rat, median lethal dose 92 mg/kg, convulsions, coma, diarrhea.

Dog, 72-hour infusion, median lethal dose estimated greater than 80 mcg/kg/minute, mortality, reddened eyes, relaxed nictitating membrane, peripheral vasodilation across skin and gums, reduced activity, vomiting, body weight loss, increased alkaline phosphatase, premature ventricular contractions, sinus and ventricular tachycardia.

**Skin Contact:** Dobutamine hydrochloride - Rabbit, nonirritant

**Eye Contact:** Dobutamine hydrochloride - Rabbit, corrosive

### Chronic Exposure

Data for the active ingredient, dobutamine hydrochloride, are reported.

**Target Organ Effects:** Dobutamine hydrochloride - Heart effects (increased strength at contraction, increased heart rate, tissue changes, increased blood pressure), circulatory effects (vasodilation).

**Reproduction:** Dobutamine hydrochloride - No effects identified in animal studies.

**Sensitization:** Dobutamine hydrochloride - Guinea pig, not a contact sensitizer.

**Mutagenicity:** Dobutamine hydrochloride - Not mutagenic in bacterial cells.

## Section 12 - Ecological Information

No data are available for mixture. Environmental data for mannitol are reported.

### Environmental Fate:

Mannitol

Log Kow: -3.10

Log Koc: 0.7

Henry's Law constant (atm\*m3/mole):  $7.3 \times 10^{-13}$

Bioconcentration factor: 1

Biological oxygen demand (5-day): 1.15

Theoretical oxygen demand (5-day): 59%

Chemical oxygen demand (5-day) : 87%

### Environmental Summary:

Mannitol - Material is not expected to be toxic to aquatic organisms. Material is expected to exist in the particulate phase if released into the air. Material is expected to have very high mobility in soil and is not expected to volatilize from aquatic environments. Material is not expected to bioconcentrate in aquatic organisms. Material is a simple sugar alcohol and should be readily biodegraded.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## Section 14 - Transport Information

### Regulatory Organizations:

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

## U.S. Regulations

Dobutamine hydrochloride

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Remaining Ingredients

TSCA - Yes

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

## EU Regulations

### EC Classification

Contains dobutamine hydrochloride (C = 52-73%)

Xi (Irritant)

### Risk Phrases

R 41 - Risk of serious damage to eyes.

### Safety Phrases

S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

S 45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## Section 16 - Other Information

**MSDS Sections Revised:** Sections 1, 2, 3, 7, 8, and 12.

**Emergency Overview Sections Revised:** Caution statement.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company  
Hazard Communication  
317-277-6029

For additional copies contact:

Eli Lilly and Company  
1-800-LILLY-Rx (1-800-545-5979)

## **GLOSSARY:**

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline

IMO = International Maritime Organization

Kow = Octanol/Water Partition Coefficient

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet

MSHA = Mine Safety and Health Administration

NA = Not Applicable, except in Section 14 where NA = North America

NADA = New Animal Drug Application

NAIF = No Applicable Information Found

NCI = National Cancer Institute

NIOSH = National Institute for Occupational Safety and Health

NOS = Not Otherwise Specified

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit (OSHA)

RCRA = Resource Conservation and Recovery Act

RQ = Reportable Quantity

RTECS = Registry of Toxic Effects of Chemical Substances

SARA = Superfund Amendments and Reauthorization Act

STEG = Lilly Short Term Exposure Guideline

STEL = Short Term Exposure Limit

TLV = Threshold Limit Value (ACGIH)

TPQ = Threshold Planning Quantity

TSCA = Toxic Substances Control Act  
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted  
UEL = Upper Explosive Limit  
UN = United Nations  
WEEL = Workplace Environmental Exposure Level (AIHA)