



SAFETY DATA SHEET

Issuing Date: 01/29/2015

Revision Date: 05/11/2017

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Identifier

MSDS Number: 1225141
Product Name: Dobutamine Hydrochloride in 5% Dextrose Injection in Viaflex Plastic Container

Other means of identification

Product Code(s): NDC-0338-1073-02, NDC-0338-1075-02, NDC-0338-1077-02, NDC-0338-1073-03, 2B0791, 2B0792, 2B0793, and 2B0796
Synonyms: None

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical.
Product Type: Regulated Prescription Drug
Uses advised against No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Rocky Mountain Poison and Drug Center: USA (888) 990-0996
OUTSIDE USA (303) 389-1422
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743) 741-6089

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label Elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Hazards not otherwise classified (HNOC)

Other Information

Unknown Acute Toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight-%
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Dobutamine Hydrochloride	49745-95-1	0.1 -0.4
Dextrose, anhydrous	50-99-7	5
Sodium Bisulfite	7631-90-5	<0.1
Water	7732-18-5	>94

4. FIRST AID MEASURES

First Aid Measures

General Advice	Treat symptomatically and supportively.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

No information available.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical

No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Follow all fire fighting procedures (Section 5). Use suitable protective equipment (Section 8).

Environmental Precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Technical measures/precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions Keep containers tightly closed in a cool, well-ventilated place. Store at 25°C (77°F). Avoid excessive heat. Protect from freezing.

Incompatible materials No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Occupational Exposure Limits****Exposure Limits:**

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Dobutamine Hydrochloride 49745-95-1	None	None	None	None	None	None
Dextrose, anhydrous 50-99-7	None	None	None	None	None	None
Sodium Bisulfite 7631-90-5	5 mg/m ³ (vacated)	None	None	5 mg/m ³	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Individual protection measures, such as personal protective equipment

Eye protection Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection Use chemical resistant, impervious gloves.

Skin and body protection Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Respiratory protection No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical state: Liquid.
Appearance: Aqueous solution
Color: Clear
Odor: Not available
Odor Threshold: No information available
pH: 2.5 - 5.5
Melting point / melting range: Not available
Boiling point / boiling range: Not available

Flash point:	Not determined
Evaporation rate:	Not available
Flammability (solid, gas):	No information available
Flammable limits	Not available.
in air-upper (%):	
Flammable limits	Not available.
in air-lower (%):	
Vapor pressure:	Not available
Vapor Density:	No information available
Density:	Not available
Solubility:	Soluble in water.
Partition coefficient	Not available
(n-octanol/water):	
Autoignition temperature:	Not available.
Decomposition Temperature:	No information available
Viscosity:	Not available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other Information**10. STABILITY AND REACTIVITY****Reactivity**

No data available

Chemical Stability

Stable under recommended storage conditions

Possibility of Hazardous Reactions

None under normal processing

Conditions to Avoid

Do not freeze.

Incompatible materials

Acids. Bases. Oxidizing agents.

Hazardous Decomposition Products

No data available

11. TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Dobutamine Hydrochloride 49745-95-1	-	-	= 2296 mg/kg (Rat)
Dextrose, anhydrous 50-99-7	-	-	= 25800 mg/kg (Rat)
Sodium Bisulfite 7631-90-5	-	-	= 1310 mg/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: May cause irritation and/or allergic reactions.

Skin contact: May cause irritation and/or allergic reactions.

Ingestion: Gastrointestinal effects (may include nausea, upset stomach, loss of appetite).
Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain).

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not classified.

Carcinogenic effects: Not classified.

Component	ACGIH	IARC	NTP	OSHA
Dobutamine Hydrochloride 49745-95-1	-	-	-	-
Dextrose, anhydrous 50-99-7	-	-	-	-
Sodium Bisulfite 7631-90-5	-	Group 3	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: Not considered fetotoxic based on animal data.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Dobutamine Hydrochloride 49745-95-1	None.	None.	None.	None.
Dextrose, anhydrous 50-99-7	None.	None.	None.	None.
Sodium Bisulfite 7631-90-5	119 mg/L EC50 48 h	240 mg/L LC50 Gambusia affinis 96 h	None.	None.

Water 7732-18-5	None.	None.	None.	None.
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Ecotoxicity

No information available

0.45 % of the mixture consists of component(s) of unknown hazards to the aquatic environment

Persistence and degradability

No information available.

Bioaccumulative potential

No information available

Mobility in soil

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Waste from residues/unused products**

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

14. TRANSPORT INFORMATION**DOT**

Not regulated

15. REGULATORY INFORMATION**U.S. Regulations:****TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Component	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Dobutamine Hydrochloride 49745-95-1	0.1 -0.4	Not Listed	Not Listed	Not Listed	Not Listed
Dextrose, anhydrous 50-99-7	5	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Bisulfite 7631-90-5	<0.1	Not Listed	5000 lb 2270 kg	Not Listed	Not Listed
Water 7732-18-5	>94	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Dobutamine Hydrochloride 49745-95-1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Dextrose, anhydrous 50-99-7	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Bisulfite 7631-90-5	Not Listed	Present	Not Listed	Present	Present	Present	Present
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:**Canada DSL Inventory List -**

This product does not comply with DSL

16. OTHER INFORMATION**This data sheet contains changes from the previous version in section(s):**

New GHS format. Changes to Section 1.

Additional information:

Not Available.

Prepared by

Baxter Research & Development

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet