SAFETY DATA SHEET

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

Product Identifier

Material Name: Dobutamine in 5% Dextrose Injection, USP (Hospira Inc.)

Trade Name: Dobutamine in 5% Dextrose Injection, USP

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as cardiovascular drug

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dobutamine Hydrochloride</td>
<td>49745-95-1</td>
<td>256-464-1</td>
<td>Eye Dam 1 (H318)</td>
<td>&lt;0.4</td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr.1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>sodium metabisulphite</td>
<td>8681-57-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Dextrose, monohydrate</td>
<td>5996-10-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>5</td>
</tr>
<tr>
<td>Disodium EDTA (dihydrate)</td>
<td>6381-92-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

** Additional Information:**

* Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Move to fresh air if discomfort occurs, get medical attention.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon.
SAFETY DATA SHEET

Material Name: Dobutamine in 5% Dextrose Injection, USP
(Hospira Inc.)
Revision date: 28-Sep-2016

Page 3 of 9

Version: 1.1

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:
Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Incompatible Materials: None known
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:
2 ppm
Australia PEAK
5 ppm
7.5 mg/m³
Austria OEL - MAKs
5 ppm
8 mg/m³
Belgium OEL - TWA
5 ppm
8 mg/m³
Bulgaria OEL - TWA
5 ppm
8 mg/m³
Cyprus OEL - TWA
5 ppm
8 mg/m³
Czech Republic OEL - TWA
8 mg/m³
Estonia OEL - TWA
5 ppm
8 mg/m³

PZ03085
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany - TRGS 900</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWA</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

### SODIUM HYDROXIDE

<table>
<thead>
<tr>
<th>Country</th>
<th>TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Dobutamine in 5% Dextrose Injection, USP (Hospira Inc.)
Revision date: 28-Sep-2016
Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety goggles if eye contact is possible (face shield recommended is splashing is possible). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Wear impervious protective clothing to prevent skin contact. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

Dobutamine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 2.5-5.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Water for Injection
No data available

HYDROCHLORIC ACID
No data available

SODIUM HYDROXIDE
No data available
sodium metabisulphite

Slovenia OEL - TWA
2 mg/m³

Sweden OEL - TWAs
1 mg/m³

Switzerland OEL - TWAs
2 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Disodium EDTA (dihydrate)
No data available

Dextrose, monohydrate
No data available

Dobutamine Hydrochloride
No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- Oxidizing Properties: None
- Conditions to Avoid: None known
- Incompatible Materials: None known
- Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, nausea, shortness of breath (dyspnea), palpitations, chest pain, increased heart rate (tachycardia), increase in blood pressure (hypertension).

Acute Toxicity: (Species, Route, End Point, Dose)

HYDROCHLORIC ACID
Rat Oral LD50 238-277 mg/kg

Dobutamine Hydrochloride
Rat Oral LD50 2296 mg/kg
Mouse Oral LD50 1324mg/kg
Rat Intravenous LD50 59.6mg/kg
Mouse Intravenous LD50 34.3mg/kg
11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Dobutamine Hydrochloride
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Corrosive

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Dobutamine Hydrochloride
Embryo / Fetal Development  Rat  No route specified  14.4 mg/kg/day  NOAEL  Not teratogenic
Embryo / Fetal Development  Rabbit  No route specified  28.8 mg/kg/day  NOAEL  Not Teratogenic

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo Micronucleus  Rat  Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

PZ03085
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Dobutamine Hydrochloride

CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
EU EINECS/ELINCS List: 256-464-1

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting: 1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs:
CERCLA/SARA - Section 302 Extremely Hazardous Substances:
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List: 231-595-7

sodium metabisulphite

CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
EU EINECS/ELINCS List: Not Listed

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting: Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
CERCLA/SARA - Section 302 Extremely Hazardous Substances:
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List: 215-185-5

Water for Injection
15. REGULATORY INFORMATION

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                  | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List              | 231-791-2  |

Dextrose, monohydrate

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | Not Listed |
| EU EINECS/ELINCS List              | Not Listed |

Disodium EDTA (dihydrate)

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | Not Listed |
| Australia (AICS):                  | Present    |
| EU EINECS/ELINCS List              | Not Listed |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 28-Sep-2016

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet