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

Product Identifier

Material Name: Milrinone Lactate Injection in 5% Dextrose (Hospira Inc.)
Trade Name: Milrinone Lactate Injection in 5% Dextrose, 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

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

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

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
SAFETY DATA SHEET

Material Name: Milrinone Lactate Injection in 5% Dextrose (Hospira Inc.)
Revision date: 09-Aug-2016
Version: 1.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milrinone Lactate</td>
<td>100286-97-3</td>
<td>Not Listed</td>
<td>Acute Tox 3 (H301)</td>
<td>0.02</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>200-018-0</td>
<td>Eye Dam. 1 (H318)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2 (H315)</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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<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</td>
<td>14431-43-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>5</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

Medical Conditions: None known

Aggravated by Exposure: None

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.

Fire / Explosion Hazards: Not applicable
SAFETY DATA SHEET

Material Name: Milrinone Lactate Injection in 5% Dextrose (Hospira Inc.)
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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.

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK: 2 mg/m³
Austria OEL - MAKs: 2 mg/m³
Bulgaria OEL - TWA: 2.0 mg/m³
Czech Republic OEL - TWA: 1 mg/m³
Estonia OEL - TWA: 1 mg/m³
France OEL - TWA: 2 mg/m³
Greece OEL - TWA: 2 mg/m³
Hungary OEL - TWA: 2 mg/m³
Japan - OELs - Ceilings: 2 mg/m³
Latvia OEL - TWA: 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA: 0.5 mg/m³
Slovakia OEL - TWA: 2 mg/m³
Slovenia OEL - TWA: 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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:

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 glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: Soluble
pH: 3.2-4.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
SODIUM HYDROXIDE
No data available
Milrinone Lactate
No data available
Dextrose
No data available
Lactic acid

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Switzerland OEL - TWAs
1 mg/m³

Sweden OEL - TWAs
2 mg/m³

Milrinone Lactate
Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

PZ03116
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Water for Injection
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.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on heart.
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, nausea, vomiting, chest pain, decrease in blood pressure (hypotension), ventricular arrhythmia, hypocalcemia, tremors, thrombocytopenia.

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

- **Milrinone Lactate**
  - Rat Oral LD50 91 mg/kg
  - Mouse Oral LD50 137 mg/kg
  - Rabbit Oral LD50 40 mg/kg
  - Rat Intravenous LD50 73 mg/kg

- **Lactic acid**
  - Rat Oral LD50 3543 mg/kg
  - Rabbit Dermal LD50 > 2000 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)
11. TOXICOLOGICAL INFORMATION

Lactic acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Moderate Severe

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

Milrinone Lactate
Reproductive & Fertility  Rat  Oral  32 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Oral  40 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  12 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rat  Intravenous  3 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Intravenous  8 mg/kg/day  LOAEL  Fetotoxicity

Lactic acid
Reproductive & Fertility  Rat  Oral  6.25 mg/kg/day  NOEL  Fertility, Not teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Milrinone Lactate
Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive with activation
Bacterial Mutagenicity (Ames)  Negative
Micronucleus  Mouse  Negative
Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative
In Vivo Bone Marrow Metaphase Analysis  Rat  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Milrinone Lactate
24 Month(s)  Mouse  Oral  40 mg/kg/day  NOAEL  Not carcinogenic
24 Month(s)  Rat  Oral  5 mg/kg/day  NOAEL  Not carcinogenic
20 Month(s)  Female Rat  Oral  25 mg/kg/day  NOAEL  Not carcinogenic
18 Month(s)  Male Rat  Oral  25 mg/kg/day  NOAEL  Not carcinogenic

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

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.

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

Water for Injection
- 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:
  - EU EINECS/ELINCS List: 231-791-2

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

Lactic acid
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-018-0
15. REGULATORY INFORMATION

SODIUM HYDROXIDE

- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb, 454 kg
- 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: Schedule 5, Schedule 6
- EU EINECS/ELINCS List: 215-185-5

Dextrose

- 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

- Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
- Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
- Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
- Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage

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

Revision date: 09-Aug-2016


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