# SAFETY DATA SHEET

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

### Product Identifier
- **Material Name**: Corlopam(TM) (Fenoldopam Mesylate Injection, USP) (Hospira Inc.)
- **Trade Name**: Corlopam(TM)
- **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
- **International CHEMTREC (24 hours)**: +1-703-527-3887

### Contact E-Mail:
- pfizer-MSDS@pfizer.com

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture
- **GHS - Classification**
  - Skin Sensitization: Category 1A
  - Specific target organ systemic toxicity (repeated exposure): Category 2

### Label Elements
- **Signal Word**: Warning
- **Hazard Statements**:
  - H317 - May cause an allergic skin reaction
  - H373 - May cause damage to organs through prolonged or repeated exposure; kidneys
- **Precautionary Statements**:
  - P260 - Do not breathe dust/fume/gas/mist/vapors/spray
  - P272 - Contaminated work clothing must not be allowed out of the workplace
  - P280 - Wear protective gloves/protective clothing/eye protection/face protection
  - P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
  - P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
  - P362 - Take off contaminated clothing and wash before reuse
  - P314 - Get medical attention/advice if you feel unwell
  - P501 - Dispose of contents/container in accordance with all local and national regulations
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>
| Fenoldopam Mesylate | 67227-57-0 | 266-612-7             | Acute Tox 4 (H302)  
Eye Irrit 2A (H319)  
Skin Sens 1A (H317)  
STOT RE 2 (H373)    | 1 |

<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>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</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>Sodium Citrate</td>
<td>6132-04-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</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>
</tbody>
</table>

Additional Information:

* Proprietary

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.
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Revision date: 26-Sep-2016

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: Extinguish fires with CO2, extinguishing powder, foam, or water.

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: Fine particles (such as dust and mists) may fuel fires/explosions.

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.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Propylene glycol
- Australia TWA: 150 ppm
- 474 mg/m³
- 10 mg/m³
- Ireland OEL - TWAs: 150 ppm
- 470 mg/m³
- 10 mg/m³
- Latvia OEL - TWA: 7 mg/m³
- Lithuania OEL - TWA: 7 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.

Fenoldopam Mesylate

Pfizer Occupational Exposure Band (OEB):

OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

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 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
Color: Colorless to pale straw-color
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture
Solvent Solubility: No data available
Water Solubility: Soluble
pH: 2.8-3.8
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
- Sodium Citrate: No data available
- Citric acid, anhydrous: No data available
- sodium metabisulphite: No data available
- Fenoldopam Mesylate: No data available
- Water for Injection: No data available
- Propylene glycol: 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

Flammablity:
- 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: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: May form toxic materials such as carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Short Term:
- May cause eye irritation (based on components).

Long Term:
- Occupational exposure has resulted in allergic reactions.

Known Clinical Effects:
The most common adverse effects seen during clinical use of this drug include headache, nausea, vomiting, decrease in blood pressure (hypotension), vasodilation, flushing, dizziness, increased heart rate (tachycardia).

Acute Toxicity: (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

Citric acid, anhydrous
- Eye Irritation: Rabbit, Severe
- Skin Irritation: Rabbit, Mild

Fenoldopam Mesylate
- Skin Irritation: Rabbit, Non-irritating
- Eye Irritation: Rabbit, Moderate
- Skin Sensitization - GPMT: Guinea Pig, Strong

Propylene glycol
- Skin Irritation: Rabbit, Mild
- Eye Irritation: Rabbit, Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Fenoldopam Mesylate
- 24 Month(s): Mouse, Oral 25 mg/kg/day, LOEL, Kidney, Bone
- 24 Month(s): Rat, Oral 10 mg/kg/day, LOEL, Kidney

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

Fenoldopam Mesylate
- Reproductive & Fertility: Rat, Oral 75 mg/kg/day, NOAEL, No effects at maximum dose
- Embryo / Fetal Development: Rat, Oral 200 mg/kg/day, NOAEL, Maternal Toxicity, Not Teratogenic

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

Fenoldopam Mesylate
- Bacterial Mutagenicity (Ames): Negative
- In Vitro Chromosome Aberration: Chinese Hamster Ovary (CHO) cells, Positive
11. TOXICOLOGICAL INFORMATION

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

Fenoldopam Mesylate

24 Month(s) Mouse Oral 50/25 mg/kg/day NOAEL Not carcinogenic
24 Month(s) Rat Oral 20/25 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

PZ03089
15. REGULATORY INFORMATION

Fenoldopam Mesylate
   CERCLA/SARA 313 Emission reporting Not Listed
   California Proposition 65 Not Listed
   EU EINECS/ELINCS List 266-612-7

Citric acid, anhydrous
   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 201-069-1

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

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

Propylene glycol
   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 200-338-0

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
SAFETY DATA SHEET

Material Name: Corlopam(TM) (Fenoldopam Mesylate Injection, USP) (Hospira Inc.)
Revision date: 26-Sep-2016

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

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

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

Revision date: 26-Sep-2016

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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