



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 26-Sep-2016

Version: 1.1

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

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

## 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

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### 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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
sodium metabisulphite	8681-57-4	Not Listed	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

### 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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**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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Propylene glycol</b>	
<b>Australia TWA</b>	150 ppm 474 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	150 ppm 470 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	7 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	7 mg/m <sup>3</sup>

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/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless to pale straw-color
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	Soluble		
<b>pH:</b>	2.8-3.8		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		

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### 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

**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:** 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)**

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### 11. TOXICOLOGICAL INFORMATION

#### Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

#### Fenoldopam Mesylate

Rat (M) Oral LD50 1048 mg/kg

Rat (F) Oral LD50 1275mg/kg

Mouse (M) Oral LD50 1657mg/kg

Mouse (F) Oral LD50 1840mg/kg

#### Propylene glycol

Rat Oral LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900mg/kg

Rabbit Dermal LD 50 20,800mg/kg

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

##### 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

Embryo / Fetal Development Rabbit Oral 25 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

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### 11. TOXICOLOGICAL INFORMATION

*In Vivo* Micronucleus Mouse Negative  
*In Vivo* Bone Marrow Metaphase Analysis Mouse Negative

#### **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**

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### 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:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3



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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**