



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 01-Feb-2017

Version: 2.0

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

### Product Identifier

**Material Name:** Meropenem for Injection, USP (Hospira Inc.)

**Trade Name:** Not established  
**Chemical Family:** Cephalosporin antibiotic

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

**Intended Use:** Pharmaceutical product used as antibiotic agent

### 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

Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1  
Acute aquatic toxicity: Category 1  
Chronic aquatic toxicity: Category 1

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

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**Precautionary Statements:**

- P261 - Avoid breathing 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
- P284 - Wear respiratory protection
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- 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
- P273 - Avoid release to the environment
- P391 - Collect spillage
- 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Meropenem Trihydrate	119478-56-7	Not Listed	Resp Sens. 1 (H334) Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	91
SODIUM CARBONATE	497-19-8	207-838-8	Eye Irrit. 2 (H319)	8

### Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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:

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

#### Skin Contact:

Wash skin with soap and water. If skin irritation persists, call a physician.

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**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:** Remove exposed person to fresh air. Refer to a physician if subject experiences difficulty breathing. If breathing has stopped, a trained person should perform cardiopulmonary resuscitation (CPR) and seek immediate medical assistance.

### 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:** People allergic to penicillins may exhibit cross reaction sensitivity.

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

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, 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 sulfur, carbon, nitrogen.

**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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Minimize dust generation and accumulation. Avoid breathing dust. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

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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 CARBONATE

Czech Republic OEL - TWA	5 mg/m <sup>3</sup>
Romania OEL - TWA	1 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.

#### Meropenem Trihydrate

**Pfizer Occupational Exposure Band (OEB):** OEB 1 - Sensitizer (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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

<b>Physical State:</b>	Crystalline powder	<b>Color:</b>	White to pale yellow
<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>	7.3-8.3
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### SODIUM CARBONATE

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Meropenem Trihydrate

No data available Log D -3

**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:** Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.

### 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:** Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Allergic reaction might occur following inhalation of dust, based on effects of other cephalosporins. Symptoms might include running nose, sneezing, itching, pulmonary obstruction or signs similar to asthma such as coughing, wheezing or difficulty breathing which may be immediate or delayed.

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. The most common side effect seen during clinical use is skin rash. Gastrointestinal effects such as diarrhea, nausea and vomiting also occur frequently following oral administration.

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

##### SODIUM CARBONATE

Rat Oral LD 50 4090 mg/kg

Mouse Oral LD 50 6600mg/kg

##### Meropenem Trihydrate

Rat Oral LD50 > 5000 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 > 5000mg/kg

Rat Intravenous LD50 2850mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### Meropenem Trihydrate

1 Month(s) Dog No route specified 125 mg/kg/day NOAEL Blood

3 Month(s) Dog No route specified 100 mg/kg/day NOAEL Blood

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

##### Meropenem Trihydrate

Embryo / Fetal Development Monkey No route specified 360 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Embryo / Fetal Development Rat No route specified 250 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

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

##### Meropenem Trihydrate

Bacterial Mutagenicity (Ames) Negative

Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Mouse Negative

#### Carcinogen Status:

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

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

The following information is available for the individual ingredients. Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment. Releases to the environment should be avoided.

#### Toxicity:

##### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### SODIUM CARBONATE

*Lepomis macrochirus* (Bluegill Sunfish) N/A LC50 96 Hours 320 mg/L

##### Meropenem Trihydrate

*Microcystis aeruginosa* (Blue-green Alga) EC50 72 Hours 0.026 mg/L

*Daphnia magna* (Water Flea) EC50 48 Hours > 900 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

#### Persistence and Degradability:

##### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Meropenem Trihydrate Not Ready

#### Bio-accumulative Potential:

No data available

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### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Meropenem Trihydrate

No data available Log D -3

**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.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number:</b>	UN 3077
<b>UN proper shipping name:</b>	Environmentally Hazardous Substance, Solid, n.o.s (meropenem trihydrate)
<b>Transport hazard class(es):</b>	9
<b>Packing group:</b>	III
<b>Environmental Hazard(s):</b>	Marine Pollutant

### 5 kg/5L Exception:

Effective January 1, 2015, UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

\* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

\* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

## 15. REGULATORY INFORMATION

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

#### Meropenem Trihydrate

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

#### SODIUM CARBONATE

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### 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
EU EINECS/ELINCS List	207-838-8

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information. Updated Section 12 - Ecological Information. Updated Section 14 - Transport Information.

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

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**End of Safety Data Sheet**