



# SAFETY DATA SHEET

Revision date 21-Feb-2023

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Meropenem for Injection, USP (Hospira Inc.)  
**Product Code(s)** PZ03110  
**Trade Name:** Not applicable  
**Chemical Family:** Carbapenem antibiotic

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antibiotic agent

### 1.3. 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

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

<b>Serious eye damage/eye irritation</b>	Category 2 - (H319)
<b>Respiratory sensitization</b>	Category 1 - (H334)
<b>Skin sensitization</b>	Category 1 - (H317)
<b>Acute aquatic toxicity</b>	Category 1 - (H400)
<b>Chronic aquatic toxicity</b>	Category 1 - (H410)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H317 - May cause an allergic skin reaction

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H319 - Causes serious eye irritation  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H410 - Very toxic to aquatic life with long lasting effects

## Precautionary Statements

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
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  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P308 + P313 - IF exposed or concerned: 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



## 2.3. 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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Substances

Not applicable

### 3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Meropenem Trihydrate (CAS #: 119478-56-7)	80 - 85		Not Listed	Resp Sens. 1 (H334) Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not Listed	10	10

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Sodium carbonate (CAS #: 497-19-8)	10 - 15		207-838-8	Eye Irrit. 2 (H319)	Not Listed	No data available	No data available
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**Full text of H- and EUH-phrases: see section 16**

## Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Meropenem Trihydrate 119478-56-7	> 5000 mg/kg	No data available	No data available	No data available	No data available
Sodium carbonate 497-19-8	4090	2000	1.15	No data available	No data available

## **Additional information**

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

## **Section 4: FIRST AID MEASURES**

### **4.1. Description of first aid measures**

<b>Inhalation</b>	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.
<b>Eye contact</b>	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Wash skin with soap and water. If skin irritation persists, call a physician.
<b>Ingestion</b>	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.

### **4.2. Most important symptoms and effects, both acute and delayed**

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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### **4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	None.
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## **Section 5: FIRE-FIGHTING MEASURES**

### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Dry chemical, CO2, alcohol-resistant foam or water spray.
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### **5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
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<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire. May include oxides of carbon,
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nitrogen and products of sulfur.

## 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.  
**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.  
**Methods for cleaning up** Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.  
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

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

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

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## Sodium carbonate

Czech Republic

5 mg/m<sup>3</sup>

Ceiling: 10 mg/m<sup>3</sup>

Romania

1 mg/m<sup>3</sup>

STEL: 3 mg/m<sup>3</sup>

Russia

MAC: 2 mg/m<sup>3</sup>

Skin

## Pfizer Occupational Exposure Band (OEB) Statement:

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>)

## 8.2. 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.

### Environmental exposure controls

No information available.

### Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Eye/face protection

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.).

### Hand protection

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.).

### Skin and body protection

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.).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Physical state

Crystalline powder

#### Color

White to pale yellow

#### Odor

No information available.

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Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

<u>Property</u>	<u>Values</u>
pH	7.3-8.3
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

**Partition Coefficient: (Method, pH, Endpoint, Value)**  
Meropenem Trihydrate  
Measured Log D -3

**9.2. Other information**  
No information available

**9.2.1. Information with regard to physical hazard classes**  
No information available

**9.2.2. Other safety characteristics**  
No information available

## Section 10: STABILITY AND REACTIVITY

**10.1. Reactivity**  
Reactivity No data available.

**10.2. Chemical stability**  
Stability Stable under normal conditions.

**Explosion data**  
Sensitivity to Mechanical Impact No data available.  
Sensitivity to Static Discharge No data available.

**10.3. Possibility of hazardous reactions**  
Possibility of hazardous reactions No information available.

**10.4. Conditions to avoid**  
Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

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## 10.5. Incompatible materials

### Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

## 10.6. Hazardous decomposition products

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

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### General Information:

The information included in this section describes the potential hazards of the individual ingredients

#### Short term

Individuals who are allergic to penicillin or carbapenem antibiotics could have allergic reaction, possibly severe (anaphylactic).

#### 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

Based on available data, the classification criteria are not met.

#### Serious eye damage/eye irritation

Classification is based on mixture calculation methods based on component data.

#### Skin corrosion/irritation

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

Classification is based on mixture calculation methods based on component data.

#### STOT - single exposure

Based on available data, the classification criteria are not met.

#### STOT - repeated exposure

Based on available data, the classification criteria are not met.

#### Reproductive toxicity

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

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

#### Meropenem Trihydrate

Rat Oral LD50 > 5000 mg/kg

Mouse Oral LD50 > 5000 mg/kg

Rat Intravenous LD50 2850 mg/kg

#### Sodium carbonate

Rat Oral LD50 4090 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium carbonate	= 4090 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	= 2300 mg/m <sup>3</sup> ( Rat ) 2 h

#### 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.

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

#### Sodium carbonate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

### 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

3 Month(s) Rat Intravenous 1000 mg/kg/day NOAEL Kidney

3 Month(s) Dog Intravenous 500 mg/kg/day NOAEL Adrenal gland, Blood

6 Month(s) Rat Intravenous 1000 mg/kg/day NOAEL None identified

6 Month(s) Dog Intravenous 500 mg/kg/day NOAEL None identified

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

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## 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

Reproductive & Fertility Rat Intravenous 1000 mg/kg/day NOAEL Fertility, Reproductive toxicity

Peri-/Postnatal Development Rat Intravenous 1000 mg/kg/day NOAEL No effects at maximum dose

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

### Meropenem Trihydrate

Bacterial Mutagenicity (Ames) Negative

Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Mouse Negative

## **Carcinogenicity**

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

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

### **Environmental Overview:**

Releases to the environment should be avoided. The following information is available for the individual ingredients. Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment. Classification is based on mixture calculation methods based on component data

## 12.1. Toxicity

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

#### Meropenem Trihydrate

*Anabaena flos-aquae* (Cyanobacteria) OECD ErC50 72 hours 0.026 mg/L

*Anabaena flos-aquae* (Cyanobacteria) OECD NOEC 72 hours 0.015 mg/L

*Daphnia Magna* (Water Flea) OECD EC50 48 hours > 900 mg/L

*Lepomis macrochirus* (Bluegill Sunfish) OECD LC50 96 hours 320 mg/L

#### Sodium carbonate

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

## 12.2. Persistence and degradability

### **Persistence and degradability**

No information available.

## 12.3. Bioaccumulative potential

### Bioaccumulation

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

#### Meropenem Trihydrate

Measured Log D -3



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## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium carbonate	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

## Section 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.**

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

### 5 kg/5L Exception:

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations 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.

**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

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## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Meropenem Trihydrate

**CERCLA/SARA Section 313 de minimus %**

Not Listed

**California Proposition 65**

Not Listed

**EINECS**

Not Listed

**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)**

Schedule 4

Sodium carbonate

**CERCLA/SARA Section 313 de minimus %**

Not Listed

**California Proposition 65**

Not Listed

**TSCA**

Present

**EINECS**

207-838-8

**AICS**

Present

**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)**

Schedule 5

Schedule 6

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

## Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium carbonate - 497-19-8	Use restricted. See item 75.	

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of H-Statements referred to under 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.

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 21-Feb-2023

**Prepared By** Pfizer Global Environment, Health, and Safety

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