SAFETY DATA SHEET

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

Product Identifier

Material Name: MERREM (meropenem for injection)

Trade Name: MERREM; MERONEM

Chemical Family: Carbapenem 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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Serious Eye Damage/Eye Irritation: Category 2A
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Acute aquatic toxicity: Category 1
Chronic aquatic toxicity: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger

Hazard Statements:
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
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
May form combustible dust concentrations in air
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
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
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

<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>Meropenem Trihydrate</td>
<td>119478-56-7</td>
<td>Not Listed</td>
<td>Resp Sens. 1 (H334)</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1 (H317)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1 (H400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1 (H410)</td>
<td></td>
</tr>
<tr>
<td>SODIUM CARBONATE</td>
<td>497-19-8</td>
<td>207-838-8</td>
<td>Eye Irr. 2 (H319)</td>
<td>15</td>
</tr>
</tbody>
</table>

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.
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: 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 firefighting 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. Cleanup 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.
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/m³
Romania OEL - TWA 1 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.

Meropenem Trihydrate
Pfizer Occupational Exposure Band (OEB):
OEB 1 - Sensitizer (control exposure to the range of 1000ug/m³ to 3000ug/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: Crystalline powder
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: Soluble
pH: 7.3-8.3
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Odor Threshold:
Molecular Weight: Mixture

PZ03303
9. PHYSICAL AND CHEMICAL PROPERTIES

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

Meropenem Trihydrate
No data available  Log D  -3

SODIUM CARBONATE
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:  No data available
  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 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: (Species, Route, End Point, Dose)

Meropenem Trihydrate
Rat  Oral  LD50  > 5000 mg/kg
Mouse  Oral  LD50  > 5000mg/kg
Rat  Intravenous  LD50  2850mg/kg

SODIUM CARBONATE
Rat  Oral  LD 50  4090 mg/kg
Mouse  Oral  LD 50  6600mg/kg
11. TOXICOLOGICAL INFORMATION

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)

Meropenem Trihydrate
Microcystis aeruginosa (Blue-green Alga)    EC50    72 Hours    0.026 mg/L
Daphnia magna (Water Flea)    EC50    48 Hours    > 900 mg/L

SODIUM CARBONATE
Lepomis macrochirius (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.

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Meropenem Trihydrate    Not Ready

Bio-accumulative Potential: No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
SAFETY DATA SHEET

Material Name: MERREM (meropenem for injection)  
Revision date: 09-Nov-2017  
Version: 1.3  

Meropenem Trihydrate  
No data available  Log D -3  

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.

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 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  
CERCLA/SARA 313 Emission reporting Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>California Proposition 65</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>207-838-8</td>
</tr>
</tbody>
</table>

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

Revision date: 09-Nov-2017

Prepared by: Product Stewardship Hazard Communication

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