

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Ertapenem Formulation

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

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                                                  |
|------------------------------------------------|----------------------------------------------------------------------------------|
| Respiratory sensitisation, Category 1          | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                                                |
| Long-term (chronic) aquatic hazard, Category 2 | H411: Toxic to aquatic life with long lasting effects.                           |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust.  
P273 Avoid release to the environment.  
P284 Wear respiratory protection.  
**Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

Hazardous components which must be listed on the label:  
Ertapenem

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                     | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|----------------------------------------------------|--------------------------|
| Ertapenem     | 153773-82-1                                           | Resp. Sens. 1;<br>H334<br>Aquatic Acute 1;<br>H400 | >= 70 - < 90             |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

|  |  |                                         |  |
|--|--|-----------------------------------------|--|
|  |  | Aquatic Chronic 2;<br>H411              |  |
|  |  | M-Factor (Acute<br>aquatic toxicity): 1 |  |

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.  
In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

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

- Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

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

Methods for cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures      | : Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Local/Total ventilation | : Use only with adequate ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Advice on safe handling | : Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures        | : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

nated clothing before re-use.

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

Requirements for storage areas and containers : Keep in properly labelled containers. Keep tightly closed.  
Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Dust 5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable dust)  
Basis: FOR-2011-12-06-1358

10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: FOR-2011-12-06-1358

| Components                | CAS-No.     | Value type (Form of exposure) | Control parameters             | Basis    |
|---------------------------|-------------|-------------------------------|--------------------------------|----------|
| Ertapenem                 | 153773-82-1 | TWA                           | 0.15 mg/m <sup>3</sup> (OEB 2) | Internal |
| Further information: RSEN |             |                               |                                |          |

### 8.2 Exposure controls

#### Engineering measures

Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

#### Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:  
Safety goggles  
Equipment should conform to NS EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

|                          |                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. |
| Skin and body protection | : Skin should be washed after contact.                                                                                                                                                                                                                                                                                                                                       |
| Respiratory protection   | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143                                                                                                                                                                 |
| Filter type              | : Particulates type (P)                                                                                                                                                                                                                                                                                                                                                      |

### SECTION 9: Physical and chemical properties

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

|                                                  |                                                                                   |
|--------------------------------------------------|-----------------------------------------------------------------------------------|
| Physical state                                   | : powder                                                                          |
| Colour                                           | : white                                                                           |
| Odour                                            | : No data available                                                               |
| Odour Threshold                                  | : No data available                                                               |
| Melting point/freezing point                     | : No data available                                                               |
| Initial boiling point and boiling range          | : No data available                                                               |
| Flammability (solid, gas)                        | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : No data available                                                               |
| Upper explosion limit / Upper flammability limit | : No data available                                                               |
| Lower explosion limit / Lower flammability limit | : No data available                                                               |
| Flash point                                      | : No data available                                                               |
| Auto-ignition temperature                        | : No data available                                                               |
| Decomposition temperature                        | : No data available                                                               |
| pH                                               | : No data available                                                               |
| Viscosity                                        |                                                                                   |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

|                                        |   |                   |
|----------------------------------------|---|-------------------|
| Viscosity, dynamic                     | : | No data available |
| Viscosity, kinematic                   | : | No data available |
| Solubility(ies)                        |   |                   |
| Water solubility                       | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure                        | : | No data available |
| Relative density                       | : | No data available |
| Density                                | : | No data available |
| Relative vapour density                | : | No data available |
| Particle characteristics               |   |                   |
| Particle size                          | : | No data available |

### 9.2 Other information

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Explosives           | : | Not explosive                                            |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate     | : | No data available                                        |
| Molecular weight     | : | No data available                                        |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

|                     |   |                                                                                                                            |
|---------------------|---|----------------------------------------------------------------------------------------------------------------------------|
| Hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
|---------------------|---|----------------------------------------------------------------------------------------------------------------------------|

### 10.4 Conditions to avoid

|                     |   |                                                   |
|---------------------|---|---------------------------------------------------|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
|---------------------|---|---------------------------------------------------|

### 10.5 Incompatible materials

|                    |   |                  |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

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

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Ertapenem:

Acute oral toxicity : LD50 (Mouse): > 500 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): > 700 mg/kg  
Application Route: Intravenous

LD50 (Rat): > 700 mg/kg  
Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Ertapenem:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Ertapenem:

Species : Rabbit  
Result : Mild eye irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

---

### Components:

#### **Ertapenem:**

|                 |   |                                                                            |
|-----------------|---|----------------------------------------------------------------------------|
| Exposure routes | : | inhalation (dust/mist/fume)                                                |
| Assessment      | : | Probability of respiratory sensitisation in humans based on animal testing |
| Result          | : | positive                                                                   |

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Ertapenem:**

|                       |   |                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Alkaline elution assay<br>Test system: rat hepatocytes<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Chinese hamster ovary cells<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: human lymphoblastoid cells<br>Result: negative |
| Genotoxicity in vivo  | : | Test Type: Micronucleus test<br>Species: Mouse<br>Result: negative                                                                                                                                                                                                                                                                                                                                       |

#### **Carcinogenicity**

Not classified based on available information.

#### **Reproductive toxicity**

Not classified based on available information.

### Components:

#### **Ertapenem:**

|                      |   |                                                                                                                                                                                                                                                                                                                                           |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Intravenous<br>Fertility: NOAEL: 700 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected.<br><br>Test Type: Fertility<br>Species: Mouse<br>Fertility: NOAEL: 700<br>Result: No effects on fertility |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 700 mg/kg body weight  
Result: No effects on early embryonic development

Test Type: Development  
Species: Mouse  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 350 mg/kg body weight  
Symptoms: Reduced body weight  
Remarks: The mechanism or mode of action may not be relevant in humans.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Ertapenem:**

Species : Rat  
LOAEL : 2 mg/kg  
Application Route : Intravenous  
Exposure time : 2 Weeks  
Target Organs : Blood  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat  
LOAEL : 60 mg/kg  
Application Route : Intravenous  
Exposure time : 6 Months  
Target Organs : Blood  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Monkey  
NOAEL : 360 mg/kg  
LOAEL : 500 mg/kg  
Application Route : Intravenous  
Exposure time : 27 Weeks  
Target Organs : Liver, Kidney  
Remarks : The mechanism or mode of action may not be relevant in humans.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

Not classified based on available information.

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### Experience with human exposure

#### Components:

##### Ertapenem:

|            |                                                    |
|------------|----------------------------------------------------|
| Inhalation | : Remarks: May cause sensitisation by inhalation.  |
| Ingestion  | : Symptoms: Diarrhoea, Nausea, Headache, vaginitis |

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Ertapenem:

|                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l<br>Exposure time: 96 h                                                                                                                                                                                                                                                                                                                                                                                       |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 500 mg/l<br>Exposure time: 48 h                                                                                                                                                                                                                                                                                                                                                                                                   |
| Toxicity to algae/aquatic plants                    | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 51 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 51 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Anabaena flos-aquae): 0,23 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae): 0,13 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

---

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC10 : 3,9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

Toxicity to fish (Chronic toxicity) : NOEC: 2,5 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 82 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

#### Components:

##### **Ertapenem:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4,7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

Stability in water : Degradation half life (DT50): 15,3 d

### 12.3 Bioaccumulative potential

#### Components:

##### **Ertapenem:**

Partition coefficient: n-octanol/water : log Pow: -2,22

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components consid-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                             |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.                                                                                                                                                  |

## SECTION 14: Transport information

### 14.1 UN number or ID number

|      |           |
|------|-----------|
| ADN  | : UN 3077 |
| ADR  | : UN 3077 |
| RID  | : UN 3077 |
| IMDG | : UN 3077 |
| IATA | : UN 3077 |

### 14.2 UN proper shipping name

|      |                                                                  |
|------|------------------------------------------------------------------|
| ADN  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem) |
| IATA | : Environmentally hazardous substance, solid, n.o.s. (Ertapenem) |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | : 9   |                  |
| <b>ADR</b>  | : 9   |                  |
| <b>RID</b>  | : 9   |                  |
| <b>IMDG</b> | : 9   |                  |
| <b>IATA</b> | : 9   |                  |

### 14.4 Packing group

|                                          |                 |
|------------------------------------------|-----------------|
| <b>ADN</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>ADR</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| Tunnel restriction code                  | : (-)           |
| <b>RID</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>IMDG</b>                              |                 |
| Packing group                            | : III           |
| Labels                                   | : 9             |
| EmS Code                                 | : F-A, S-F      |
| <b>IATA (Cargo)</b>                      |                 |
| Packing instruction (cargo aircraft)     | : 956           |
| Packing instruction (LQ)                 | : Y956          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |
| <b>IATA (Passenger)</b>                  |                 |
| Packing instruction (passenger aircraft) | : 956           |
| Packing instruction (LQ)                 | : Y956          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |

### 14.5 Environmental hazards

|                           |       |
|---------------------------|-------|
| <b>ADN</b>                |       |
| Environmentally hazardous | : yes |
| <b>ADR</b>                |       |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |                       |                     |                     |
|----|-----------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|-----------------------|---------------------|---------------------|

### Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### The components of this product are reported in the following inventories:

AICS : not determined

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### Full text of H-Statements

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H400 : Very toxic to aquatic life.  
H411 : Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Resp. Sens. : Respiratory sensitisation  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ertapenem Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 5.4     | 14.04.2025     | 20985-00025 | Date of first issue: 03.11.2014 |

Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|                   |      |
|-------------------|------|
| Resp. Sens. 1     | H334 |
| Aquatic Acute 1   | H400 |
| Aquatic Chronic 2 | H411 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN