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

1.1 Product identifier
   Trade name : Imipenem / Cilastatin / Relebactam Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

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)
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Respiratory sensitisation, Category 1 : H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H319 Causes serious eye irritation.
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

H334 May cause allergy or asthma symptoms or breathing 
difficulties if inhaled.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or 
repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :  
Prevention:
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.
Response:
P304 + P340 IF INHALED: Remove person to fresh air and 
keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ 
attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Imipenem
Relebactam

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumula-
tive 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 regu-
lation (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.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1 279-694-4</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
generated by Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 3.12 Revision Date: 27.08.2021 SDS Number: 68826-00024 Date of last issue: 09.04.2021 Date of first issue: 27.02.2015

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>Resp. Sens. 1A; H334</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repr. 2; H361d</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>toxicity): 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>Relebactam</td>
<td>1174020-13-3</td>
<td>STOT RE 2; H373 (Kidney)</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

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.

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 : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

**Risks**
- Causes serious eye irritation.
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure.

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.

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 (CO2)
- Dry chemical

**Unsuitable extinguishing media**
- None known.

5.2 Special hazards arising from the substance or mixture

**Specific hazards during firefighting**
- 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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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. 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. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
Imipenem / Cilastatin / Relebactam Formula- 

Version 3.12 Revision Date: 27.08.2021 SDS Number: 68826-00024 Date of last issue: 09.04.2021
Date of first issue: 27.02.2015

Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. 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 contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1</td>
<td>TWA</td>
<td>5 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>TWA</td>
<td>1000 ug/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Relebactam</td>
<td>1174020-13-3</td>
<td>TWA</td>
<td>0.3 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 3.12  Revision Date: 27.08.2021  SDS Number: 68826-00024  Date of last issue: 09.04.2021  Date of first issue: 27.02.2015

Personal protective equipment
Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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 to light yellow
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) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Flash point : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : Not applicable
### Solubility(ies)
- Water solubility: soluble
- Partition coefficient: n-octanol/water: Not applicable
- Vapour pressure: Not applicable
- Relative density: No data available
- Density: No data available
- Relative vapour density: Not applicable
- 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: Not applicable
- 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. Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid
- Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

#### 10.5 Incompatible materials
- Materials to avoid: Oxidizing agents

#### 10.6 Hazardous decomposition products
No hazardous decomposition products are known.
Imipenem / Cilastatin / Relebactam Formula-
tion

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:

Cilastatin:
- Acute oral toxicity: LD50 (Rat): > 10.000 mg/kg
  LD50 (Mouse): > 10.000 mg/kg

Imipenem:
- Acute oral toxicity: LD50 (Mouse): 10.000 mg/kg
- Acute toxicity (other routes of administration):
  LD50 (Rat): > 2.000 mg/kg
  Application Route: Intravenous
  LD50 (Mouse): 1.500 mg/kg
  Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:

Cilastatin:
- Species: Rabbit
- Result: No skin irritation

Relebactam:
- Method: EpiDerm
- Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Cilastatin:
- Species: Rabbit
- Result: Moderate eye irritation
Relebactam:
Method: Bovine cornea (BCOP)
Result: No 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.

Components:

Cilastatin:
Exposure routes: Skin contact
Remarks: No data available

Exposure routes: Inhalation
Remarks: No data available

Imipenem:
Remarks: May cause sensitisation of susceptible persons by inhalation of aerosol or dust.

Exposure routes: Skin contact
Remarks: Not classified due to lack of data.

Relebactam:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Result: Not a skin sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Cilastatin:
Genotoxicity in vitro: Test Type: Microbial mutagenesis assay (Ames test)
Result: negative

Imipenem:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Result: negative

Test Type: reverse mutation assay
Result: negative
Imipenem / Cilastatin / Relebactam Formulation

Test Type: unscheduled DNA synthesis assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intravenous
Result: negative

Relebactam:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: negative

Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Cilastatin:
Effects on fertility: Test Type: Fertility/early embryonic development
Application Route: Intravenous
Fertility: LOAEL: 1.000
Symptoms: No adverse effects
Result: No effects on fertility and early embryonic development were detected.

Imipenem:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Intravenous
Fertility: LOAEL: 80 mg/kg body weight
Symptoms: No adverse effects, Reduced foetal weight  
Result: No effects on fertility and early embryonic development were detected.

Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Application Route: Subcutaneous  
Fertility: LOAEL: 320 mg/kg body weight  
Symptoms: No adverse effects, Reduced foetal weight  
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development  
: Test Type: Development  
Species: Monkey  
Application Route: Intravenous  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Intravenous  
Developmental Toxicity: NOAEL: 60 mg/kg body weight  
Result: No teratogenic effects

Test Type: Development  
Species: Rat  
Application Route: Intravenous  
Developmental Toxicity: NOAEL: 60 mg/kg body weight  
Result: No teratogenic effects

Reproductive toxicity - Assessment  
: Some evidence of adverse effects on development, based on animal experiments.

Relebactam:  

Effects on fertility  
: Test Type: Pre-/postnatal development  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 450 mg/kg body weight

Effects on foetal development  
: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal injection  
Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight  
Result: No effects on foetal development

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal injection  
Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight  
Result: No effects on foetal development
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>3.12</td>
<td>27.08.2021</td>
<td>68826-00024</td>
<td>09.04.2021</td>
<td>27.02.2015</td>
</tr>
</tbody>
</table>

Test Type: Development
Species: Rat
Application Route: Intravenous
Developmental Toxicity: NOAEL: \( \geq 450 \) mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Development
Species: Rabbit
Application Route: Intravenous
Developmental Toxicity: NOAEL: 450 mg/kg body weight
Result: No effects on foetal development

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Relebactam:
Target Organs: Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cilastatin:
Species: Rat
NOAEL: \( \geq 500 \) mg/kg
Application Route: Intravenous
Exposure time: 90 Days
Remarks: No significant adverse effects were reported

Species: Monkey
NOAEL: \( \geq 500 \) mg/kg
Application Route: Intravenous
Exposure time: 5 Weeks
Remarks: No significant adverse effects were reported

Imipenem:
Species: Monkey
NOAEL: 60 mg/kg
LOAEL: 150 mg/kg
Application Route: Intravenous
Exposure time: 6 Months
Target Organs: Kidney
Species: Monkey
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

Version: 3.12
Revision Date: 27.08.2021
SDS Number: 68826-00024
Date of last issue: 09.04.2021
Date of first issue: 27.02.2015

NOAEL: 120 mg/kg
Application Route: Subcutaneous
Exposure time: 6 Months
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 180 mg/kg
Application Route: Intravenous
Exposure time: 6 Months
Remarks: No significant adverse effects were reported

Species: Rabbit
LOAEL: 150 mg/kg
Application Route: Intravenous
Target Organs: Kidney

Relebactam:
Species: Rat, female
NOAEL: 150 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Rat, male
NOAEL: 450 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Monkey
NOAEL: 25 mg/kg
Application Route: Intravenous
Exposure time: 30 d
Target Organs: Kidney

Species: Monkey
NOAEL: 37.5 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Monkey
NOAEL: 50 mg/kg
LOAEL: 150 mg/kg
Application Route: Intravenous
Exposure time: 3 Months
Target Organs: Kidney

Aspiration toxicity
Not classified based on available information.
11.2 Information on other hazards

Endocrine disrupting properties

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:
Imipenem:
Inhalation: Symptoms: Nausea, Vomiting, Diarrhoea, Fever, hypotension, Dizziness, Drowsiness, Convulsions, pruritis, Rash
Remarks: May cause sensitisation of susceptible persons by inhalation of aerosol or dust.

Relebactam:
Skin contact: Symptoms: Pain, Discomfort, Diarrhoea, Abdominal pain, insomnia, Nausea, sore throat, Vertigo

SECTION 12: Ecological information

12.1 Toxicity

Components:

Cilastatin:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 99 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Anabaena flos-aquae): > 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Imipenem / Cilastatin / Relebactam Formulation

NOEC (Pseudokirchneriella subcapitata (green algae)): 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms
EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity)
EC10: > 9.9 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)
EC10: > 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Imipenem:
Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): > 78 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants
EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0046 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.002 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 74 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 74 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity)
100

Toxicity to microorganisms
EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Imipenem / Cilastatin / Relebactam Formulation

Toxicity to fish (Chronic toxicity): NOEC: 9.4 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: 11 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

**Relebactam:**

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

- EC50 (Americamysis): > 100 mg/l
  Exposure time: 96 h

Toxicity to algae/aquatic plants:

- EC50 (Pseudokirchneriella subcapitata (green algae)): 86 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 12 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- EC50 (Anabaena flos-aquae (cyanobacterium)): > 11 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Anabaena flos-aquae (cyanobacterium)): 11 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms:

- EC50 : > 1.000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

- NOEC : 96.3 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):

- NOEC: 9.2 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: 2.7 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Cilastatin:

Imipenem:

Relebactam:

12.3 Bioaccumulative potential

Components:

Cilastatin:
Partition coefficient: n-octanol/water: log Pow: -3.53

Imipenem:
Partition coefficient: n-octanol/water: log Pow: < -1

Relebactam:
Partition coefficient: n-octanol/water: log Pow: < -2

12.4 Mobility in soil

Components:

Cilastatin:
Distribution among environmental compartments: log Koc: 2.3

Relebactam:
Distribution among environmental compartments : log Koc: 2,3

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 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.

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.

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,
<table>
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<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
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<td>3.12</td>
<td>27.08.2021</td>
<td>68826-00024</td>
<td>09.04.2021</td>
<td>27.02.2015</td>
</tr>
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</table>

N.O.S. (Imipenem)

**ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)

**RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)

**IMDG**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)

**IATA**: Environmentally hazardous substance, solid, n.o.s. (Imipenem)

### 14.3 Transport hazard class(es)

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<td>IMDG</td>
<td>9</td>
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<td>IATA</td>
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### 14.4 Packing group

#### ADN

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#### ADR

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#### RID

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#### IMDG

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</table>

#### IATA (Cargo)

| Packing instruction (cargo aircraft) | 956 |

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20 / 24
Imipenem / Cilastatin / Relebactam Formula- 
tion

Version: 3.12  Revision Date: 27.08.2021  SDS Number: 68826-00024  Date of last issue: 09.04.2021
Date of first issue: 27.02.2015

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
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, preparations 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 (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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

Regulation (EC) No 649/2012 of the European Parlia-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 3.12
Revision Date: 27.08.2021
SDS Number: 68826-00024
Date of last issue: 09.04.2021
Date of first issue: 27.02.2015

ment and the Council concerning the export and import
of dangerous chemicals
major-accident hazards involving dangerous substances.

E1

ENVIRONMENTAL HAZARDS

Quantity 1 Quantity 2
100 t 200 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,
where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product profes-
sionally. Young people above the age of 15 are, however, except from this rule if the product is
a necessary part of their education.

The components of this product are reported in the following inventories:
AICS : not determined
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
H319 : Causes serious eye irritation.
H334 : May cause allergy or asthma symptoms or breathing difficul-
ties if inhaled.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated
exposure.
H400 : Very toxic to aquatic life.
H410 : Very 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
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland
Waterways; ADR - European Agreement concerning the International Carriage of Dangerous
Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for
### Imipenem / Cilastatin / Relebactam Formula-

**Version**: 3.12  
**Revision Date**: 27.08.2021  
**SDS Number**: 68826-00024  
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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 mate-

<table>
<thead>
<tr>
<th>Sources of key data used to compile the Safety Data Sheet</th>
<th>Further information</th>
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<tr>
<td>Classification procedure:</td>
<td></td>
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</tbody>
</table>

- **Eye Irrit. 2**: H319  
- **Resp. Sens. 1**: H334  
- **Repr. 2**: H361d  
- **STOT RE 2**: H373  
- **Aquatic Acute 1**: H400  
- **Aquatic Chronic 1**: H410
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