1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Imipenem / Cilastatin / Relebactam Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India  412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Serious eye damage/eye irritation : Category 2A
Respiratory sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Kidney)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : [Diagram]
Signal word: Danger

Hazard statements:
- H319 Causes serious eye irritation.
- 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 (Kidney) through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
- Prevention:
  - P203 Obtain, read and follow all safety instructions before use.
  - P260 Do not breathe dust.
  - P264 Wash skin thoroughly after handling.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
  - P284 Wear respiratory protection.
- Response:
  - P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P318 IF exposed or concerned, get medical advice.
  - P342 + P316 IF experiencing respiratory symptoms: Get emergency medical help immediately.
  - P391 Collect spillage.
- Storage:
  - P405 Store locked up.
- Disposal:
  - P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification:
Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Relebactam</td>
<td>1174020-13-3</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
4. 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.

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.

Most important symptoms and effects, both acute and delayed: 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.

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).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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
6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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 assessment. 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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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

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.

Personal protective equipment

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type:
- Particulates type

Hand protection:
- Material: Chemical-resistant gloves

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.

Skin and body protection:
- Work uniform or laboratory coat.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working
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 decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>White to light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity  : Not classified as a reactivity hazard.

Chemical stability  : Stable under normal conditions.

Possibility of hazardous reactions  : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

Incompatible materials  : Oxidizing agents

Hazardous decomposition products  : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Imipenem:
Acute oral toxicity  : LD50 (Mouse): 10,000 mg/kg

Acute toxicity (other routes of)  : LD50 (Rat): > 2,000 mg/kg
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Imipenem / Cilastatin / Relebactam Formulation

Version 4.11  Revision Date: 27.08.2021  SDS Number: 68823-00023  Date of last issue: 10.10.2020  Date of first issue: 27.02.2015

administration)  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

Relebactam:
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
  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:
  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.

  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
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: 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.


**STOT - single exposure**: Not classified based on available information.

**STOT - repeated exposure**: May cause damage to organs (Kidney) through prolonged or repeated exposure.

**Components**: Relebactam:
- **Target Organs Assessment** : Kidney. May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Cilastatin:**
- **Species:** Rat
- **NOAEL:** \( \geq 500 \text{ mg/kg} \)
- **Application Route:** Intravenous
- **Exposure time:** 90 Days
- **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
- **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 Organ : 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 Organ : Kidney  

Aspiration toxicity  
Not classified based on available information.  

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  

12. ECOLOGICAL INFORMATION  

Ecotoxicity  

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  

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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

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

Persistence and degradability

Components:

Cilastatin:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 27 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Imipenem:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 29 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Relebactam:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 11.3 %
Exposure time: 28 d
Method: OECD Test Guideline 314

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
octanol/water

**Mobility in soil**

**Components:**

**Cilastatin:**
Distribution among environmental compartments : log Koc: 2.3

**Relebactam:**
Distribution among environmental compartments : log Koc: 2.3

**Other adverse effects**
No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- **Waste from residues:** Dispose of in accordance with local regulations.
- **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.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- **UN number:** UN 3077
- **Proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)
- **Class:** 9
- **Packing group:** III
- **Labels:** 9

**IATA-DGR**
- **UN/ID No.:** UN 3077
- **Proper shipping name:** Environmentally hazardous substance, solid, n.o.s. (Imipenem)
- **Class:** 9
- **Packing group:** III
- **Labels:** Miscellaneous
- **Packing instruction (cargo aircraft):** 956
- **Packing instruction (passenger aircraft):** 956
- **Environmentally hazardous:** yes

**IMDG-Code**
SAFETY DATA SHEET

Imipenem / Cilastatin / Relebactam Formulation

Version 4.11  Revision Date: 27.08.2021  SDS Number: 68823-00023  Date of last issue: 10.10.2020

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA
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.