

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Imipenem / Cilastatin / Relebactam Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/14/2025  |
| 8.0     | 06/17/2025     | 67733-00031 | Date of first issue: 02/27/2015 |

### SECTION 1. IDENTIFICATION

Product name : Imipenem / Cilastatin / Relebactam Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Eye irritation : Category 2A  
Respiratory sensitization : Sub-category 1A  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Kidney)  
- repeated exposure

#### GHS label elements

|                          |   |
|--------------------------|---|
| Hazard pictograms        | :   |
| Signal Word              | : Danger  |
| Hazard Statements        | : H319 Causes serious eye irritation.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>H361d Suspected of damaging the unborn child.<br>H373 May cause damage to organs (Kidney) through prolonged or repeated exposure. |
| Precautionary Statements | : <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.  |

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P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves, protective clothing, eye protection and 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.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

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

Substance / Mixture : Mixture

### Components

| Chemical name | Common Name/Synonym | CAS-No.      | Concentration (% w/w) |
|---------------|---------------------|--------------|-----------------------|
| Cilastatin    | No data available   | 81129-83-1   | $\geq 30 - < 60$ *    |
| Imipenem      | No data available   | 74431-23-5   | $\geq 30 - < 60$ *    |
| Relebactam    | No data available   | 1174020-13-3 | $\geq 10 - < 30$ *    |

\* Actual concentration or concentration range is withheld as a trade secret

## SECTION 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.

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|   |   |
|---|---|
| In case of skin contact                                     | : If breathing is difficult, give oxygen.<br>Get medical attention.<br>In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br>Contact with dust can cause mechanical irritation or drying of the skin.<br>Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure. |
| 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.   |

### SECTION 5. FIRE-FIGHTING MEASURES

|                                       |   |
|---------------------------------------|---|
| Suitable extinguishing media          | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical   |
| Unsuitable extinguishing media        | : None known.   |
| 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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products         | : Carbon oxides<br>Metal oxides   |
| Specific extinguishing methods        | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do     |

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so.  
Evacuate area.

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

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.  
tive equipment and emer- Follow safe handling advice (see section 7) and personal  
gency procedures 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 : Surround spill with absorbents and place a damp covering  
containment and cleaning up over the area to minimize 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.

### SECTION 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

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assessment  
Keep container tightly closed.  
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
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 labeled 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components                      | CAS-No.      | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|---------------------------------|--------------|----------------------------------|--|----------|
| Cilastatin                      | 81129-83-1   | TWA                              | 5 mg/m3 (OEB 1)                                | Internal |
| Imipenem                        | 74431-23-5   | TWA                              | 3000 ug/m3 (OEB 1)                             | Internal |
| Further information: RSEN, DSEN |              |                                  |  |          |
|                                 |              | Wipe limit                       | 100 µg/100 cm2                                 | Internal |
| Relebactam                      | 1174020-13-3 | TWA                              | 0.3 mg/m3 (OEB 2)                              | Internal |

**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 : Chemical-resistant gloves

Material

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.

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|                          |  |
|--------------------------|--|
| Skin and body protection | : Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.   |
| Hygiene measures         | : Work uniform or laboratory coat.<br>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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. |

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |
|--|---|
| Appearance                                       | : powder  |
| Color  | : White to light yellow   |
| Odor   | : No data available   |
| Odor Threshold                                   | : No data available   |
| pH   | : No data available   |
| Melting point/freezing point                     | : No data available   |
| Initial boiling point and boiling range          | : No data available   |
| Flash point                                      | : Not applicable  |
| Evaporation rate                                 | : Not applicable  |
| 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   |
| Vapor pressure                                   | : Not applicable  |
| Relative vapor density                           | : Not applicable  |
| Relative density                                 | : No data available   |

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|   |   |  |
|---|---|--|
| Density                                   | : | No data available  |
| Solubility(ies)<br>Water solubility       | : | soluble  |
| Partition coefficient: n-octanol/water    | : | Not applicable   |
| Autoignition temperature                  | : | No data available  |
| Decomposition temperature                 | : | No data available  |
| Viscosity<br>Viscosity, dynamic           | : | No data available  |
| Viscosity, kinematic                      | : | Not applicable   |
| Explosive properties                      | : | Not explosive  |
| Oxidizing properties                      | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                          | : | No data available  |
| Particle characteristics<br>Particle size | : | No data available  |

### SECTION 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

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### Components:

#### **Cilastatin:**

|                     |   |                           |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): 8,000 mg/kg   |
|                     |   | LD50 (Mouse): 8,000 mg/kg |

#### **Imipenem:**

|   |   |   |
|---|---|---|
| Acute oral toxicity                             | : | LD50 (Mouse): 10,000 mg/kg                                  |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): > 2,000 mg/kg<br>Application Route: Intravenous |
|   |   | LD50 (Mouse): 1,500 mg/kg<br>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:**

|        |   |                      |
|--------|---|----------------------|
| Result | : | No eye irritation    |
| Method | : | Bovine cornea (BCOP) |

#### **Respiratory or skin sensitization**

##### **Skin sensitization**

Not classified based on available information.

##### **Respiratory sensitization**

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



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### Components:

#### **Cilastatin:**

|                    |   |                   |
|--------------------|---|-------------------|
| Routes of exposure | : | Skin contact      |
| Remarks            | : | No data available |

|                    |   |                   |
|--------------------|---|-------------------|
| Routes of exposure | : | Inhalation        |
| Remarks            | : | No data available |

#### **Imipenem:**

|         |   |  |
|---------|---|--|
| Remarks | : | May cause sensitization of susceptible persons by inhalation of aerosol or dust. |
|---------|---|--|

|                    |   |                                     |
|--------------------|---|-------------------------------------|
| Routes of exposure | : | Skin contact                        |
| Remarks            | : | Not classified due to lack of data. |

#### **Relebactam:**

|                    |   |                               |
|--------------------|---|-------------------------------|
| Test Type          | : | Local lymph node assay (LLNA) |
| Routes of exposure | : | 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)<br>Result: negative |
|-----------------------|---|--|

#### **Imipenem:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test<br>Test system: Chinese hamster lung cells<br>Result: negative |
|-----------------------|---|--|

|   |
|---|
| Test Type: reverse mutation assay<br>Result: negative |
|---|

|  |
|--|
| Test Type: unscheduled DNA synthesis assay<br>Result: negative |
|--|

|   |
|---|
| Test Type: Chromosomal aberration<br>Result: negative |
|---|

|  |
|--|
| Test Type: sister chromatid exchange assay<br>Result: negative |
|--|

|                      |   |  |
|----------------------|---|--|
| Genotoxicity in vivo | : | Test Type: In vivo micronucleus test<br>Species: Mouse<br>Application Route: Intravenous |
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|                                     |  |
|-------------------------------------|--|
|                                     | Result: negative   |
| <b>Relebactam:</b>                  |  |
| Genotoxicity in vitro               | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative                                   |
| Genotoxicity in vivo                | : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Application Route: Intraperitoneal injection<br>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<br>Application Route: Intravenous<br>Fertility: LOAEL: 1,000<br>Symptoms: No adverse effects.<br>Result: No effects on fertility and early embryonic development were detected. |
|----------------------|--|

#### Imipenem:

|                      |  |
|----------------------|--|
| Effects on fertility | : Test Type: Fertility/early embryonic development<br>Species: Rat, male and female<br>Application Route: Intravenous<br>Fertility: LOAEL: 80 mg/kg body weight<br>Symptoms: No adverse effects., Reduced fetal weight.<br>Result: No effects on fertility and early embryonic development were detected.<br><br>Test Type: Fertility/early embryonic development<br>Species: Rat, male and female<br>Application Route: Subcutaneous<br>Fertility: LOAEL: 320 mg/kg body weight<br>Symptoms: No adverse effects., Reduced fetal weight.<br>Result: No effects on fertility and early embryonic development were detected. |
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Effects on fetal 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intraperitoneal injection  
Embryo-fetal toxicity.: NOAEL: 450 mg/kg body weight  
Result: No effects on fetal development.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Intraperitoneal injection  
Embryo-fetal toxicity.: NOAEL: 450 mg/kg body weight  
Result: No effects on fetal 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.

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

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II

### 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 : 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  
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

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|                   |               |
|-------------------|---------------|
| 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.

### Experience with human exposure

#### Components:

#### Imipenem:

|            |   |
|------------|---|
| Inhalation | : Symptoms: Nausea, Vomiting, Diarrhea, Fever, hypotension, Dizziness, Drowsiness, Convulsions, pruritis, Rash<br>Remarks: May cause sensitization of susceptible persons by inhalation of aerosol or dust. |
|------------|---|

#### Relebactam:

|              |  |
|--------------|--|
| Skin contact | : Symptoms: Pain, Discomfort, Diarrhea, Abdominal pain, insomnia, Nausea, sore throat, Vertigo |
|--------------|--|

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|---------|----------------|-------------|---------------------------------|
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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Cilastatin:**

|  |  |
|--|--|
| Toxicity to fish   | : LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203  |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): > 99 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202   |
| Toxicity to algae/aquatic plants                                       | : EC50 (Anabaena flos-aquae): > 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): > 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae): 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity)                                    | : EC10 (Pimephales promelas (fathead minnow)): > 9.9 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : EC10 (Daphnia magna (Water flea)): > 10 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211   |
| Toxicity to microorganisms   | : EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209   |

##### **Imipenem:**

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

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|  |   |
|--|---|
| Toxicity to algae/aquatic plants                                       | : EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0046 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae (cyanobacterium)): 0.002 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): > 74 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 74 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 11 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211  |
| Toxicity to microorganisms   | : EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209  |

### Relebactam:

|   |  |
|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br><br>EC50 (Americamysis): > 100 mg/l<br>Exposure time: 96 h  |
| Toxicity to algae/aquatic plants                    | : EC50 (Pseudokirchneriella subcapitata (green algae)): 86 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 12 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Anabaena flos-aquae (cyanobacterium)): > 11 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

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|  |   |  |
|--|---|--|
|  |   | NOEC (Anabaena flos-aquae (cyanobacterium)): 11 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201   |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 2.7 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211            |
| Toxicity to microorganisms   | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
|  |   | NOEC: 96.3 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209    |

### Persistence and degradability

#### Components:

##### **Cilastatin:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 27 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |
|------------------|---|---|

##### **Imipenem:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 29 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |
|------------------|---|---|

##### **Relebactam:**

|                  |   |  |
|------------------|---|--|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 11.3 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
|------------------|---|--|

### Bioaccumulative potential

#### Components:

##### **Cilastatin:**

|                           |   |                |
|---------------------------|---|----------------|
| Partition coefficient: n- | : | log Pow: -3.53 |
|---------------------------|---|----------------|



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||octanol/water

### Imipenem:

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

### Relebactam:

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

### Mobility in soil

### Components:

### Cilastatin:

||Distribution among environ- : log Koc: 2.3  
||mental compartments

### Relebactam:

||Distribution among environ- : log Koc: 2.3  
||mental compartments

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

|                        |  |
|------------------------|--|
| Waste from residues    | : Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.  |
| Contaminated packaging | : Empty containers should be taken to an approved waste<br>handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

|                           |   |
|---------------------------|---|
| UN number                 | : UN 3077   |
| Proper shipping name      | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Imipenem) |
| Class                     | : 9   |
| Packing group             | : III   |
| Labels                    | : 9   |
| Environmentally hazardous | : yes   |

#### IATA-DGR

|                      |  |
|----------------------|--|
| UN/ID No.            | : UN 3077  |
| Proper shipping name | : Environmentally hazardous substance, solid, n.o.s.<br>(Imipenem) |
| Class                | : 9  |
| Packing group        | : III  |

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Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

### IMDG-Code

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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)  
Class : 9  
Packing group : III  
Labels : 9  
ERG Code : 171  
Marine pollutant : yes(Imipenem)

### 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.

## SECTION 15. REGULATORY INFORMATION

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

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### SECTION 16. OTHER INFORMATION

#### 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 - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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; WHMIS - Workplace Hazardous Materials Information System

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

Revision Date : 06/17/2025  
Date format : mm/dd/yyyy

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

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

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