SAFETY DATA SHEET
according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formulation

Version 7.2  Revision Date: 09/30/2023  SDS Number: 67733-00029  Date of last issue: 08/09/2023  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 - repeated exposure : Category 2 (Kidney)

GHS label elements
Hazard pictograms :

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.

Precautionary Statements : Prevention:
                          P201 Obtain special instructions before use.
                          P202 Do not handle until all safety precautions have been read and understood.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixtures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>No data available</td>
<td>81129-83-1</td>
<td>39.5</td>
</tr>
<tr>
<td>Imipenem</td>
<td>No data available</td>
<td>74431-23-5</td>
<td>39.4</td>
</tr>
<tr>
<td>Relebactam</td>
<td>No data available</td>
<td>1174020-13-3</td>
<td>19.5</td>
</tr>
</tbody>
</table>

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. 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.

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.

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).

Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides

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.

In the event of fire, wear self-contained breathing apparatus.
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 7.2  
Revision Date: 09/30/2023  
SDS Number: 67733-00029  
Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

for fire-fighters  
Use personal protective equipment.

SECTION 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

: Surround spill with absorbents and place a damp covering 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 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 sensitzers.
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

<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>3000 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, DSEN  
Wipe limit 100 µg/100 cm2 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 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
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.

SECTION 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>Color</td>
<td>White to light yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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 range</td>
<td>No data available</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 flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor 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>Water solubility: soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Imipenem / Cilastatin / Relebactam Formulation

**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. 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.

**SECTION 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): 8,000 mg/kg
LD50 (Mouse): 8,000 mg/kg
**SAFETY DATA SHEET**

according to the Hazardous Products Regulations

**Imipenem / Cilastatin / Relebactam Formulation**

<table>
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<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 08/09/2023</th>
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<tr>
<td>7.2</td>
<td>09/30/2023</td>
<td>67733-00029</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:**

- **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.

**Components:**

**Cilastatin:**

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

- **Routes of exposure**: Inhalation
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 7.2  Revision Date: 09/30/2023  SDS Number: 67733-00029  Date of last issue: 08/09/2023  Date of first issue: 02/27/2015

Remarks : No data available

Imipenem:
Remarks : May cause sensitization of susceptible persons by inhalation of aerosol or dust.
Routes of exposure Remarks : Skin contact
Remarks : Not classified due to lack of data.

Relebactam:
Test Type : Local lymph node assay (LLNA)
Routes of exposure Result : Not a skin sensitizer.
Result

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Imipenem:
Genotoxicity in vitro Result: negative
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
Species: Mouse
Application Route: Intravenous
Result: negative

Relebactam:
Genotoxicity in vitro Result: negative
Test Type: Bacterial reverse mutation assay (AMES)
**Imipenem / Cilastatin / Relebactam Formula-\-tion**

<table>
<thead>
<tr>
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<td>67733-00029</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test Type:** Chromosome aberration test in vitro  
**Result:** negative

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Test Type: Mutagenicity (in vivo mammalian bone-marrow</td>
</tr>
<tr>
<td>cytogenetic test, chromosomal analysis)</td>
</tr>
<tr>
<td>: Species: Rat</td>
</tr>
<tr>
<td>: Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td>: Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Germ cell mutagenicity - Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Weight of evidence does not support classification as a</td>
</tr>
<tr>
<td>germ cell mutagen.</td>
</tr>
</tbody>
</table>

**Carcinogenicity**  
Not classified based on available information.

**Reproductive toxicity**  
Suspected of damaging the unborn child.

**Components:**

**Cilastatin:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td>: Application Route: Intravenous</td>
</tr>
<tr>
<td>: Fertility: LOAEL: 1,000</td>
</tr>
<tr>
<td>: Symptoms: No adverse effects.</td>
</tr>
<tr>
<td>: Result: No effects on fertility and early embryonic</td>
</tr>
<tr>
<td>development were detected.</td>
</tr>
</tbody>
</table>

**Imipenem:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td>: Species: Rat, male and female</td>
</tr>
<tr>
<td>: Application Route: Intravenous</td>
</tr>
<tr>
<td>: Fertility: LOAEL: 80 mg/kg body weight</td>
</tr>
<tr>
<td>: Symptoms: No adverse effects., Reduced fetal weight.</td>
</tr>
<tr>
<td>: Result: No effects on fertility and early embryonic</td>
</tr>
<tr>
<td>development were detected.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td>: Species: Rat, male and female</td>
</tr>
<tr>
<td>: Application Route: Subcutaneous</td>
</tr>
<tr>
<td>: Fertility: LOAEL: 320 mg/kg body weight</td>
</tr>
<tr>
<td>: Symptoms: No adverse effects., Reduced fetal weight.</td>
</tr>
<tr>
<td>: Result: No effects on fertility and early embryonic</td>
</tr>
<tr>
<td>development were detected.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Test Type: Development</td>
</tr>
<tr>
<td>: Species: Monkey</td>
</tr>
<tr>
<td>: Application Route: Intravenous</td>
</tr>
<tr>
<td>: Developmental Toxicity: LOAEL: 100 mg/kg body weight</td>
</tr>
<tr>
<td>: Result: Embryotoxic effects and adverse effects on the</td>
</tr>
<tr>
<td>offspring were detected., No teratogenic effects.</td>
</tr>
</tbody>
</table>
Imipenem / Cilastatin / Relebactam Formula-
tion

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.

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**: \( \geq 500 \text{ mg/kg} \)
- **Application Route**: Intravenous
- **Exposure time**: 90 Days
- **Remarks**: No significant adverse effects were reported

- **Species**: Monkey
- **NOAEL**: \( \geq 500 \text{ mg/kg} \)
- **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

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

#### Relebactam:
- **Species**: Rat, female
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formula-
tion

| 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
Target Organs: Kidney

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
Target Organs: Kidney

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
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

SECTION 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

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

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

Toxicity to fish (Chronic toxicity):
EC10 (Pimephales promelas (fathead minnow)): > 9.9 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
EC10 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms:
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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
### Imipenem / Cilastatin / Relebactam Formulation

**Version:** 7.2  
**Revision Date:** 09/30/2023  
**SDS Number:** 67733-00029  
**Date of last issue:** 08/09/2023  
**Date of first issue:** 02/27/2015

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/l Exposition time: 72 h Method: OECD Test Guideline 201</td>
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<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 74 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
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<tr>
<td>Toxicity to fish (Chronic toxicity) NOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) NOEC (Daphnia magna (Water flea)): 11 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
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<tr>
<td>Toxicity to microorganisms EC50: &gt; 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
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<td><strong>Relebactam:</strong></td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
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<tr>
<td>EC50 (Americamysis): &gt; 100 mg/l Exposure time: 96 h</td>
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<tr>
<td>Toxicity to algae/aquatic plants EC50 (Pseudokirchneriella subcapitata (green algae)): 86 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
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<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 12 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
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<tr>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): &gt; 11 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
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</tr>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 11 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
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</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity) NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
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</tr>
<tr>
<td>Toxicity to daphnia and other NOEC (Daphnia magna (Water flea)): 2.7 mg/l</td>
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</tbody>
</table>
SAFETY DATA SHEET according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 08/09/2023</th>
</tr>
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<tbody>
<tr>
<td>7.2</td>
<td>09/30/2023</td>
<td>67733-00029</td>
<td>Date of first issue: 02/27/2015</td>
</tr>
</tbody>
</table>

aquatic invertebrates (Chronic toxicity)
Exposure time: 21 d
Method: OECD Test Guideline 211

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

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
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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not dispose of waste into sewer. 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.

SECTION 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
Environmentally hazardous: yes

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
UN number: UN 3077
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formulation

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

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
SAFETY DATA SHEET according to the Hazardous Products Regulations

Imipenem / Cilastatin / Relebactam Formula-
tion

Version 7.2  Revision Date: 09/30/2023  SDS Number: 67733-00029  Date of last issue: 08/09/2023


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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 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.

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