

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

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### SECTION 1. IDENTIFICATION

Product name : Imipenem / Cilastatin / Relebactam Formulation

#### 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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

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

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
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.

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Date of first issue: 02/27/2015

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.  
P285 In case of inadequate ventilation wear respiratory protection.

**Response:**  
P304 + P341 IF INHALED: If breathing is difficult, 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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cilastatin	81129-83-1	39.5
Imipenem	74431-23-5	39.4
Relebactam	1174020-13-3	19.5

## 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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Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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---

- In case of skin contact : If breathing is difficult, give oxygen.  
Get medical attention.  
: 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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.
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# SAFETY DATA SHEET

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Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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---

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

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### 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.

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### 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

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## Imipenem / Cilastatin / Relebactam Formula-tion

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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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

inert or nuisance dust      50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

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

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according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version	Revision Date:	SDS Number:	Date of last issue: 08/09/2023
11.2	09/30/2023	67748-00028	Date of first issue: 02/27/2015

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**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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**  
**Hygiene measures**

: Work uniform or laboratory coat.  
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder  
**Color** : White to light yellow  
**Odor** : No data available  
**Odor Threshold** : No data available

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Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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---

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
Density	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity 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 size	:	No data available

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Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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---

### 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.

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### 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

##### **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



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



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Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
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---

### 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  
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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

### 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.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is  
identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

on OSHA's list of regulated carcinogens.

**NTP**      No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### **Cilastatin:**

Effects on fertility      :    Test Type: Fertility/early embryonic development  
Application Route: Intravenous  
Fertility: LOAEL: 1,000  
Symptoms: No adverse effects.  
Result: No effects on fertility and early embryonic development were detected.

#### **Imipenem:**

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

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version	Revision Date:	SDS Number:	Date of last issue: 08/09/2023
11.2	09/30/2023	67748-00028	Date of first issue: 02/27/2015

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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

### 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

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

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  
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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## 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

---

Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

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

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

### 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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 2.7 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



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

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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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

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### Relebactam:

Distribution among environmental compartments : log Koc: 2.3

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## 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  
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

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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Imipenem)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Imipenem)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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.

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## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Respiratory or skin sensitization  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Cilastatin 81129-83-1  
Imipenem 74431-23-5

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formulation

Version 11.2      Revision Date: 09/30/2023      SDS Number: 67748-00028      Date of last issue: 08/09/2023  
Date of first issue: 02/27/2015

Relebactam

1174020-13-3

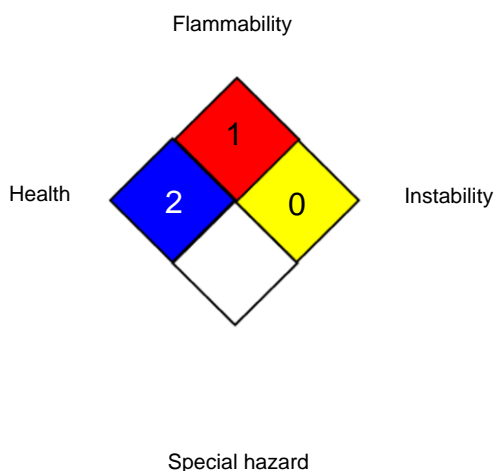
**The ingredients of this product are reported in the following inventories:**

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

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)  
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts  
CAL PEL / PEL : Permissible exposure limit  
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC -

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Imipenem / Cilastatin / Relebactam Formula-tion

Version	Revision Date:	SDS Number:	Date of last issue: 08/09/2023
11.2	09/30/2023	67748-00028	Date of first issue: 02/27/2015

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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 : 09/30/2023

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.

US / Z8