

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

---

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

#### 1.1 Product identifier

Trade name : Imipenem / Cilastatin Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
120 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Eye irritation, Category 2 H319: Causes serious eye irritation.

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758





## Imipenem / Cilastatin Formulation

Version 4.5      Revision Date: 14.04.2025      SDS Number: 9371295-00010      Date of last issue: 28.09.2024  
Date of first issue: 27.08.2021

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

- 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.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P261 Avoid breathing dust.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

Hazardous components which must be listed on the label:  
Imipenem

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Cilastatin	81129-83-1	Eye Irrit. 2; H319	>= 50 - < 70

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version 4.5      Revision Date: 14.04.2025      SDS Number: 9371295-00010      Date of last issue: 28.09.2024  
Date of first issue: 27.08.2021

Imipenem	279-694-4 74431-23-5	Resp. Sens. 1A; H334 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10	>= 30 - < 50
----------	-------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

Risks : 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.

Causes serious eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Suspected of damaging the unborn child.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise 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.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version 4.5      Revision Date: 14.04.2025      SDS Number: 9371295-00010      Date of last issue: 28.09.2024  
Date of first issue: 27.08.2021

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.

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

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dust of any kind      10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Inhalable)  
Basis: GB EH40

4 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Respirable fraction)  
Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cilastatin	81129-83-1	TWA	5 mg/m <sup>3</sup> (OEB 1)	Internal

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version 4.5      Revision Date: 14.04.2025      SDS Number: 9371295-00010      Date of last issue: 28.09.2024  
Date of first issue: 27.08.2021

Imipenem	74431-23-5	TWA	3000 ug/m3 (OEB 1)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm2	Internal

### 8.2 Exposure controls

#### Engineering measures

Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	white
Odour	:	sulphurous
Odour 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	:	No data available

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

---

flammability limit

Lower explosion limit / Lower  
flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : 1 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Auto-ignition 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.

### 9.2 Other information

Molecular weight : No data available

Particle size : No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

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

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

---

Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

##### Cilastatin:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

Species : Rabbit  
Result : Moderate eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

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

#### Components:

##### Cilastatin:

Exposure routes : Skin contact  
Remarks : No data available

Exposure routes : Inhalation  
Remarks : No data available

##### Imipenem:

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

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

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Cilastatin:

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

##### Imipenem:

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

Test Type: reverse mutation assay  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: sister chromatid exchange assay

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

Result: negative

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

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Cilastatin:

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

#### Imipenem:

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

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

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

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

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.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Imipenem:**

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### **Cilastatin:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 99 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae): > 99 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  EC50 (Pseudokirchneriella subcapitata (green algae)): > 99 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Anabaena flos-aquae): 99 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 99 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

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

### Imipenem:

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

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

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

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

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

M-Factor (Acute aquatic toxicity) : 100

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 11 mg/l  
Exposure time: 21 d

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

ic toxicity) Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

### 12.2 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

### 12.3 Bioaccumulative potential

#### Components:

##### **Cilastatin:**

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

##### **Imipenem:**

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

### 12.4 Mobility in soil

#### Components:

##### **Cilastatin:**

Distribution among environmental compartments : log Koc: 2.3

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
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.

### SECTION 14: Transport information

#### 14.1 UN number

ADN : UN 3077  
ADR : UN 3077  
RID : UN 3077  
IMDG : UN 3077  
IATA : UN 3077

#### 14.2 UN proper shipping name

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

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

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

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

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

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

---

<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9

<b>ADR</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)

<b>RID</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9

<b>IMDG</b>	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F

<b>IATA (Cargo)</b>	
Packing instruction (cargo aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

<b>IATA (Passenger)</b>	
Packing instruction (passenger aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

### 14.5 Environmental hazards

<b>ADN</b>	
Environmentally hazardous	: yes

<b>ADR</b>	
Environmentally hazardous	: yes

<b>RID</b>	
Environmentally hazardous	: yes

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

H319 : Causes serious eye irritation.  
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361d : Suspected of damaging the unborn child.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Irrit. : Eye irritation  
Repr. : Reproductive toxicity  
Resp. Sens. : Respiratory sensitisation  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.5	14.04.2025	9371295-00010	Date of first issue: 27.08.2021

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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

### Further information

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

### Classification of the mixture:

Eye Irrit. 2	H319
Resp. Sens. 1	H334
Repr. 2	H361d
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

GB / EN