

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Imipenem / Cilastatin Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Serious eye damage/eye irritation : Category 2A

Respiratory sensitisation : Category 1

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

#### 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.

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1	Revision Date: 2025/04/14	SDS Number: 15834-00033	Date of last issue: 2024/09/28 Date of first issue: 2014/11/05
-----------------	------------------------------	----------------------------	---

H361d Suspected of damaging the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.

### Precautionary statements

#### **Prevention:**

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing dust.  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
P284 Wear respiratory protection.

#### **Response:**

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

#### **Storage:**

P405 Store locked up.

#### **Disposal:**

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

### Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed : Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cilastatin	81129-83-1	>= 50 - < 60	
Imipenem	74431-23-5	>= 40 - < 50	-

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

### 4. FIRST AID MEASURES

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

---

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (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.

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

Hazardous combustion products : Carbon 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.

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

---

## 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 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.

---

## 7. HANDLING AND STORAGE

### Handling

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

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1	Revision Date: 2025/04/14	SDS Number: 15834-00033	Date of last issue: 2024/09/28 Date of first issue: 2014/11/05
-----------------	------------------------------	----------------------------	---

Local/Total ventilation	and bonding, or inert atmospheres.
Advice on safe handling	<ul style="list-style-type: none"><li>: Use only with adequate ventilation.</li><li>: Do not breathe dust.</li><li>Do not swallow.</li><li>Do not get in eyes.</li><li>Avoid prolonged or repeated contact with skin.</li><li>Wash skin thoroughly after handling.</li></ul>
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	Keep container tightly closed.
Avoidance of contact	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.
Hygiene measures	<ul style="list-style-type: none"><li>Minimize dust generation and accumulation.</li><li>Keep container closed when not in use.</li><li>Keep away from heat and sources of ignition.</li><li>Take precautionary measures against static discharges.</li><li>Take care to prevent spills, waste and minimize release to the environment.</li></ul>
<b>Storage</b>	
Conditions for safe storage	<ul style="list-style-type: none"><li>: Keep in properly labelled containers.</li><li>Store locked up.</li><li>Keep tightly closed.</li><li>Store in accordance with the particular national regulations.</li></ul>
Materials to avoid	<ul style="list-style-type: none"><li>: Do not store with the following product types:</li><li>Strong oxidizing agents</li></ul>
Packaging material	: Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1 Revision Date: 2025/04/14 SDS Number: 15834-00033 Date of last issue: 2024/09/28 Date of first issue: 2014/11/05

Cilastatin	81129-83-1	TWA	5 mg/m3 (OEB 1)	Internal
Imipenem	74431-23-5	TWA	3000 ug/m3 (OEB 1)	Internal
Further information: RSEN, DSEN		Wipe limit	100 µg/100 cm <sup>2</sup>	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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : white

Odour : sulphurous

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- per flammability limit : No data available

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 15834-00033      Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	Not applicable
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Density and / or relative density		
Relative density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Relative vapour density	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

---

## 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.

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 15834-00033      Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Cilastatin:**

Acute oral toxicity : LD50 (Rat): 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:**

Species : Rabbit  
Result : Moderate eye irritation

**Imipenem / Cilastatin Formulation**Version  
12.1Revision Date:  
2025/04/14SDS Number:  
15834-00033Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05**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  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

**Imipenem / Cilastatin Formulation**

Version 12.1	Revision Date: 2025/04/14	SDS Number: 15834-00033	Date of last issue: 2024/09/28 Date of first issue: 2014/11/05
-----------------	------------------------------	----------------------------	---

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

Test Type: Development  
Species: Rat

**Imipenem / Cilastatin Formulation**Version  
12.1Revision Date:  
2025/04/14SDS Number:  
15834-00033Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

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 : >= 500 mg/kg  
Application Route : Intravenous  
Exposure time : 90 Days  
Remarks : No significant adverse effects were reported

Species : Monkey  
NOAEL : >= 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

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1 Revision Date: 2025/04/14 SDS Number: 15834-00033 Date of last issue: 2024/09/28 Date of first issue: 2014/11/05

---

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.

---

## 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

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

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  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

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

M-Factor (Chronic aquatic toxicity) : 10

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

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 15834-00033      Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

### 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

### Bioaccumulative potential

#### Components:

##### **Cilastatin:**

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

##### **Imipenem:**

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

### Mobility in soil

#### Components:

##### **Cilastatin:**

Distribution among environmental compartments : log Koc: 2.3

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

---

## 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.

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version 12.1 Revision Date: 2025/04/14 SDS Number: 15834-00033 Date of last issue: 2024/09/28 Date of first issue: 2014/11/05

---

### 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

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

Not applicable for product as supplied.

#### National Regulations

Refer to section 15 for specific national regulation.

#### 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.

ERG Code : 171

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

##### Substances Subject to be Notified Names

Not applicable

##### Substances Subject to be Indicated Names

Not applicable

##### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

##### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

##### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

##### Ordinance on Prevention of Lead Poisoning

Not applicable

##### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

##### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

---

### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

### **Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### **Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

## 16. OTHER INFORMATION

### **Further information**

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/>

# SAFETY DATA SHEET



## Imipenem / Cilastatin Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
15834-00033

Date of last issue: 2024/09/28  
Date of first issue: 2014/11/05

Date format : yyyy/mm/dd

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN