

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
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.

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
 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 out- : Contact with dust can cause mechanical irritation or drying of
 lines of the emergency as- the skin.
 sumed 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	

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	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 | : | Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging the unborn child.
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. |

5. FIREFIGHTING MEASURES

- | | | |
|---------------------------------------|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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 prod- | : | Carbon oxides |

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

ucts

- 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 and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Avoid breathing dust.
Do not swallow.
-

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
 Date of first issue: 2014/11/05

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 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.

Avoidance of contact : Oxidizing agents
 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.

Storage

Conditions for safe storage : Keep in properly labelled 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

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 parameters / Reference concentration / Permissible concentration	Basis
Cilastatin	81129-83-1	TWA	5 mg/m ³ (OEB 1)	Internal
Imipenem	74431-23-5	TWA	3000 ug/m ³ (OEB 1)	Internal
Further information: RSEN, DSEN				

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

		Wipe limit	100 µg/100 cm ²	Internal
--	--	------------	----------------------------	----------

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

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
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- : No data available
per flammability limit

Lower explosion limit / : No data available
Lower flammability limit

Flash point : Not applicable

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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 ³
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.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
 Date of first issue: 2014/11/05

products

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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 Species: Mouse Application Route: Intravenous Result: negative
----------------------	---	--

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
 Date of first issue: 2014/11/05

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
 Application Route: Intravenous
 Developmental Toxicity: NOAEL: 60 mg/kg body weight
 Result: No teratogenic effects

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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
 Application Route : Intravenous
 Target Organs : Kidney

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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 Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic)	: EC10 (Daphnia magna (Water flea)): > 10 mg/l Exposure time: 21 d

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

ic toxicity) 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

Persistence and degradability**Components:****Cilastatin:**

Imipenem / Cilastatin Formulation

Version 10.0 Revision Date: 2023/09/26 SDS Number: 15834-00030 Date of last issue: 2023/08/08
Date of first issue: 2014/11/05

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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3077

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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

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

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

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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/>

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

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 -

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/08/08
10.0	2023/09/26	15834-00030	Date of first issue: 2014/11/05

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