

# Imipenem / Cilastatin / Relebactam Formulation

Version Date of last issue: 30.09.2023 Revision Date: SDS Number: 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

**Section 1: Identification** 

**Product identifier** Imipenem / Cilastatin / Relebactam Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

Manufacturer or supplier's details

MSD Company

: 50 Tuas West Drive Address

Singapore - Singapore 638408

Telephone +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Serious eye damage/eye irri-: Category 2

tation

Respiratory sensitisation : Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - :

repeated exposure

Category 2 (Kidney)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

: Category 1

GHS Label elements, including precautionary statements

Hazard pictograms





# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Kidney) through pro-

longed or repeated exposure.

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.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection/ hearing 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/ at-

tention.

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

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

Substance / Mixture : Mixture

Components



# Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.0
 06.04.2024
 67747-00030
 Date of first issue: 27.02.2015

Chemical name	CAS-No.	Concentration (% w/w)
Cilastatin	81129-83-1	>= 30 -< 50
Imipenem	74431-23-5	>= 30 -< 50
Relebactam	1174020-13-3	>= 10 -< 20

#### Section 4: First-aid measures

Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

## **Section 5: Fire-fighting measures**

**Extinguishing media** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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 prod: :

ucts

Carbon oxides Metal oxides

## Special protective actions for fire-fighters

Special protective equipment :

for firefighters

Specific extinguishing meth-

ods

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### Section 6: Accidental release measures

# Personal precautions, protective equipment and emergency procedures

Personal precautions

: Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

**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.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials 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



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## Section 7: Handling and storage

#### 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. Use only with adequate ventilation.

Local/Total ventilation

Advice on safe handling : Do not breathe dust.

Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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 respira-

tory 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



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

use of administrative controls.

## Conditions for safe storage, including any incompatibilities

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

#### Section 8: Exposure controls/personal protection

#### **Control parameters**

## **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Cilastatin	81129-83-1	TWA	5 mg/m3 (OEB 1)	Internal		
Imipenem	74431-23-5	TWA	3000 ug/m3 (OEB 1)	Internal		
	Further inform	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	Internal		
Relebactam	1174020-13- 3	TWA	0.3 mg/m3 (OEB 2)	Internal		

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

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.

Skin protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection

Material : Chemical-resistant gloves



# Imipenem / Cilastatin / Relebactam Formulation

Version 7.0

Revision Date: 06.04.2024

SDS Number: 67747-00030

Date of last issue: 30.09.2023 Date of first issue: 27.02.2015

Section 9: Physical and chemical properties

Appearance : powder

Colour : White to light yellow

Odour : No data available

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, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

### **Section 11: Toxicological information**

Information on likely routes of : Inhalation

exposure

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



# Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.0
 06.04.2024
 67747-00030
 Date of first issue: 27.02.2015

LD50 (Mouse): 1,500 mg/kg Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

#### Cilastatin:

Species : Rabbit

Result : No skin irritation

#### Relebactam:

Method : EpiDerm Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

### Cilastatin:

Species : Rabbit

Result : Moderate eye irritation

#### Relebactam:

Result : No eye irritation

Method : Bovine cornea (BCOP)

#### Respiratory or skin 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 / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

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.

Relebactam:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal

Result : Not a skin sensitizer.

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

Relebactam:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

### Carcinogenicity

Not classified based on available information.

#### 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 develop-

ment 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 develop-

ment 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 develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Development

Species: Monkey

Application Route: Intravenous

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected., No teratogenic effects



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Test Type: Development

Species: Rabbit

Application Route: Intravenous

Developmental Toxicity: NOAEL: 60 mg/kg body weight

Result: No teratogenic effects

Test Type: Development

Species: Rat

Application Route: Intravenous

Developmental Toxicity: NOAEL: 60 mg/kg body weight

Result: No teratogenic effects

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### Relebactam:

Effects on fertility : Test Type: Pre-/postnatal development

Species: Rat

Application Route: Subcutaneous

Fertility: NOAEL: 450 mg/kg body weight

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intraperitoneal injection

Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight

Result: No effects on foetal development

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Intraperitoneal injection

Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight

Result: No effects on foetal development

Test Type: Development

Species: Rat

Application Route: Intravenous

Developmental Toxicity: NOAEL: >= 450 mg/kg body weight Result: No effects on fertility and early embryonic develop-

ment were detected.

Test Type: Development

Species: Rabbit

Application Route: Intravenous

Developmental Toxicity: NOAEL: 450 mg/kg body weight

Result: No effects on foetal development

#### STOT - single exposure

Not classified based on available information.



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

#### STOT - repeated exposure

May cause damage to organs (Kidney) through prolonged or repeated exposure.

#### Components:

#### Relebactam:

Target Organs : Kidney

Assessment : May cause damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### **Components:**

### Cilastatin:

Species : Rat

NOAEL : >= 500 mg/kg
Application Route : Intravenous
Exposure time : 90 Days

Remarks : No significant adverse effects were reported

Species: MonkeyNOAEL: >= 500 mg/kgApplication Route: IntravenousExposure time: 5 Weeks

Remarks : No significant adverse effects were reported

### Imipenem:

Species: MonkeyNOAEL: 60 mg/kgLOAEL: 150 mg/kgApplication Route: IntravenousExposure time: 6 MonthsTarget 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



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Target Organs : Kidney

Relebactam:

Species : Rat, female NOAEL : 150 mg/kg Application Route : Intravenous

Exposure time : 30 d

Species : Rat, male

NOAEL : 450 mg/kg

Application Route : Intravenous

Exposure time : 30 d

Species : Monkey
NOAEL : 25 mg/kg
Application Route : Intravenous
Exposure time : 30 d
Target Organs : Kidney

Species : Monkey
NOAEL : 37.5 mg/kg
Application Route : Intravenous

Exposure time : 30 d

Species: MonkeyNOAEL: 50 mg/kgLOAEL: 150 mg/kgApplication Route: IntravenousExposure time: 3 MonthsTarget 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.

Relebactam:

Skin contact : Symptoms: Pain, Discomfort, Diarrhoea, Abdominal pain,

insomnia, Nausea, sore throat, Vertigo



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

## **Section 12: Ecological information**

### **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 fish (Chronic tox-

icity)

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 (Chron-

ic 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



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

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

100

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icitv'

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 11 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

10

EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Relebactam:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

EC50 (Americamysis): > 100 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 86 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 12

ng/l



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): > 11 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 11 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 2.7 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 96.3 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

#### **Components:**

Cilastatin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 27 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Imipenem:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 29 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Relebactam:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 11.3 % Exposure time: 28 d



# Imipenem / Cilastatin / Relebactam Formulation

Version 7.0

Revision Date: 06.04.2024

SDS Number: 67747-00030

Date of last issue: 30.09.2023 Date of first issue: 27.02.2015

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Cilastatin:

Partition coefficient: n-

octanol/water

: log Pow: -3.53

Imipenem:

Partition coefficient: n-

octanol/water

: log Pow: < -1

Relebactam:

Partition coefficient: n-

octanol/water

: log Pow: < -2

Mobility in soil

**Components:** 

Cilastatin:

Distribution among environ-

mental compartments

log Koc: 2.3

Relebactam:

Distribution among environ-

mental compartments

: log Koc: 2.3

Other adverse effects

No data available

Section 13: Disposal considerations

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information** 

**International Regulations** 

**UNRTDG** 

**UN** number UN 3077

UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

> N.O.S. (Imipenem)



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

Transport hazard class(es) : 9
Packing group : III
Labels : 9
Environmental hazards : yes

**IATA-DGR** 

UN/ID No. : UN 3077

UN proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Imipenem)

956

Transport hazard class(es) : 9
Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen- : 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Imipenem)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

## Special precautions for user

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

### Section 15: Regulatory information

### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Not applicable

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable

Regulations



# Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 06.04.2024 67747-00030 Date of first issue: 27.02.2015

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### Section 16: Other information

Revision Date : 06.04.2024

**Further information** 

Sheet

Sources of key data used to compile the Safety Data

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, 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 : dd.mm.yyyy

#### 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; 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 - Trans-



# Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.0
 06.04.2024
 67747-00030
 Date of first issue: 27.02.2015

portation 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.

SG / EN