

Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

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

1.1 Product identifier

Trade name Imipenem / Cilastatin / Relebactam Formulation

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

Use of the Sub-Pharmaceutical

stance/Mixture

on use

1.3 Details of the supplier of the safety data sheet

Company

117 16th Road

Not applicable

1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person

Recommended restrictions

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child. Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure. Category 2

longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

Hazard pictograms :





Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor. P391 Collect spillage.

Hazardous components which must be listed on the label:

Imipenem

Relebactam

2.3 Other hazards

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

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

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Cilastatin	81129-83-1 279-694-4	Eye Irrit. 2; H319	>= 30 - < 50
Imipenem	74431-23-5	Resp. Sens. 1A; H334	>= 30 - < 50



Imipenem / Cilastatin / Relebactam Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
5.2	30.09.2023	67750-00030	Date of first issue: 27.02.2015

		Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10	
Relebactam	1174020-13-3	STOT RE 2; H373 (Kidney)	>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

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

Use personal protective equipment.

Specific extinguishing meth-

ods

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.



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Surround spill with absorbents and place a damp covering

over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

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 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 contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

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

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
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 cm2	Internal
Relebactam	1174020-	TWA	0.3 mg/m3 (OEB 2)	Internal
	13-3			



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.

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

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.

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



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

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

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : 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

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



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

Relebactam:

Method : Bovine cornea (BCOP)

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

Components:

Cilastatin:

Exposure routes : Skin contact Remarks : No data available

Exposure routes : Inhalation

Remarks : No data available

Imipenem:

Remarks : May cause sensitisation of susceptible persons by inhalation

of aerosol or dust.

Exposure routes : Skin contact

Remarks : Not classified due to lack of data.

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



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: 5.2 30.09.2023 67750-00030

Date of last issue: 09.08.2023 Date of first issue: 27.02.2015

Test Type: unscheduled DNA synthesis assay

Result: negative

Test Type: Chromosomal aberration

Result: negative

Test Type: sister chromatid exchange assay

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Intravenous

Result: negative

Relebactam:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity- As-

sessment

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



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

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

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



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

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.

STOT - repeated exposure

May cause damage to organs 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 : 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



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Rat

NOAEL : 180 mg/kg

Application Route : Intravenous

Exposure time : 6 Months

Remarks : No significant adverse effects were reported

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

Relebactam:

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

Exposure time : 30 d

Species : Rat, male
NOAEL : 450 mg/kg
Application Route : Intravenous

Exposure time : 30 d

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

Species : Monkey
NOAEL : 37,5 mg/kg
Application Route : Intravenous

Exposure time : 30 d

Species : Monkey
NOAEL : 50 mg/kg
LOAEL : 150 mg/kg
Application Route : Intravenous
Exposure time : 3 Months
Target Organs : Kidney

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Imipenem:

Inhalation : Symptoms: Nausea, Vomiting, Diarrhoea, Fever, hypotension,

Dizziness, Drowsiness, Convulsions, pruritis, Rash



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

Cilastatin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 99 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): > 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 99

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

EC10: > 9,9 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

EC10: > 10 mg/l Exposure time: 21 d

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



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

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 tox-

icity)

100

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 9,4 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 11 mg/l

Exposure time: 21 d

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

M-Factor (Chronic aquatic

toxicity)

10

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



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 12

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to 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

Toxicity to fish (Chronic tox-

icity)

NOEC: 9,2 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 2,7 mg/l Exposure time: 21 d

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

12.2 Persistence and degradability

Components:

Cilastatin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 27 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Imipenem:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 29 % Exposure time: 28 d

Method: OECD Test Guideline 301B



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

Relebactam:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 11,3 % Exposure time: 28 d

Method: OECD Test Guideline 314

12.3 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

12.4 Mobility in soil

Components:

Cilastatin:

Distribution among environ-

mental compartments

: log Koc: 2,3

Relebactam:

Distribution among environ-

mental compartments

log Koc: 2,3

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to

REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

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

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Imipenem)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Imipenem)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Imipenem)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Imipenem)

IATA : Environmentally hazardous substance, solid, n.o.s.

(Imipenem)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes



Imipenem / Cilastatin / Relebactam Formulation

Version Revision Date: SDS Number: Date of last issue: 09.08.2023 5.2 30.09.2023 67750-00030 Date of first issue: 27.02.2015

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H319 : Causes serious eye irritation.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation

STOT RE : Specific target organ toxicity - repeated exposure



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Eye Irrit. 2	H319	Calculation method
Resp. Sens. 1	H334	Calculation method
Repr. 2	H361d	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be



Imipenem / Cilastatin / Relebactam Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 5.2
 30.09.2023
 67750-00030
 Date of first issue: 27.02.2015

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.

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