

Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

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

1.1 Product identifier

Trade name : Ceftolozane / Tazobactam Injection Formulation

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

Use of the Sub-

stance/Mixture

Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

117 16th Road

1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

breathing difficulties if inhaled.

Specific target organ toxicity - repeated

exposure, Category 2

H373: May cause damage to organs through pro-

H410: Very toxic to aquatic life with long lasting

longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

nory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

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. P284 Wear respiratory 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:

Ceftolozane

Tazobactam

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.

Dust contact with the eyes can lead to mechanical irritation.

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) |
|---------------|---|---|--------------------------|
| Ceftolozane | 689293-68-3 | Resp. Sens. 1B; H334 STOT RE 2; H373 (Kidney) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic | >= 30 - < 50 |



Ceftolozane / Tazobactam Injection Formula- tion

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

| II | | aquatic toxicity): 10 | |
|------------|------------|---|--------------|
| Tazobactam | 89786-04-9 | Resp. Sens. 1B; H334 STOT RE 2; H373 (Liver) Aquatic Acute 1; H400 Aquatic Chronic 2; H411 ——— M-Factor (Acute aquatic toxicity): 1 | >= 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.

Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

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

ties if inhaled.

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-



Ceftolozane / Tazobactam Injection Formula- tion

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

tive airways dysfunction syndrome).

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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

Chlorine compounds Nitrogen oxides (NOx)

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.

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).



Ceftolozane / Tazobactam Injection Formulation

Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

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.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

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.



Ceftolozane / Tazobactam Injection Formula- tion

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

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. 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 of exposure) | Control parameters | Basis |
|-------------|---------------------------------|-------------------------------|----------------------------|----------|
| Ceftolozane | 689293-68- 3 | TWA | 1000 μg/m3 (OEB 1) | Internal |
| | Further information: DSEN, RSEN | | | |
| | | Wipe limit | 100 μg/100 cm ² | Internal |
| Tazobactam | 89786-04-9 | TWA | 250 μg/m3 (OEB 2) | Internal |
| | Further information: RSEN | | | |
| | | Wipe limit | 100 μg/100 cm2 | Internal |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-----------------|---------|-----------------|----------------------------|------------------------|
| Sodium chloride | Workers | Inhalation | Long-term systemic effects | 2068,62 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 2068,62 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 295,52 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 295,52 mg/kg bw/day |



Ceftolozane / Tazobactam Injection Formulation

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

| | Consumers | Inhalation | Long-term systemic effects | 443,28 mg/m3 |
|-------------------------------|-----------|--------------|----------------------------|------------------------|
| | Consumers | Inhalation | Acute systemic effects | 443,28 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 126,65 mg/kg bw/day |
| L-Arginine hydrochlo- ride | Workers | Inhalation | Long-term systemic effects | 668,2 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 947,5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 164,8 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 473,8 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 47,8 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|--------------------------|---------------------------|------------------------------|
| Sodium chloride | Fresh water | 5 mg/l |
| | Sewage treatment plant | 500 mg/l |
| | Soil | 4,86 mg/kg dry weight (d.w.) |
| L-Arginine hydrochloride | Fresh water | 2,2 mg/l |
| | Marine water | 0,22 mg/l |
| | Intermittent use/release | 22 mg/l |
| | Sewage treatment plant | 12000 mg/l |
| | Fresh water sediment | 4,437 mg/kg |
| | Marine sediment | 0,444 mg/kg |

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

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.



Ceftolozane / Tazobactam Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

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 : No data available
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 : No data available

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 : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : No data available

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

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

9.2 Other information

Flammability (liquids) : No data available

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

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:

Ceftolozane:

Acute toxicity (other routes of : LD50 (Rat): > 2.000 mg/kg

administration)

Application Route: Intravenous



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

LD50 (Mouse): > 1.500 mg/kg Application Route: Intravenous

LD50 (Dog): > 2.000 mg/kg Application Route: Intravenous

Tazobactam:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

LD50 (Mouse): > 5.000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): > 5.000 mg/kg Application Route: Intravenous

LD50 (Mouse): > 5.000 mg/kg

Application Route: Intravenous

LD50 (Dog): > 5.000 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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:

Ceftolozane:

Test Type : Maximisation Test

Species : Guinea pig Result : Sensitiser

Tazobactam:

Result : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Ceftolozane:

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

Result: negative



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Mouse Result: negative

Tazobactam:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: positive

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster fibroblasts

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Ceftolozane:

Effects on fertility : Test Type: Fertility/early embryonic development



Ceftolozane / Tazobactam Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

Species: Rat

Application Route: Intravenous injection Fertility: NOAEL: 1.000 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 2.000 mg/kg body weight Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 1.000 mg/kg body weight Remarks: No significant adverse effects were reported

Tazobactam:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intraperitoneal injection Fertility: NOAEL: 640 mg/kg body weight

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intraperitoneal injection

Developmental Toxicity: NOAEL: 40 mg/kg body weight

Result: Effects on early embryonic development

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 3.000 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:

Ceftolozane:

Target Organs : Kidney

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Tazobactam:

Target Organs : Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.



Ceftolozane / Tazobactam Injection Formulation

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

Repeated dose toxicity

Components:

Ceftolozane:

Species : Rat

NOAEL : 1.000 mg/kg
Application Route : Intravenous
Exposure time : 28 days
Target Organs : Kidney

Symptoms : No adverse effects

Species : Dog
LOAEL : 300 mg/kg
Exposure time : 28 days
Target Organs : Kidney

Tazobactam:

Species : Rat

NOAEL : 40 mg/kg

Application Route : Intraperitoneal

Exposure time : 6 Months

Target Organs : Liver

Species : Dog
NOAEL : 40 mg/kg
LOAEL : 80 mg/kg
Application Route : Intraperitoneal
Exposure time : 6 Months
Target Organs : Liver

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ceftolozane:

Ingestion : Symptoms: Diarrhoea, Fever, Headache, Nausea, Skin irrita-

tion, Gastrointestinal discomfort

Tazobactam:

Inhalation : Remarks: May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ceftolozane:

Toxicity to algae/aquatic

plants

: EC50 (Anabaena flos-aquae): 0,0401 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0,0018 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 560 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 10 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: 9,6 mg/l Exposure time: 21 d

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

M-Factor (Chronic aquatic

toxicity)

10

Tazobactam:

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): 0,96 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0,44 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

city

•



Ceftolozane / Tazobactam Injection Formula- tion

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1.000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 10,6 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: 9,6 mg/l Exposure time: 21 d

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

12.2 Persistence and degradability

Components:

Ceftolozane:

Biodegradability : Result: Not readily biodegradable.

Method: OECD Test Guideline 301D

Tazobactam:

Biodegradability : Result: Not readily biodegradable.

Method: OECD Test Guideline 301D

12.3 Bioaccumulative potential

Components:

Ceftolozane:

Partition coefficient: n-

log Pow: -0,21

octanol/water

Tazobactam:

Partition coefficient: n-

: log Pow: -0,63

octanol/water

12.4 Mobility in soil

Components:

Ceftolozane:

Distribution among environ-

log Koc: 3.3

mental compartments Method: OECD Test Guideline 106

Tazobactam:



Ceftolozane / Tazobactam Injection Formula- tion

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

Distribution among environmental compartments

log Koc: 0,87

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.

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.

(Ceftolozane, Tazobactam)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.



Ceftolozane / Tazobactam Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

(Ceftolozane, Tazobactam)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Ceftolozane, Tazobactam)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Ceftolozane, Tazobactam)

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

(Ceftolozane, Tazobactam)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 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)



Ceftolozane / Tazobactam Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

956

Packing instruction (passen-

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

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.



Ceftolozane / Tazobactam Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 06.04.2024 438911-00021 Date of first issue: 06.01.2016

Full text of H-Statements

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

ties if inhaled.

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.H411 : 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

Resp. Sens. : Respiratory sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

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

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/



Ceftolozane / Tazobactam Injection Formulation

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

 6.0
 06.04.2024
 438911-00021
 Date of first issue: 06.01.2016

Classification of the mixture: Classification procedure:

| Resp. Sens. 1 | H334 | Calculation method |
|-------------------|------|--------------------|
| STOT RE 2 | H373 | Calculation method |
| Aquatic Acute 1 | H400 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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

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.

ZA / EN