

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

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 prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848 and subsequent amendments

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version 7.1 Revision Date: 14.04.2025 SDS Number: 2438214-00015 Date of last issue: 28.09.2024
Date of first issue: 09.02.2018

- Hazard pictograms :
- Signal word : Danger
- 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

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. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Ceftolozane	689293-68-3	Resp. Sens. 1B; H334 STOT RE 2; H373 (Kidney) Aquatic Acute 1; H400	>= 30 - < 50

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version 7.1 Revision Date: 14.04.2025 SDS Number: 2438214-00015 Date of last issue: 28.09.2024
Date of first issue: 09.02.2018

		Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic 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 advice 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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

4.2 Most important symptoms and effects, both acute and delayed

Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause damage to organs through prolonged or repeated exposure.

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 products : Carbon oxides
Metal oxides
Chlorine compounds
Nitrogen oxides (NO_x)

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 methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 protective 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 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.

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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 assessment
Keep container tightly closed.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

Dust 15 mg/m³
Value type (Form of exposure): ZOAD/TWA (Total dust)
Basis: TR OEL DU
Further information: Allowable occupational exposure limit values of mineral dusts

5 mg/m³
Value type (Form of exposure): ZOAD/TWA (Respirable part)
Basis: TR OEL DU
Further information: Allowable occupational exposure limit values

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version 7.1 Revision Date: 14.04.2025 SDS Number: 2438214-00015 Date of last issue: 28.09.2024
Date of first issue: 09.02.2018

of mineral dusts

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ceftolozane	689293-68-3	TWA	1000 µg/m ³ (OEB 1)	Internal
Further information: DSEN, RSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Tazobactam	89786-04-9	TWA	250 µg/m ³ (OEB 2)	Internal
Further information: RSEN				
		Wipe limit	100 µg/100 cm ²	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m ³
	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
	Consumers	Inhalation	Long-term systemic effects	443,28 mg/m ³
	Consumers	Inhalation	Acute systemic effects	443,28 mg/m ³
	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
	Workers	Inhalation	Long-term systemic effects	668,2 mg/m ³
	Workers	Skin contact	Long-term systemic effects	947,5 mg/kg bw/day
L-Arginine hydrochloride	Consumers	Inhalation	Long-term systemic effects	164,8 mg/m ³
	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
	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m ³
	Workers	Skin contact	Long-term systemic	295,52 mg/kg

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version 7.1 Revision Date: 14.04.2025 SDS Number: 2438214-00015 Date of last issue: 28.09.2024
Date of first issue: 09.02.2018

			effects	bw/day
	Workers	Skin contact	Acute systemic effects	295,52 mg/kg bw/day
	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 hydrochloride	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):

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 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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

Hand protection	aerosols.
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Equipment should conform to TS EN 143 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, handling or other means.
Flammability (liquids)	: No data available
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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

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, handling 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 exposure : Inhalation
Skin contact
Ingestion
Eye contact

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

Acute toxicity

Not classified based on available information.

Components:

Ceftolozane:

Acute toxicity (other routes of administration) : LD50 (Rat): > 2.000 mg/kg
Application Route: Intravenous

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:

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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

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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 Species: Rat Application Route: Intravenous injection Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility
Effects on foetal development	:	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 development	:	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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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.

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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

Experience with human exposure

Components:

Ceftolozane:

Ingestion : Symptoms: Diarrhoea, Fever, Headache, Nausea, Skin irritation, Gastrointestinal discomfort

Tazobactam:

Inhalation : Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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 toxicity) : 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 toxicity) : 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 (Chronic 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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 toxicity) | : | 1 |
| 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 toxicity) | : | 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 (Chronic 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 |
|---------------------------|---|----------------|

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

octanol/water

Tazobactam:

Partition coefficient: n-octanol/water : log Pow: -0,63

12.4 Mobility in soil

Components:

Ceftolozane:

Distribution among environmental compartments : log Koc: 3,3
Method: OECD Test Guideline 106

Tazobactam:

Distribution among environmental compartments : log Koc: 0,87

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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)
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	

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

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 aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023 : Not applicable

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.

The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

Full text of H-Statements

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H373 : May cause damage to organs through prolonged or repeated

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

	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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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
TR OEL DU	: Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
TR OEL DU / ZOAD/TWA	: Time Weighted Average Value

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 : Internal technical data, data from raw material SDSs, OECD

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	2438214-00015	Date of first issue: 09.02.2018

compile the Safety Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Resp. Sens. 1	H334
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
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 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.

TR / EN