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## **Ceftolozane / Tazobactam Injection Formula**tion

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### 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

120 Moorgate

EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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

breathing difficulties if inhaled.

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.

gory 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

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### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :



¥2

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breath-

ing 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.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		

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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 aquatic toxicity): 10	>= 30 - < 50
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.

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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-

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.

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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).

### 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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Surround spill v

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.

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Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not breathe dust. Do not swallow.

A side 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. 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

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 of any kind 10 mg/m3

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

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4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ceftolozane	689293-68- 3	TWA	1000 μg/m3 (OEB 1)	Internal
	Further inform	Further information: DSEN, RSEN		
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal
Tazobactam	89786-04-9	TWA	250 μg/m3 (OEB 2)	Internal
	Further inform	Further information: RSEN		
		Wipe limit	100 μg/100 cm2	Internal

### **Derived No Effect Level (DNEL)**

End Use	Exposure routes	Potential health ef-	Value
Workers	Inhalation		2068.62
			mg/m3
Workers	Inhalation		2068.62
			mg/m3
Workers	Skin contact		295.52 mg/kg
			bw/day
Workers	Skin contact	Acute systemic ef-	295.52 mg/kg
		fects	bw/day
Consumers	Inhalation	Long-term systemic	443.28 mg/m3
		effects	
Consumers	Inhalation	Acute systemic ef-	443.28 mg/m3
		fects	
Consumers	Skin contact	Long-term systemic	126.65 mg/kg
		effects	bw/day
Consumers	Skin contact	Acute systemic ef-	126.65 mg/kg
		fects	bw/day
Consumers	Ingestion	Long-term systemic	126.65 mg/kg
		effects	bw/day
Consumers	Ingestion	Acute systemic ef-	126.65 mg/kg
		fects	bw/day
Workers	Inhalation	Long-term systemic	668.2 mg/m3
		effects	
Workers	Skin contact	Long-term systemic	947.5 mg/kg
		effects	bw/day
Consumers	Inhalation	Long-term systemic	164.8 mg/m3
		effects	
Consumers	Skin contact	Long-term systemic	473.8 mg/kg
		effects	bw/day
Consumers	Ingestion	Long-term systemic	47.8 mg/kg
		effects	bw/day
	Workers Workers Workers Workers Consumers Consumers Consumers Consumers Consumers Workers Workers Workers Consumers Consumers	Workers Inhalation  Workers Inhalation  Workers Skin contact  Workers Skin contact  Consumers Inhalation  Consumers Skin contact  Consumers Skin contact  Consumers Ingestion  Consumers Ingestion  Workers Inhalation  Workers Inhalation  Workers Skin contact  Consumers Ingestion  Consumers Ingestion  Workers Skin contact  Consumers Skin contact  Consumers Skin contact  Consumers Skin contact	Morkers

### **Predicted No Effect Concentration (PNEC)**

Substance name Environmental Compartment Value	е
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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

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.

Equipment should conform to BS EN 143

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 : No data available

range

Flash point : Not applicable

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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
Partition coefficient: n-

octanol/water

: No data available

No data available

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

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.

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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:

exposure

Inhalation Skin contact

Ingestion Eye contact

**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

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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

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

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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

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

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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.

### 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

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**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 : Intraperitoneal Application Route : 6 Months Exposure time Target Organs : Liver

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### Components:

Ceftolozane:

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

tion, Gastrointestinal discomfort

Tazobactam:

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

ing difficulties if inhaled.

### **SECTION 12: Ecological information**

### 12.1 Toxicity

### **Components:**

Ceftolozane:

Toxicity to algae/aquatic EC50 (Anabaena flos-aquae): 0.0401 mg/l

Exposure time: 72 h plants

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- :

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icity)

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- :

icity)

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 tox-

icity)

NOEC: 10.6 mg/l Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

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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:

: Result: Not readily biodegradable. Biodegradability

Method: OECD Test Guideline 301D

Tazobactam:

Result: Not readily biodegradable. Biodegradability

Method: OECD Test Guideline 301D

12.3 Bioaccumulative potential

Components:

Ceftolozane:

Partition coefficient: n-

octanol/water

log Pow: -0.21

Tazobactam:

Partition coefficient: n-

octanol/water

: log Pow: -0.63

12.4 Mobility in soil

**Components:** 

Ceftolozane:

Distribution among environ-

log Koc: 3.3

mental compartments

Method: OECD Test Guideline 106

Tazobactam:

Distribution among environ-

mental 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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Ceftolozane / Tazobactam Injection Formula- tion**

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### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

### **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)

**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)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Ceftolozane / Tazobactam Injection Formula- tion**

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### 14.3 Transport hazard class(es)

Class Subsidiary risks

DN : 9

 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)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Ceftolozane / Tazobactam Injection Formula- tion**

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**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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer
UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Ceftolozane / Tazobactam Injection Formulation**

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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**

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 GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

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 - Interna-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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tional 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 Agen-

cy, http://echa.europa.eu/

### 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

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.

GB / EN