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

1.3 Details of the supplier of the safety data sheet
  Company : MSD
             Innishannon
             County Cork - Ireland
  Telephone : 353 214329300
  Telefax : 908-735-1496
  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
  Specific target organ toxicity - repeated exposure, Category 2
  Short-term (acute) aquatic hazard, Category 1
  Long-term (chronic) aquatic hazard, Category 1

2.2 Label elements
  Labelling (REGULATION (EC) No 1272/2008)
  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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftolozane</td>
<td>689293-68-3</td>
<td></td>
<td>Resp. Sens. 1B; H334 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>Tazobactam</td>
<td>89786-04-9</td>
<td></td>
<td>Resp. Sens. 1B; H334 STOT RE 2; H373</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formulation

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014 Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

Aquatic Acute 1; H400
Aquatic Chronic 2; H411
M-Factor (Acute aquatic toxicity): 1

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause allergy or asthma symptoms or breathing difficulties 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, 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.
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 firefighting:
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 (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 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.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:
Discharge into the environment must be avoided. 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.
6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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. 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 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftolozane</td>
<td>689293-68-3</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Further information:</strong> DSEN, RSEN</td>
<td></td>
</tr>
<tr>
<td>Tazobactam</td>
<td>89786-04-9</td>
<td>TWA</td>
<td>250 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Further information:</strong> RSEN</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>443.28 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>443.28 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>
### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Fresh water</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>500 mg/l</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>4.86 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>L-Arginine hydrochloride</td>
<td>Fresh water</td>
<td>2.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.22 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>22 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>12000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>4.437 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.444 mg/kg</td>
</tr>
</tbody>
</table>

### 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 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

  - Equipment should conform to I.S. EN 143

**Filter type**: Particulates type (P)
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formulation

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-000014 Date of last issue: 13.09.2019
Date of first issue: 06.01.2016

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information
SAFETY DATA SHEET
generated by Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formula-
tion

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014 Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

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, 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

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
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
Test Type: Chromosome aberration test in vitro
Result: negative
Ceftolozane / Tazobactam Injection Formula-
tion

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
  Species: Rat
  Application Route: Intravenous injection
### Ceftolozane / Tazobactam Injection Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3</td>
<td>23.03.2020</td>
<td>441468-00014</td>
<td>13.09.2019</td>
<td>06.01.2016</td>
</tr>
</tbody>
</table>

#### Fertility: NOAEL: 1,000 mg/kg body weight

Result: No effects on fertility

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Mouse</th>
<th>Application Route: Intravenous injection</th>
<th>Developmental Toxicity: NOAEL: 2,000 mg/kg body weight</th>
<th>Remarks: No significant adverse effects were reported</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Application Route: Intravenous injection</th>
<th>Developmental Toxicity: NOAEL: 1,000 mg/kg body weight</th>
<th>Remarks: No significant adverse effects were reported</th>
</tr>
</thead>
</table>

### Tazobactam:

#### Effects on fertility

<table>
<thead>
<tr>
<th>Test Type: Fertility/early embryonic development</th>
<th>Species: Rat</th>
<th>Application Route: Intraperitoneal injection</th>
<th>Fertility: NOAEL: 640 mg/kg body weight</th>
</tr>
</thead>
</table>

#### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Application Route: Intraperitoneal injection</th>
<th>Developmental Toxicity: NOAEL: 40 mg/kg body weight</th>
<th>Result: Effects on early embryonic development</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Application Route: Intravenous injection</th>
<th>Developmental Toxicity: NOAEL: 3,000 mg/kg body weight</th>
<th>Result: No effects on foetal development</th>
</tr>
</thead>
</table>

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### Components:

#### Ceftolozane:

<table>
<thead>
<tr>
<th>Target Organs Assessment</th>
<th>Kidney</th>
<th>May cause damage to organs through prolonged or repeated exposure.</th>
</tr>
</thead>
</table>

#### Tazobactam:

<table>
<thead>
<tr>
<th>Target Organs Assessment</th>
<th>Liver</th>
<th>May cause damage to organs through prolonged or repeated exposure.</th>
</tr>
</thead>
</table>
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 irritation, Gastrointestinal discomfort

**Tazobactam:**
- **Inhalation:** Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formulation

Version 4.3  Revision Date: 23.03.2020  SDS Number: 441468-00014  Date of last issue: 13.09.2019
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 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

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-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 environmental compartments: log Koc: 3.3
Method: OECD Test Guideline 106
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formulation

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014 Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

**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:** 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.
- **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.

### 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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formula-
tion

Version 4.3
Revision Date: 23.03.2020
SDS Number: 441468-00014
Date of last issue: 13.09.2019
Date of first issue: 06.01.2016

(Ceftolozane, Tazobactam)

14.3 Transport hazard class(es)

| 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 (ENVIRONM.)

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

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9 (ENVIRONM.)

**IMDG**
- Packing group: III
- Labels: 9 (ENVIRONM.)
- 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 (passen-
ger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous,

14.5 Environmental hazards

| ADN | Environmentally hazardous: yes |
| ADR | |

---

(Ceftolozane, Tazobactam)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formula-
tion

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014 Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

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
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).: Not applicable
REACH - List of substances subject to authorisation (Annex XIV) Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined

DSL: not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formula-
tion

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014 Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

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 difficulties 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 - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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 Substanc-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ceftolozane / Tazobactam Injection Formulation

Version 4.3 Revision Date: 23.03.2020 SDS Number: 441468-00014
Date of last issue: 13.09.2019 Date of first issue: 06.01.2016

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
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.

IE / EN