1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ceftolozane / Tazobactam Injection Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | powder |
| Colour     | No data available |
| Odour      | No data available |

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
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

GHS label elements
Hazard pictograms : 
Signal word : Danger
SAFETY DATA SHEET
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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.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftolozane</td>
<td>689293-68-3</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Tazobactam</td>
<td>89786-04-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

4. 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.

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.

Most important symptoms and effects, both acute and delayed
: 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.

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).

Notes to physician
: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

| 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. |

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
</tbody>
</table>

| 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 |
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<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
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<td>2019/09/13</td>
<td>2016/01/06</td>
</tr>
</tbody>
</table>

Evacuate area.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

**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 cannot be contained.

**Methods and materials for containment and 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.

7. HANDLING AND STORAGE

**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.
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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.

**Avoidance of contact**  :  Oxidizing agents

**Storage**
**Conditions for safe storage**  :  Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

**Materials to avoid**  :  Do not store with the following product types: Strong oxidizing agents

**Packaging material**  :  Unsuitable material: None known.

---

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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>Wipe limit</td>
<td>100 µg/100 cm²</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>
</tbody>
</table>

**Further information:** DSEN, RSEN

**Further information:** RSEN

**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**

**Respiratory protection**  :  If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**  :  Particulates type

**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.

**Skin and body protection**  :  Work uniform or laboratory coat.

**Hand protection**
**Material**  :  Chemical-resistant gloves

**Hygiene measures**  :  If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-
ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</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</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></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>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></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-</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Ceftolozane:
Acute toxicity (other routes of administration): LD50 (Rat): > 2,000 mg/kg
Application Route: Intravenous
LD50 (Mouse): > 1,500 mg/kg
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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

Sodium chloride:
Acute oral toxicity: LD50 (Rat): 3,550 mg/kg
Acute inhalation toxicity:
LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Sodium chloride:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Sodium chloride:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.
**Respiratory sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

**Ceftolozane:**
- **Test Type:** Maximisation Test
- **Species:** Guinea pig
- **Result:** Sensitiser

**Tazobactam:**
- **Result:** Sensitiser

**Sodium chloride:**
- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Result:** negative

**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
Ceftolozane / Tazobactam Injection Formulation

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

Sodium chloride:

Genotoxicity in vitro

: Test Type: In vitro mammalian cell gene mutation test
  Result: positive

: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

: Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
  Result: positive

: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: positive

: Test Type: Chromosome aberration test in vitro
  Result: positive

: Test Type: Chromosome aberration test in vitro
  Result: negative

Genotoxicity in vivo

: Test Type: In vivo micronucleus test
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Intraperitoneal injection
  Result: positive
**Germ cell mutagenicity**
Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Sodium chloride:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

**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
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</tr>
</tbody>
</table>

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

Species: Dog
- NOAEL: 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
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Exposure time: 6 Months
Target Organs: Liver

Sodium chloride:
Species: Rat
LOAEL: 2,533 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

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 fish (Chronic toxicity):
 NOEC (Pimephales promelas (fathead minnow)): 10 mg/l
 Exposure time: 32 d
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
 NOEC (Daphnia magna (Water flea)): 9.6 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

Toxicity to microorganisms: EC50: > 1,000 mg/l
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</tr>
</tbody>
</table>

### 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 fish (Chronic toxicity)**
  - NOEC (Pimephales promelas (fathead minnow)): 10.6 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC (Daphnia magna (Water flea)): 9.6 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **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

### Sodium chloride:
- **Toxicity to fish**
  - LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
  - Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): 4,136 mg/l
  - Exposure time: 48 h

- **Toxicity to algae/aquatic plants**
  - EC50: > 2,000 mg/l
  - Exposure time: 96 h

- **Toxicity to fish (Chronic toxicity)**
  - NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
  - Exposure time: 33 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia pulex (Water flea)): 314 mg/l
- Exposure time: 21 d

Toxicity to microorganisms:

- EC10: > 1,000 mg/l

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

Bioaccumulative potential

**Components:**

**Ceftolozane:**
- Partition coefficient: n-octanol/water: log Pow: -0.21

**Tazobactam:**
- Partition coefficient: n-octanol/water: log Pow: -0.63

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

Other adverse effects

No data available

**13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

- **Waste from residues**: Dispose of in accordance with local regulations.
- **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.
14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ceftolozane, Tazobactam)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Ceftolozane, Tazobactam)
Class : 9
Packing group : III
Labels : Miscellaneous,
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ceftolozane, Tazobactam)
Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ceftolozane, Tazobactam)
Class : 9
Packing group : III
Labels : 9
Ceftolozane / Tazobactam Injection Formulation

Version: 3.11
Revision Date: 2020/03/23
SDS Number: 438898-00014
Date of last issue: 2019/09/13
Date of first issue: 2016/01/06

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ceftolozane / Tazobactam Injection Formula-
tion

Version 3.11 Revision Date: 2020/03/23 SDS Number: 438898-00014 Date of last issue: 2019/09/13 Date of first issue: 2016/01/06

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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

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