SAFETY DATA SHEET

Ceftolozane / Tazobactam Injection Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ceftolozane / Tazobactam Injection Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Respiratory sensitisation: Category 1
Specific target organ toxicity - repeated exposure: Category 2 (Kidney, Liver)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
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 (Kidney, Liver) 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.

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 advice 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.
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Date of first issue: 06.01.2016

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

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

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.

Hazardous combustion products: Carbon oxides
Metal oxides
Chlorine compounds
Nitrogen oxides (NOx)

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.

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

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.

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

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)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
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tion

<table>
<thead>
<tr>
<th></th>
<th>exposure)</th>
<th>concentration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftolozane</td>
<td>689293-68-3</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</td>
</tr>
<tr>
<td>Tazobactam</td>
<td>89786-04-9</td>
<td>TWA</td>
<td>250 µg/m³ (OEB 2)</td>
</tr>
</tbody>
</table>

Further information: DSEN, RSEN

Wipe limit: 100 µg/100 cm² | Internal

Further information: RSEN

5. 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.

6. 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

Hand protection

Material: Chemical-resistant gloves

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.

Skin and body protection

Work uniform or laboratory coat.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
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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

Information on likely routes of exposure:
- 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
  Application Route: Intravenous
  LD50 (Dog): > 2,000 mg/kg
  Application Route: Intravenous

Tazobactam:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  LD50 (Mouse): > 5,000 mg/kg

- Acute toxicity (other routes of administration): LD50 (Rat): > 5,000 mg/kg
  Application Route: Intravenous
  LD50 (Mouse): > 5,000 mg/kg
  Application Route: Intravenous
  LD50 (Dog): > 5,000 mg/kg
  Application Route: Intravenous

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
- **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
SAFETY DATA SHEET

Ceftolozane / Tazobactam Injection Formula-

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

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Remarks: No significant adverse effects were reported

Tazobactam:
Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intraperitoneal injection
Fertility: NOAEL: 640 mg/kg body weight

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

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Components:

Ceftolozane:
Target Organs: Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.

Tazobactam:
Target Organs: Liver
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Ceftolozane:**
- **Species:** Rat
- **NOAEL:** 1,000 mg/kg
- **Application Route:** Intravenous
- **Exposure time:** 28 days
- **Target Organs:** Kidney
- **Symptoms:** No adverse effects

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

**Tazobactam:**
- **Species:** Rat
- **NOAEL:** 40 mg/kg
- **Application Route:** Intraperitoneal
- **Exposure time:** 6 Months
- **Target Organs:** Liver

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

**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 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

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 microorganisms: EC10: > 1,000 mg/l

Toxicity to fish (Chronic toxicity): NOEC: 252 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 314 mg/l
Exposure time: 21 d
Species: Daphnia pulex (Water flea)

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

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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 IMO instruments
Not applicable for product as supplied.

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

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

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

16. OTHER INFORMATION

Further information

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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.