SAFETY DATA SHEET

Ceftiofur Formulation

Version 2.0  Revision Date: 22.12.2020  SDS Number: 7674017-00002  Date of last issue: 15.12.2020
Date of first issue: 15.12.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ceftiofur Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Respiratory sensitization: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2

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 through prolonged or repeated exposure if swallowed.

Precautionary Statements:

Prevention:
P260 Do not breathe mist or vapors.
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 or doctor/physician.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
None known.
SAFETY DATA SHEET

Ceftiofur Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftiofur</td>
<td>103980-44-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

SECTION 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: Wash with water and soap as a precaution. Get medical attention if symptoms occur.

In case of eye contact: Flush eyes with water as a precaution. 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 if swallowed. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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 fire-fighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

#### Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- 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
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

#### Technical measures
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

#### Local/Total ventilation
- Use only with adequate ventilation.

#### Advice on safe handling
- Do not breathe mist or vapors.
- 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 sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.
- 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 decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
- Keep in properly labeled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Ceftiofur</td>
<td>103980-44-5</td>
<td>TWA</td>
<td>100 mcg/m³ ((\text{OEB 2}))</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

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:
- Combined particulates and organic vapor 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:
- suspension

Color:
- white to off-white, cream
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Density: 0.850 - 1.050 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition 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.
Molecular weight: No data available
Particle size: Not applicable
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute oral toxicity estimate:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 10 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

Exposure time: 4 h
Test atmosphere: dust/mist

Method:

OECD Test Guideline 403

Components:

Ceftiofur:
Acute oral toxicity: LD50 (Rat): > 7,760 mg/kg

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation
Not classified based on available information.

Components:

Benzyl alcohol:
Species: Rabbit
SAFETY DATA SHEET
Ceftiofur Formulation

Method : OECD Test Guideline 404
Result : No skin irritation

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

**Components:**

**Benzyl alcohol:**
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

**Ceftiofur:**
Routes of exposure : Inhalation
Result : Sensitizer
Remarks : May cause sensitization by inhalation.

**Benzyl alcohol:**
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Ceftiofur:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

Test Type: unscheduled DNA synthesis assay
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: Intraperitoneal
Result: negative
**SAFETY DATA SHEET**

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**Benzyl alcohol:**
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative
- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
  Species: Mouse  
  Application Route: Intraperitoneal injection  
  Result: negative

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

**Components:**

**Benzyl alcohol:**
- **Species**: Mouse  
- **Application Route**: Ingestion  
- **Exposure time**: 103 weeks  
- **Method**: OECD Test Guideline 451  
- **Result**: negative

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**Ceftiofur:**
- **Effects on fertility**: Test Type: Fertility  
  Application Route: Oral  
  Fertility: NOAEL: 1,000 mg/kg body weight  
  Result: No adverse effects.
- **Effects on fetal development**: Test Type: Development  
  Application Route: Oral  
  Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
  Result: No adverse effects.

**Benzyl alcohol:**
- **Effects on fertility**: Test Type: Fertility/early embryonic development  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative  
  Remarks: Based on data from similar materials
- **Effects on fetal development**: Test Type: Embryo-fetal development  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative
SAFETY DATA SHEET

Ceftiofur Formulation

**STOT-single exposure**
Not classified based on available information.

**STOT-repeated exposure**
May cause damage to organs through prolonged or repeated exposure if swallowed.

**Components:**

**Ceftiofur:**
- **Routes of exposure:** Oral
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Ceftiofur:**
- **Species:** Rat
- **NOAEL:** 30 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Target Organs:** Gastrointestinal tract
- **Symptoms:** Gastrointestinal disturbance
- **Remarks:** May cause damage to organs.

- **Species:** Dog
- **NOAEL:** 30 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Target Organs:** Blood, Central nervous system
- **Remarks:** May cause damage to organs.

**Benzyl alcohol:**
- **Species:** Rat
- **NOAEL:** 1.072 mg/l
- **Application Route:** inhalation (dust/mist/fume)
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 412

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Ceftiofur:**
- **General Information:** Repeated contact may cause allergic reactions in very susceptible persons.
- **Inhalation:** Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, colitis
SAFETY DATA SHEET

Ceftiofur Formulation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 51 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Persistence and degradability

Components:

Benzyl alcohol:
- Biodegradability: Result: Readily biodegradable.
  Biodegradation: 92 - 96 %
  Exposure time: 14 d

Bioaccumulative potential

Components:

Benzyl alcohol:
- Partition coefficient: n-octanol/water: log Pow: 1.05

Mobility in soil
No data available

Other adverse effects
No data available
SAFETY DATA SHEET

Ceftiofur Formulation

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

DSL: not determined
AICS: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 22.12.2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8