SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cefuroxime Formulation

SECTION 1. IDENTIFICATION

Product name: Cefuroxime Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
         Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification according to the Hazardous Products Regulations
Respiratory sensitization: Category 1
Specific target organ toxicity - repeated exposure: 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.

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 doctor.
Disposal:
P501 Dispose of contents and container to an approved waste
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Cefuroxime Formulation

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Revision Date: 09/30/2023
SDS Number: 10844573-00004
Date of last issue: 04/04/2023
Date of first issue: 09/06/2022

disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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</thead>
<tbody>
<tr>
<td>Cefuroxime</td>
<td>No data available</td>
<td>55268-75-2</td>
<td>8.33</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:
In case of contact, immediately flush skin with soap and plenty of water. 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. 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:
None known.
Specific hazards during fire fighting:
- Exposure to combustion products may be a hazard to health.
- Carbon oxides
- Nitrogen oxides (NOx)
- Sulfur 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.
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cefuroxime Formulation

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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Take care to prevent spills, waste and minimize release to the environment.

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
  - Gases

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>
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</thead>
<tbody>
<tr>
<td>Cefuroxime</td>
<td>55268-75-2</td>
<td>TWA</td>
<td>100 µg/m³ (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: 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
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
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<td>Color</td>
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<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
<td></td>
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<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
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</tbody>
</table>
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.

Components:

Cefuroxime:
Acute oral toxicity: LD50 (Rat): > 10,000 mg/kg
LD50 (Mouse): > 10,000 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): > 4,000 mg/kg
Application Route: Intravenous
LD50 (Mouse): > 10,000 mg/kg
Application Route: Intravenous
LD50 (Rabbit): > 1,500 mg/kg
Application Route: Intravenous

LD50 (Dog): > 1,500 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 sensitization

Skin sensitization
Not classified based on available information.

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

Components:

Cefuroxime:
Result: Sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosomal aberration
Result: positive

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

Cefuroxime:
Cefuroxime Formulation

Effects on fertility:
Test Type: Fertility
Species: Mouse
Application Route: Oral
Fertility: NOAEL: 6,400 mg/kg body weight
 Symptoms: No adverse effects.

Test Type: Fertility
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
 Symptoms: No adverse effects.

STOT-single exposure
Not classified based on available information.

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

Components:
Cefuroxime:
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Cefuroxime:
Species: Rat
NOAEL: 900 mg/kg
Application Route: Subcutaneous
Exposure time: 3 M
Symptoms: No adverse effects.

Species: Dog
NOAEL: 400 mg/kg
LOAEL: 1,600 mg/kg
Application Route: Oral
Exposure time: 27 W
Target Organs: Blood
Symptoms: Gastrointestinal disturbance

Species: Monkey
NOAEL: 450 mg/kg
Application Route: Subcutaneous
Exposure time: 1 M
Target Organs: Blood, Urinary tract
Remarks: May cause damage to organs.

Aspiration toxicity
Not classified based on available information.
Experience with human exposure

**Components:**

**Cefuroxime:**

**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

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**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cefuroxime:**

**Ecotoxicology Assessment**

**Acute aquatic toxicity:** Toxic effects cannot be excluded

**Chronic aquatic toxicity:** Toxic effects cannot be excluded

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**Cefuroxime:**

**Partition coefficient:** $\text{log Pow: } -0.429$

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

**Waste from residues:** Do not dispose of waste into sewer. 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.

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**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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIC - Australian Inventory of Industrial Chemicals; 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; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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CA / Z8