SAFETY DATA SHEET
Cephapirin Formulation

Version 3.0  Revision Date: 2020/03/23  SDS Number: 420293-00012  Date of last issue: 2019/09/13  Date of first issue: 2016/01/28

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Cephapirin Formulation

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Respiratory sensitisation: Category 1

GHS label elements

Hazard pictograms:

Signal word: Danger

Hazard statements: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:
Prevention:
P261 Avoid breathing mist or vapours.
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.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.
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Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cefapirin</td>
</tr>
<tr>
<td></td>
<td>Alcohols, C16-18, ethoxylated</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: 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. 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.

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: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing method: Use extinguishing measures that are appropriate to local cir-
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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. 
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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling:
Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
Use only with adequate ventilation.

Advice on safe handling:
Avoid inhalation of vapour or mist. 
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. 
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
Oxidizing agents
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.

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

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Cefapirin</td>
<td>21593-23-7</td>
<td>TWA</td>
<td>0.4 mg/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: Combined particulates and organic vapour 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 face shield 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.
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</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>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</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: Can react with strong oxidizing agents.
Conditions to avoid: None known.
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.

Components:

Cefapirin:
Acute oral toxicity: LD50 (Mouse): 26,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): > 7,600 mg/kg
Application Route: Intraperitoneal
LD50 (Rat): 7,800 mg/kg
Application Route: Intraperitoneal

Alcohols, C16-18, ethoxylated:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Alcohols, C16-18, ethoxylated:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials
Serious eye damage/eye irritation
Not classified based on available information.

Components:

**Alcohols, C16-18, ethoxylated:**

- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405
- **Remarks:** Based on data from similar materials

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:

**Cefapirin:**

- **Assessment:** Probability or evidence of high respiratory sensitisation rate in humans

**Alcohols, C16-18, ethoxylated:**

- **Test Type:** Buehler Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative
- **Remarks:** Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

**Cefapirin:**

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

**Alcohols, C16-18, ethoxylated:**

- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)  Method: OECD Test Guideline 471  Result: negative  Remarks: Based on data from similar materials
  - Test Type: In vitro mammalian cell gene mutation test  Method: OECD Test Guideline 476  Result: negative  Remarks: Based on data from similar materials
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Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Cephapirin:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effects on fertility</strong></td>
<td>Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td>Fertility: LOAEL: &gt; 500 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility</td>
</tr>
<tr>
<td><strong>Effects on foetal development</strong></td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: &gt; 200 mg/kg body weight</td>
</tr>
</tbody>
</table>

Alcohols, C16-18, ethoxylated:

| **Effects on fertility** | Test Type: Two-generation reproduction toxicity study |
| | Species: Rat |
| | Application Route: Skin contact |
| | Result: negative |
| | Remarks: Based on data from similar materials |
| **Effects on foetal development** | Test Type: Two-generation reproduction toxicity study |
| | Species: Rat |
| | Application Route: Skin contact |
| | Result: negative |
| | Remarks: Based on data from similar materials |

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

<table>
<thead>
<tr>
<th>Cephapirin:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>&gt;= 200 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Blood</td>
</tr>
</tbody>
</table>
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| Remarks | : | anemia |
| Species | : | Dog |
| LOAEL | : | 20 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 4 Months |
| Target Organs | : | Gastrointestinal tract |

| Species | : | Dog |
| LOAEL | : | 100 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 10 Months |
| Target Organs | : | Blood, Gastrointestinal tract |
| Remarks | : | anemia |

**Alcohols, C16-18, ethoxylated:**

| Species | : | Rat |
| NOAEL | : | > 100 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 408 |
| Remarks | : | Based on data from similar materials |

Aspiration toxicity
Not classified based on available information.

**Experience with human exposure**

Components:

**Cefapirin:**

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, vaginitis, colitis, anorexia, Rash, anaphylaxis

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Components:

**Alcohols, C16-18, ethoxylated:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

**Persistence and degradability**

Components:

**Alcohols, C16-18, ethoxylated:**
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Biodegradability
Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:
Alcohols, C16-18, ethoxylated:
Bioaccumulation
Species: Fish
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water
: log Pow: > 4

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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
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.

National Regulations
Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
### 16. OTHER INFORMATION

**Further information**

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


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

**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

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**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

- **Bulk transportation**: Not classified as noxious liquid substance
- **Pack transportation**: Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

- **Not applicable**

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

- **Not applicable**

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined
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.

JP / EN