SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Cephapirin Formulation

Version  2.10  Revision Date:  2020/10/10  SDS Number:  420287-00013  Date of last issue:  2020/03/23

1. PRODUCT AND COMPANY IDENTIFICATION

Product name  :  Cephapirin Formulation

Manufacturer or supplier’s details
Company  :  MSD
Address  :  No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China  200331

Telephone  :  +1-908-740-4000
Emergency telephone number  :  86-571-87268110
E-mail address  :  EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance  :  liquid
Colour  :  No data available
Odour  :  No data available

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

GHS Classification
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
Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>&gt;= 1 - &lt; 2.5</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).
Safet y Data Sheet  
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Date of first issue: 2016/01/28

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 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 (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 drying 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 breathing mist or vapours.
- 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

**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>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
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 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: liquid

Colour: No data available

Odour: No data available

Odour 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

Vapour pressure: No data available
Cephapirin Formulation

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

Exposure routes : 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
Cephapirin Formulation

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
Method: OECD Test Guideline 405
Result: No eye irritation
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
Cephapirin Formulation

Germ cell mutagenicity
Not classified based on available information.

Components:

Cephapirin:
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

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:

Cephapirin:
Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intraperitoneal injection
Fertility: LOAEL: > 500 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal injection
Developmental Toxicity: LOAEL: > 200 mg/kg body weight

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
Cephapirin Formulation

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:

Cefapirin:
Species: Rat
LOAEL: >= 200 mg/kg
Application Route: Intraperitoneal
Target Organs: Blood
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:
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

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

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

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

AIIC - 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 Civil Aviation Organization; IBC - International Convention for the Prevention of Pollution from Ships; 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, 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 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

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