SAFETY DATA SHEET

Cephapirin (with Peanut Oil) Formulation

Section 1: Identification

Product name : Cephapirin (with Peanut Oil) Formulation

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +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: Hazard identification

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 POISON CENTER/ doctor.

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

Cephapirin (with Peanut Oil) Formulation

Version 1.4  Revision Date: 27.08.2021  SDS Number: 4037827-00005  Date of last issue: 10.10.2020  Date of first issue: 01.03.2019

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>&gt;= 0.1 &lt;- 10</td>
</tr>
<tr>
<td></td>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>&lt; 10</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. 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
Metal oxides

Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
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 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.

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**: 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.

- **Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working
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.

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

### Section 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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter) 10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter) 3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter) 1 mg/m³ (Aluminium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

#### 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 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</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>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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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
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
LD50 (Rat): 7,800 mg/kg
Application Route: Intraperitoneal

Aluminum tristearate:
Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Remarks: Based on data from similar materials
Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials
Skin corrosion/irritation
Not classified based on available information.

**Components:**

**Aluminum tristearate:**
Species: reconstructed human epidermis (RhE)  
Method: OECD Test Guideline 439  
Remarks: Based on data from similar materials

Result: No skin irritation

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

**Components:**

**Aluminum tristearate:**
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.

**Components:**

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

**Aluminum tristearate:**
Test Type: Local lymph node assay (LLNA)  
Exposure routes: Skin contact  
Species: Mouse  
Method: OECD Test Guideline 429  
Result: negative  
Remarks: Based on data from similar materials

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

**Components:**

**Cefapirin:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
### Aluminum tristearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>OECD Test Guideline 476</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>OECD Test Guideline 471</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>OECD Test Guideline 474</td>
<td></td>
<td></td>
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</tbody>
</table>

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Cefapirin:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Fertility/early embryonic development</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fertility: LOAEL: &gt; 500 mg/kg body weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on foetal development</td>
<td>Embryo-foetal development</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: &gt; 200 mg/kg body weight</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Aluminum tristearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Two-generation reproduction toxicity study</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OECD Test Guideline 416</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
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<td>Effects on foetal development</td>
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<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

**Aluminum tristearate:**
- **Species:** Rat
- **NOAEL:** >= 5,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **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
Section 12: Ecological information

**Ecotoxicity**

**Components:**

Aluminum tristearate:

**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**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**

UN number: Not applicable

Proper shipping name: Not applicable

Class: Not applicable

Subsidiary risk: Not applicable

Packing group: Not applicable

Labels: Not applicable

**IATA-DGR**

UN/ID No.: Not applicable

Proper shipping name: Not applicable

Class: Not applicable

Subsidiary risk: Not applicable

Packing group: Not applicable

Labels: Not applicable

Packing instruction (cargo aircraft): Not applicable
Packing instruction (passenger aircraft): Not applicable

**IMDG-Code**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- EmS Code: Not applicable
- Marine pollutant: Not applicable

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

**National Regulations**

**NZS 5433**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- Hazchem Code: Not applicable

**Special precautions for user**
Not applicable

**Section 15: Regulatory information**

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

**HSNO Approval Number**
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

**HSW Controls**
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**
- AICS: not determined
- DSL: not determined
- IECSC: not determined
Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

All - 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 Observeable 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 and of the Council 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; TECI - Thailand Existing Chemicals Inventory; 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

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.

NZ / EN