## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name** : Cephapirin (with Peanut Oil) Formulation

**Manufacturer or supplier’s details**

- **Company** : MSD
- **Address** : JL Raya Pandaan KM. 48 Pandaan, Jawa Timur - Indonesia
- **Telephone** : 908-740-4000
- **Emergency telephone number** : 1-908-423-6000
- **E-mail address** : EHSDATASTEWARD@msd.com
- **Telefax** : 908-735-1496

**Recommended use of the chemical and restrictions on use**

- **Recommended use** : Veterinary product

## 2. HAZARDS IDENTIFICATION

**GHS Classification**

- **Respiratory sensitisation** : Category 1

**GHS label elements**

- **Hazard pictograms** :

<table>
<thead>
<tr>
<th>Signal word</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danger</td>
<td>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
</tr>
</tbody>
</table>

**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 1.1  Revision Date: 09/13/2019  SDS Number: 4037822-00002  Date of last issue: 2019/03/01  Date of first issue: 2019/03/01

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3.2 %

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>Peanut oil</td>
</tr>
<tr>
<td></td>
<td>Cefapirin</td>
</tr>
<tr>
<td></td>
<td>Aluminum tristearate</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 fire-: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides, Metal 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 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

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.
SAFETY DATA SHEET

Cephapirin (with Peanut Oil) Formulation

Version 1.1  Revision Date: 09/13/2019  SDS Number: 4037822-00002  Date of last issue: 2019/03/01  Date of first issue: 2019/03/01

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 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

8. EXPOSURE CONTROLS/PERSOAL 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>Peanut oil</td>
<td>8002-03-7</td>
<td>NAB (Mist)</td>
<td>10 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>TWA</td>
<td>0.4 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>NAB</td>
<td>10 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: RSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Pneumoconiosis, Lower respiratory tract irritation, Neurotoxicity, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>1 mg/m3 (Aluminium)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m3</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

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Filter type</th>
<th>Hand protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
<td>Combined particulates and organic vapour type</td>
<td></td>
</tr>
</tbody>
</table>
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 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 : suspension

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

Relative vapour density : No data available
SAFETY DATA SHEET

Cephapirin (with Peanut Oil) Formulation

Version 1.1
Revision Date: 09/13/2019
SDS Number: 4037822-00002
Date of last issue: 2019/03/01
Date of first issue: 2019/03/01

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:

Peanut oil:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials
Cephapirin:
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:

Peanut oil:
Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Aluminum tristearate:
Method : OECD Test Guideline 439
Result : No skin irritation
Remarks : Based on data from similar materials

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

Components:

Peanut oil:
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

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.

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Aluminum tristearate:
Genotoxicity in vitro : 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: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 474
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:

Cefapirin:
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

Aluminum tristearate:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
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
## 10. APPLICATION ROUTE

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>4 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
</tbody>
</table>

| 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 |

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Peanut oil:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Danio rerio (zebra fish)): &gt; 10,000 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Aluminum tristearate:

### Ecotoxicology Assessment

<table>
<thead>
<tr>
<th>Acute aquatic toxicity</th>
<th>Toxic effects cannot be excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
</tbody>
</table>

### Persistence and degradability

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health: Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances:
- Hazardous substances approved for use: Not applicable
- Prohibited substances: Not applicable
- Restricted substances: Not applicable
SAFETY DATA SHEET

Cephapirin (with Peanut Oil) Formulation

Version 1.1
Revision Date: 09/13/2019
SDS Number: 4037822-00002
Date of last issue: 2019/03/01
Date of first issue: 2019/03/01

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

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 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 Standardisation; 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 and of the Council concerning the Registration, Evalu-
SAFETY DATA SHEET

Cephapirin (with Peanut Oil) Formulation

Version | Revision Date: | SDS Number: | Date of last issue: 2019/03/01
---|---|---|---
1.1 | 09/13/2019 | 4037822-00002 | Date of first issue: 2019/03/01

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.

ID / EN