SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Cephapirin / Prednisolone Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger

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

Precautionary statements : 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.

Hazardous components which must be listed on the label:
**SAFETY DATA SHEET**

**Cephapirin / Prednisolone Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

Cefapirin

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cefapirin</td>
<td>21593-23-7 244-466-5</td>
<td>Resp. Sens. 1A; H334</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>prednisolone</td>
<td>50-24-8 200-021-7</td>
<td>Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow, Adrenal gland, Liver) Aquatic Chronic 2; H411</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures**

**4.1 Description of 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.

**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).

**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. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks: 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).

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
              Alcohol-resistant foam
              Carbon dioxide (CO2)
              Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
              Metal oxides
              Silicon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
Use personal protective equipment. 
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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 spills cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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 sensitizers. 
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 place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
<tr>
<td></td>
<td></td>
<td>Further information: RSEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment:
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.

Hand protection
Material: Chemical-resistant gloves

Remarks: Consider double gloving.
Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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 (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</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>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>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>Density</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>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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation

Ingestion

Skin contact

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

**prednisolone:**
- Acute oral toxicity: LD50 (Mouse): 1.680 mg/kg
  LD50 (Rat): > 3.857 mg/kg
- Acute inhalation toxicity: Remarks: No data available
- Acute dermal toxicity: Remarks: No data available
- Acute toxicity (other routes of administration): LD50 (Rat): 147 mg/kg
  Application Route: Subcutaneous
  LD50 (Mouse): 767 mg/kg
  Application Route: Intraperitoneal

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**
- **prednisolone:**
  Remarks: No data available

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

**Components:**
- **prednisolone:**
  Remarks: No data available

**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

- **prednisolone:**
  Remarks: No data available
Germ cell mutagenicity
Not classified based on available information.

**Components:**

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

**Prednisolone:**
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Mouse Lymphoma
  - Result: negative
  - Test Type: sister chromatid exchange assay
  - Result: negative
- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Rat
    - Application Route: Oral
    - Result: negative
  - Test Type: sister chromatid exchange assay
    - Species: Humans
    - Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Prednisolone:**
- Species: Rat
- Application Route: Oral
- Exposure time: 18 Months
- Result: negative

**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

Prednisolone:

Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Subcutaneous
- Fertility: NOAEL: 1 mg/kg body weight
- Result: No effects on fertility

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Oral
- Developmental Toxicity: LOAEL: 0,5 mg/kg body weight
- Result: Malformations were observed., Cleft palate

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 30 mg/kg body weight
  - Result: decreased blood formation

- Species: Rat
  - Application Route: Subcutaneous
  - Developmental Toxicity: NOAEL: 25 mg/kg body weight
  - Result: No effects on foetal development

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Prednisolone:
- Target Organs: Bone marrow, Adrenal gland, Liver
- Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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

- **Species**: Dog
- **LOAEL**: 20 mg/kg
- **Application Route**: Oral
- **Exposure time**: 4 Months
- **Target Organs**: Gastrointestinal tract

### prednisolone:

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

### prednisolone:

- **Species**: Rat
- **LOAEL**: 0.6 mg/kg
- **Application Route**: Oral
- **Exposure time**: 63 Days
- **Target Organs**: Bone marrow

- **Species**: Dog
- **LOAEL**: 2.5 mg/kg
- **Application Route**: Oral
- **Exposure time**: 6 Weeks
- **Target Organs**: Adrenal gland

- **Species**: Rabbit
- **LOAEL**: 1 mg/kg
- **Application Route**: Oral
- **Exposure time**: 24 Weeks
- **Target Organs**: Liver

### 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

**prednisolone:**

- **Ingestion**: Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities
SECTION 12: Ecological information

12.1 Toxicity

Components:

prednisolone:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 85 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.23 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

prednisolone:
Partition coefficient: n-octanol/water: log Pow: 1.46

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Version 4.5
Revision Date: 09.04.2021
SDS Number: 764063-00011
Date of last issue: 25.08.2020

Full text of H-Statements

H302 : Harmful if swallowed.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
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.