SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Cephapirin / Prednisolone Formulation

Version 4.3          Revision Date: 23.03.2020
SDS Number: 766831-00009          Date of last issue: 13.09.2019
Date of first issue: 16.06.2016

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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
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
Hazardous components which must be listed on the label:

Cefapirin

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC-No.</td>
<td>Index-No.</td>
<td>Registration number</td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>244-466-5</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>200-021-7</td>
<td></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 and personal protective equipment recommendations.

6.2 Environmental precautions

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.

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 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
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.

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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 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. Equipment should conform to NS EN 14387 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

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
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
Density : No data available
Solubility(ies) : Water solubility : No data available
Partition coefficient: n- : 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
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

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:** 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

**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
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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
Not relevant

12.6 Other adverse effects
No data available

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable


Other regulations: Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is
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 are highlighted in the body of this document by two vertical lines.

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; AICS - Australian Inventory of Chemical Substances; 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

Classification of the mixture: Resp. Sens. 1
Classification procedure: Calculation method

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.

NO / EN