SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cephapirin / Prednisolone Formulation

Manufacturer or supplier's details

Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 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. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitization: Category 1
Reproductive toxicity: Category 2

GHS label elements

Hazard pictograms:

Signal Word: Danger

Hazard Statements:
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361d Suspected of damaging the unborn child.

Precautionary Statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapors.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
</tr>
<tr>
<td>Zeolites</td>
<td>1318-02-1</td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</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: 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.

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.

Most important symptoms and effects, both acute and delayed: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. 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
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Version: 2.3
Revision Date: 23.03.2020
SDS Number: 764058-00009
Date of last issue: 13.09.2019
Date of first issue: 16.06.2016

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Metal oxides
Silicon 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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 inhalation of vapor 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 sensitized 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.
- 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 labeled 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

#### Ingredients 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>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td>Zeolites</td>
<td>1318-02-1</td>
<td>VLE-PPT (Respirable fraction)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>TWA (Respirable particulate matter)</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: RSEN

<table>
<thead>
<tr>
<th>Prednisolone</th>
<th>TWA</th>
<th>Wipe limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-24-8</td>
<td>30 µg/m³ (OEB 3)</td>
<td>300 µg/100 cm²</td>
</tr>
</tbody>
</table>

**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**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**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. 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: liquid

**Color**: No data available

**Odor**: No data available

**Odor Threshold**: No data available

**pH**: No data available

**Melting point/freezing point**: No data available

**Initial boiling point and boiling range**: No data available
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Version 2.3 revision date: 23.03.2020
SDS number: 764058-00009
Date of last issue: 13.09.2019
Date of first issue: 16.06.2016

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
Vapor pressure: No data available
Relative vapor density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
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: No data available

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

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Glyceryl monostearate:
Acute oral toxicity : LD50 (Rat): > 5,000 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

Zeolites:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 3.35 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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 : LD50 (Rat): 147 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

Glyceryl monostearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Zeolites:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Prednisolone:
Remarks: No data available

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

Components:

Glyceryl monostearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Zeolites:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Prednisolone:
Remarks: No data available

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Components:

Glyceryl monostearate:
- Test Type: Buehler Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative
- Remarks: Based on data from similar materials

Zeolites:
- Test Type: Buehler Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Cefapirin:
- Assessment: Probability or evidence of high respiratory sensitization rate in humans

Prednisolone:
- Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Glyceryl monostearate:
- Genotoxicity in vitro:
  - Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - 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
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Remarks: Based on data from similar materials

Zeolites:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative
  - Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: positive
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

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

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:

Zeolites:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 104 weeks
- Result: negative

Species: Rat
- Application Route: inhalation (dust/mist/fume)
- Exposure time: 22 Months
- Result: negative
Prednisolone:
Species: Rat
Application Route: Oral
Exposure time: 18 Months
Result: negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Glyceryl monostearate:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Zeolites:
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
Result: Malformations were observed, Cleft palate

Test Type: Embryo-fetal 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 fetal 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:

Zeolites:
Assessment: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

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

Repeated dose toxicity
Components:

Glyceryl monostearate:
Species: Rat
NOAEL: >= 12,500 mg/kg
Application Route: Ingestion
Exposure time: 84 Days
Remarks: Based on data from similar materials

Zeolites:
Species: Rat
NOAEL: 250 - 300 mg/kg
Application Route: Ingestion
Cephapirin / Prednisolone Formulation

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Monkey</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.001 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Months</td>
</tr>
</tbody>
</table>

**Cefapirin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>&gt;= 200 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
<tr>
<td>Remarks</td>
<td>anemia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
<tr>
<td>Remarks</td>
<td>anemia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Gastrointestinal tract</td>
</tr>
<tr>
<td>Remarks</td>
<td>anemia</td>
</tr>
</tbody>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>63 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Cefapirin:**
<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea, vaginitis, colitis, anorexia, Rash, anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prednisolone:</strong></td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities</td>
</tr>
</tbody>
</table>

### SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Glycerol monostearate:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LL50 (Leuciscus idus (Golden orfe)): $&gt; 100$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EL50 (Daphnia magna (Water flea)): $&gt; 32$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>47 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility. Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)): $&gt; 100$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOELR (Pseudokirchneriella subcapitata (green algae)): $&gt; 1$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): $&gt; 0.22$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility. Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC10 (Pseudomonas putida): $&gt; 1$ mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>18 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zeolites:**

Toxicity to fish
- LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
- EL50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: ISO 6341

Toxicity to algae/aquatic plants
- EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201

  NOELR (Desmodesmus subspicatus (green algae)): > 1 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity)
- NOELR (Pimephales promelas (fathead minnow)): > 1 mg/l
  Exposure time: 30 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- NOELR (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Toxicity to microorganisms
- EC50 (Pseudomonas putida): > 100 mg/l
  Exposure time: 16 h
  Method: DIN 38 412 Part 8

Prednisolone:
- 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 (Ceriodaphnia dubia (water flea)): 0.23 mg/l
  Exposure time: 7 d

Persistence and degradability

Components:

Glyceryl monostearate:
- Biodegradability: Result: Readily biodegradable.
  Remarks: Based on data from similar materials
Bioaccumulative potential

**Components:**

**Glyceryl monostearate:**
Partition coefficient: n-octanol/water
: log Pow: 6.1

**Zeolites:**
Bioaccumulation
: Species: Oysters
    Bioconcentration factor (BCF): 0.34 - 1.44

Partition coefficient: n-octanol/water
: Remarks: No data available

**Prednisolone:**
Partition coefficient: n-octanol/water
: log Pow: 1.46

**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**
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.

**Domestic regulation**

**NOM-002-SCT**
Not regulated as a dangerous good

**Special precautions for user**
Not applicable
SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value

Abbreviations:

- AIICS - 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 Organization for Standardization
- KECI - Korea Existing Chemicals Inventory
- LC50 - Lethal Concentration to 50% of a test population
- LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
- MARPOL - International Convention for the Prevention of Pollution from Ships
- n.o.s. - Not Otherwise Specified
- Nch - Chilean Norm
- NO(A)EC - No Observed (Adverse) Effect Concentration
- NO(A)EL - No Observed (Adverse) Effect Level
- NOELR - No Observable Effect Loading Rate
- NOM - Official Mexican Norm
- NTP - National Toxicology Program
- NZIoC - New Zealand Inventory of Chemicals
- OECD - Organization for Economic Co-operation and Development
- OPPTS - Office of Chemical Safety and Pollution Prevention
- PBT - Persistent, Bioaccumulative and Toxic substance
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- (Q)SAR - (Quantitative) Structure Activity Relationship
- SADT - Self-Accelerating Decomposition Tempera-
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

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ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based on the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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