1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Cephapirin / Prednisolone Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kemagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Respiratory sensitisation : Category 1

GHS label elements
Hazard pictograms : 

Signal word : Danger
Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements : Prevention:
P261 Avoid breathing mist or vapours.
P284 Wear respiratory protection.

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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

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Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-669</td>
</tr>
<tr>
<td></td>
<td>Zeolites</td>
<td>1318-02-1</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td></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: 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.

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.
media
Specific hazards during firefighting
Hazardous combustion products: Exposure to combustion products may be a hazard to health.
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 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

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.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practices.
practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact
Oxidizing agents

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.

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

Packaging material
Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³ (ACGIH)</td>
<td>TWA (Respirable particulate matter)</td>
</tr>
<tr>
<td>Zeolites</td>
<td>1318-02-1</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminium) (ACGIH)</td>
<td>TWA</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>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>

Further information: RSEN

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

<table>
<thead>
<tr>
<th>Personal protective equipment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
<td>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td>Filter type</td>
<td>: Combined particulates and organic vapour type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>: Chemical-resistant gloves</td>
</tr>
<tr>
<td>Remarks</td>
<td>: Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>: 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.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>: 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.</td>
</tr>
</tbody>
</table>

### 9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state               | : liquid |
| Colour                       | : No data available |
| Odour                        | : No data available |
| Odour Threshold              | : No data available |
| Melting point/freezing point | : No data available |
| Boiling point, initial boiling point and boiling range | : No data available |
| Flammability (solid, gas)    | : Not applicable |
| Flammability (liquids)       | : No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
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
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exposure  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 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:**

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

**Zeoites:**
- **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

**Zeoites:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** No eye irritation

**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:**

**Glyceryl monostearate:**
- **Test Type:** Buehler Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
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

- 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
Not classified based on available information.

**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 foetal 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 foetal development**
  - Test Type: Embryo-foetal 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 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
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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:

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
Exposure time: 90 Days

Species: Monkey
LOAEL: 0.001 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 24 Months
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
- **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
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irregularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glyceryl monostearate:

Toxicity to fish
Toxicity to daphnia and other aquatic invertebrates
Toxicity to algae/aquatic plants
Toxicity to fish (Chronic toxicity)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
Toxicity to microorganisms
Zeolites:

Toxicity to fish
Toxicity to daphnia and other aquatic invertebrates

Ecotoxicity Components:

Glyceryl monostearate:

Toxicity to fish: LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 32 mg/l
Exposure time: 47 h
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Toxicity to algae/aquatic plants:
EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Toxicity to fish (Chronic toxicity):
NOELR (Oryzias latipes (Japanese medaka)): > 1 mg/l
Exposure time: 14 d
Method: OECD Test Guideline 204
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): > 0.22 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Toxicity to microorganisms:
EC10 (Pseudomonas putida): > 1 mg/l
Exposure time: 18 h
Remarks: Based on data from similar materials

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
### Cephapirin / Prednisolone Formulation

<table>
<thead>
<tr>
<th>Aquatic Invertebrates</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EL50 (Desmodesmus subspicatus (green algae)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOELR (Desmodesmus subspicatus (green algae)): &gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOELR (Pimephales promelas (fathead minnow)): &gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 30 d</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOELR (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50 (Pseudomonas putida): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 16 h</td>
</tr>
<tr>
<td></td>
<td>Method: DIN 38 412 Part 8</td>
</tr>
</tbody>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 85 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 160 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
</tr>
</tbody>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 85 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</td>
</tr>
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<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
</tr>
</tbody>
</table>
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
  Remarks: No data available

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

**Mobility in soil**
No data available

**Hazardous to the ozone layer**
Not applicable

**Other adverse effects**
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**
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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>
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<tr>
<td>4.0</td>
<td>2020/03/23</td>
<td>764056-00009</td>
<td>2019/09/13</td>
<td>2016/06/16</td>
</tr>
</tbody>
</table>

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.

**National Regulations**

Refer to section 15 for specific national regulation.

## 15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicicy - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not applicable as a dangerous good

Aviation Law
Not applicable as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
 Bulk transportation: Noxious liquid substance (Category Y)
 Pack transportation: Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Cephapirin / Prednisolone Formulation

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Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

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; ErM - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No 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, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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