SECTION 1. IDENTIFICATION

Product name: Cephapirin / Prednisolone Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc.
Address: 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
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 and face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doc-
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Peanut oil</td>
<td>8002-03-7</td>
</tr>
<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>

Actual concentration is withheld as a trade secret.

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. 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: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child.

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).

<table>
<thead>
<tr>
<th>Notes to physician</th>
<th>: Treat symptomatically and supportively.</th>
</tr>
</thead>
</table>

### SECTION 5. FIRE-FIGHTING MEASURES

| Suitable extinguishing media | : Water spray  
|                             | Alcohol-resistant foam  
|                             | Carbon dioxide (CO2)  
| Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during firefighting | : 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 (see section 7) and personal protective equipment recommendations (see section 8). |
| 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 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 breathing mist or vapors.
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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly 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
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut oil</td>
<td>8002-03-7</td>
<td>TWA (mist-total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (mist-respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zeolites</td>
<td>1318-02-1</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</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></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</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>
</tbody>
</table>

Further information: RSEN
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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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.

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
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:

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

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

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 (Rabbit): > 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
Cephapirin:
Acute oral toxicity : LD50 (Mouse): 26,000 mg/kg
Acute toxicity (other routes of administration) : LD50 (Mouse): > 7,600 mg/kg
Application Route: Intraperitoneal
LD50 (Rat): 7,800 mg/kg
Application Route: Intraperitoneal

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:

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

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:**

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

**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.

**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:

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

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
Genotoxicity in vivo:

- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Oral
  - 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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity:
Suspected of damaging the unborn child.

Components:

Glyceryl monostearate:
- Effects on fertility: Test Type: Combined repeated dose toxicity study with the
### Effects on fetal development

**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:** 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

**Cephapirin:**

- **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
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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
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
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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, Diarrhea, 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

Ecotoxicity

**Components:**

**Peanut oil:**
- **Toxicity to fish:** LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**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.

**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
**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>
<tbody>
<tr>
<td>6.3</td>
<td>04/04/2023</td>
<td>764062-00014</td>
<td>10/01/2022</td>
<td>06/16/2016</td>
</tr>
</tbody>
</table>

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

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:**

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 (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:
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Cephapirin / Prednisolone Formulation

Version: 6.3
Revision Date: 04/04/2023
SDS Number: 764062-00014
Date of last issue: 10/01/2022
Date of first issue: 06/16/2016

Partition coefficient: n-octanol/water

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
Remarks: No data available

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.
Do not dispose of waste into sewer.
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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Respiratory or skin sensitization
- Reproductive toxicity

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Peanut oil 8002-03-7
- Glyceryl monostearate 123-94-4
- Zeolites 1318-02-1
- Cefapirin 21593-23-7

California Permissible Exposure Limits for Chemical Contaminants
- Peanut oil 8002-03-7
- Glyceryl monostearate 123-94-4

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

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Version 6.3  Revision Date: 04/04/2023  SDS Number: 764062-00014  Date of last issue: 10/01/2022  Date of first issue: 06/16/2016

NFPA 704:

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<th>Instability</th>
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HMIS® IV:

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<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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<tbody>
<tr>
<td>*</td>
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HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The * represents a chronic hazard, while the ,/ represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; BC - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable
Cephapirin / Prednisolone Formulation

Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals 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


Revision Date: 04/04/2023

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.

US / Z8