SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cephapirin / Prednisolone Formulation

SECTION 1. IDENTIFICATION

Product name: Cephapirin / Prednisolone Formulation
Other means of identification: No data available

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 Hazardous Products Regulations
Respiratory sensitization: Sub-category 1A
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.
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 attention.
P342 + P311 IF experiencing respiratory symptoms: Call a doc-
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cephapirin / Prednisolone Formulation

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
</table>
| Peanut oil          | Chemical name: Peanut oil  
|                     | Common Name/Synonym: No data available  
|                     | CAS-No.: 8002-03-7  
|                     | Concentration (% w/w): >= 80 - <= 100 *  
| Glyceryl monostearate | Chemical name: Octadecanoic acid, 2,3-dihydroxypropyl ester  
|                     | Common Name/Synonym: No data available  
|                     | CAS-No.: 123-94-4  
|                     | Concentration (% w/w): >= 5 - < 10 *  
| Zeolites            | Chemical name: Zeolites  
|                     | Common Name/Synonym: No data available  
|                     | CAS-No.: 1318-02-1  
|                     | Concentration (% w/w): >= 5 - < 10 *  
| Cefapirin           | Chemical name: Cefapirin  
|                     | Common Name/Synonym: No data available  
|                     | CAS-No.: 21593-23-7  
|                     | Concentration (% w/w): >= 1 - < 5 *  
| Prednisolone        | Chemical name: Prednisolone  
|                     | Common Name/Synonym: No data available  
|                     | CAS-No.: 50-24-8  
|                     | Concentration (% w/w): >= 0.1 - < 1 *  

* Actual concentration or concentration range 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:**
- 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**

- **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 (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>Ingredients with workplace control parameters</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>TWA EV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA EV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
</tbody>
</table>
### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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**: Combined particulates and organic vapor 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zeolites 1318-02-1</td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cefapirin 21593-23-7</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>prednisolone 50-24-8</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Hygiene measures:

- If exposure to the 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

according to the Hazardous Products Regulations

**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>3.4</td>
<td>09/30/2023</td>
<td>764047-00017</td>
<td>04/04/2023</td>
<td>06/16/2016</td>
</tr>
</tbody>
</table>

- **Partition coefficient: n-octanol/water**: No data available
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**: 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:**

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SAFETY DATA SHEET  
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Cephapirin / Prednisolone Formulation

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</tr>
</tbody>
</table>

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:

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
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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
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
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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

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: \(\text{LC}_{50} (\text{Danio rerio (zebra fish)}): > 10,000 \text{mg/l} \)
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: \(\text{EC}_{50} (\text{Daphnia magna (Water flea)}): > 100 \text{mg/l} \)
Exposure time: 48 h
Remarks: Based on data from similar materials

Glyceryl monostearate:
Toxicity to fish: \(\text{LL}_{50} (\text{Leuciscus idus (Golden orfe)}): > 100 \text{mg/l} \)
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: \(\text{EL}_{50} (\text{Daphnia magna (Water flea)}): > 32 \text{mg/l} \)
Exposure time: 47 h
Remarks: No toxicity at the limit of solubility.
Based on data from similar materials

Toxicity to algae/aquatic plants: \(\text{EL}_{50} (\text{Pseudokirchneriella subcapitata (green algae)}): > 100 \text{mg/l} \)
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
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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

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:

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
Cephapirin / Prednisolone Formulation

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: Do not dispose of waste into sewer.
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**

TDG
Not regulated as a dangerous good

**Special precautions for user**
Not applicable

### SECTION 15. REGULATORY INFORMATION

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)
- **CA AB OEL**: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
- **CA BC OEL**: Canada. British Columbia OEL
- **CA QC OEL**: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CA AB OEL / TWA**: 8-hour Occupational exposure limit
- **CA BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWAEV**: Time-weighted average exposure value

Abbreviations:

- AICL - Australian Inventory of Industrial Chemicals
- 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 con-
centration; 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; 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; WHMIS - Workplace Hazardous Materials Information System


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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.