SAFETY DATA SHEET according to the OSHA Hazard Communication Standard

Cephapirin / Prednisolone Formulation

SECTION 1. IDENTIFICATION

Product name : Cephapirin / Prednisolone Formulation
Other means of identification : Mastiplan (A011329)

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.
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P308 + P313 IF exposed or concerned: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.

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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut oil</td>
<td>8002-03-7</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Zeolites</td>
<td>1318-02-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 1</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: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging the unborn child.
Excessive exposure may aggravate preexisting asthma and
SECTION 5. FIRE-FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Protection of first-aiders</th>
<th>Notes to physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td>Treat symptomatically and supportively.</td>
</tr>
</tbody>
</table>

- **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

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Environmental precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
<td>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.</td>
</tr>
</tbody>
</table>

- **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

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Exposure Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephapirin</td>
<td>21593-23-7</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>

Further information: RSEN

<table>
<thead>
<tr>
<th>Substance</th>
<th>Wipe limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>100 µg/100 cm²</td>
<td>Internal</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:
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid, oily</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>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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:
Conditions to avoid: None known.
Compatible materials:
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 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Zeolites:
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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

Prednisolone:
Acute oral toxicity: LD50 (Mouse): 1,680 mg/kg
LD50 (Rat): > 3,857 mg/kg

Acute dermal toxicity: Remarks: No data available

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:
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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
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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

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: 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

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Genotoxicity in vitro: 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
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Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

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

Genotoxicity in vitro:
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

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 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
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<td>06/16/2016</td>
</tr>
</tbody>
</table>

**Application Route:** Subcutaneous
**Fertility:** NOAEL: 1 mg/kg body weight
**Result:** No effects on fertility.

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

- **Test Type:** Embryo-fetal development
  **Species:** Rat
  **Application Route:** Oral
  **Developmental Toxicity:** LOAEL: 30 mg/kg body weight
  **Result:** decreased blood formation

  **Species:** Rat
  **Application Route:** Subcutaneous
  **Developmental Toxicity:** NOAEL: 25 mg/kg body weight
  **Result:** No effects on fetal development.

**Reproductive toxicity - Assessment**
- Some evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**
Not classified based on available information.

**STOT-repeated exposure**
Not classified based on available information.

**Components:**

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

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

**Repeated dose toxicity**

**Components:**

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

### 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
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

#### 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

### 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:
Partition coefficient: n-octanol/water
log Pow: 6.1

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

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
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

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**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
Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
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</thead>
<tbody>
<tr>
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<td>1</td>
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Special hazard

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
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<tr>
<td>*</td>
<td>0</td>
<td>1</td>
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</table>

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

AIIIC - 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; 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; 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
Cephapirin / Prednisolone Formulation

of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-
stance; 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 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: 12/04/2023

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