1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephapirin / Prednisolone Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Respiratory sensitisation : Category 1

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements :
Prevention:
P261 Avoid breathing mist or vapours.
P284 Wear respiratory protection.
Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P316 If experiencing respiratory symptoms: Get emer-
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Version 4.4
Revision Date: 25.08.2020
SDS Number: 766828-00010
Date of last issue: 23.03.2020
Date of first issue: 16.06.2016

Emergency medical help immediately.

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

Other hazards which do not result in classification
None known.

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>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;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES
SAFETY DATA SHEET
Cephapirin / Prednisolone Formulation

Version: 4.4
Revision Date: 25.08.2020
SDS Number: 766828-00010
Date of last issue: 23.03.2020
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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 firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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 vapours.
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 sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>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 (Aluminium)</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>prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
- Minimize open handling.
Personal protective equipment

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

Filter type: Combined particulates and organic vapour type

Hand protection: Chemical-resistant gloves

Material

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: No data available

Odour: No data available

Odour 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
Vapour pressure : No data available
Relative vapour density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition 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

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure : Inhalation
                              Skin contact
                              Ingestion
                              Eye contact
**SAFETY DATA SHEET**

Cephapirin / Prednisolone Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
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<td>23.03.2020</td>
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</tr>
</tbody>
</table>

### Acute toxicity

Not classified based on available information.

### Components:

**Glyceryl monostearate:**

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| Acute oral toxicity     | LD50 (Rat): > 5,000 mg/kg | Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zeolites:**

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>Method: OECD Test Guideline 401</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| Acute inhalation toxicity | LC50 (Rat): > 3.35 mg/l | Exposure time: 4 h  
Test atmosphere: dust/mist |

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

**Cefapirin:**

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Mouse): 26,000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| Acute oral toxicity     | LD50 (Mouse): 1,680 mg/kg  
LD50 (Rat): > 3,857 mg/kg |

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>Remarks: No data available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>Remarks: No data available</td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity (other routes of administration):**

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>Calculation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Rat): 7,800 mg/kg</td>
<td>Application Route: Intraperitoneal</td>
<td></td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Not classified based on available information.
Components:

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

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

Prednisolone:
Remarks: No data available

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

Components:

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

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

Prednisolone:
Remarks: No data available

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Glyceryl monostearate:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Zeolites:
SAFETY DATA SHEET

Cephapirin / Prednisolone Formulation

Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

Prednisolone:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Zeolites:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

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

Prednisolone:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Mouse Lymphoma
Result: negative
Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative
Test Type: sister chromatid exchange assay
Species: Humans
Result: negative

Carcinogenicity
Not classified based on available information.

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

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

Prednisolone:
Species : Rat
Application Route : Oral
Exposure time : 18 Months
Result : negative

Reproductive toxicity
Not classified based on available information.
Components:

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

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

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

Cefapirin:
Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Intraperitoneal injection
- Fertility: LOAEL: > 500 mg/kg body weight
- Result: No effects on fertility

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Intraperitoneal injection
- Developmental Toxicity: LOAEL: > 200 mg/kg body weight

Prednisolone:
Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Subcutaneous
- Fertility: NOAEL: 1 mg/kg body weight
- Result: No effects on fertility

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Oral
- Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
- Result: Malformations were observed., Cleft palate
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: decreased blood formation

Species: Rat
Application Route: Subcutaneous

Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No effects on foetal development

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

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

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

**Components:**

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

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

**Repeated dose toxicity**

**Components:**

**Glyceryl monostearate:**
Species: Rat
NOAEL: >= 12.500 mg/kg
Application Route: Ingestion
Exposure time: 84 Days
Remarks: Based on data from similar materials

**Zeolites:**
Species: Rat
NOAEL: 250 - 300 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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

**Cefapirin:**
Species: Rat
LOAEL: >= 200 mg/kg
Application Route: Intraperitoneal
Target Organs: Blood
Remarks: anemia

Species: Dog
LOAEL: 20 mg/kg
Application Route: Oral
Exposure time: 4 Months
Target Organs: Gastrointestinal tract
Remarks: anemia

prednisolone:
Species: Rat
LOAEL: 0.6 mg/kg
Application Route: Oral
Exposure time: 63 Days
Target Organs: Bone marrow

Species: Dog
LOAEL: 2.5 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Target Organs: Adrenal gland

Species: Rabbit
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Target Organs: Liver

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Cefapirin:
Ingestion: Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, vaginitis, colitis, anorexia, Rash, anaphylaxis

prednisolone:
Ingestion: Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glyceryl monostearate:

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

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

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: > 0.22 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility
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 microorganisms: EC50 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOELR: > 1 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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: 0.23 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

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

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to IMO instruments**
Not applicable for product as supplied.

### 15. REGULATORY INFORMATION

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

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

AICS : not determined
16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average

AIIIC - 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; ICS0 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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