1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cephapirin / Prednisolone Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
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. HAZARDSDS IDENTIFICATION

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 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
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Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Peanut oil</td>
</tr>
<tr>
<td></td>
<td>Glyceryl monostearate</td>
</tr>
<tr>
<td></td>
<td>Zeolites</td>
</tr>
<tr>
<td></td>
<td>Cefapirin</td>
</tr>
<tr>
<td></td>
<td>Prednisolone</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

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

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

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

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

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

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Avoid inhalation of vapour or mist. 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 as-
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>Peanut oil</td>
<td>8002-03-7</td>
<td>NAB (Mist)</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanut oil</td>
<td></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>NAB</td>
<td>1 mg/m³ (Aluminium)</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Pneumoconiosis, Lower respiratory tract irritation, Neurotoxicity, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefapirin</td>
<td>21593-23-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: RSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory protection</strong></td>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td><strong>Filter type</strong></td>
<td>Combined particulates and organic vapour type</td>
</tr>
<tr>
<td><strong>Hand protection</strong></td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Wear safety glasses with side shields or goggles. When 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. Consider double gloving.</td>
</tr>
<tr>
<td><strong>Eye protection</strong></td>
<td>Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td><strong>Skin and body protection</strong></td>
<td>Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
<tr>
<td><strong>Hygiene measures</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

### 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>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour 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>
</tbody>
</table>
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Date of first issue: 2016/06/16

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
# SAFETY DATA SHEET

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

### 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:
- **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 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:
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:
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)
Zeolites:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: positive
- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Ingestion
  Method: OECD Test Guideline 474
  Result: negative

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

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

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Oral
  Result: negative
- Test Type: sister chromatid exchange assay
  Species: Humans
  Result: negative
Carcinogenicity
Not classified based on available information.

Components:

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

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

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

Reproductive toxicity
Not classified based on available information.

Components:

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

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

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

Cefapirin:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
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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
- **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
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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:

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 fish (Chronic toxicity):

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

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

Toxicity to microorganisms:

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

Zeolites:

Toxicity to fish:

LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

EL50 (Daphnia magna (Water flea)): > 100 mg/l
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
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</tr>
</tbody>
</table>

**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
- 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.
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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with % response; ELx - Loading rate associated with % response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with % growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals and Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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