1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Prednisolone / Neomycin / Tetracycline Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: powder
Colour: No data available
Odour: No data available

May cause an allergic skin reaction. May damage the unborn child. May cause harm to breast-fed children. Very toxic to aquatic life with long lasting effects.

GHS Classification
Skin sensitisation: Category 1
Reproductive toxicity: Category 1A

Effects on or via lactation
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy/ while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P270 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause an allergic skin reaction. May damage the unborn child. May cause harm to breast-fed children.

Environmental hazards
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.8 Revision Date: 2021/08/27 SDS Number: 407508-00015 Date of last issue: 2020/08/25 Date of first issue: 2016/01/07

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>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 0.25</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. 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: If in eyes, rinse well with water. 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 an allergic skin reaction. May damage the unborn child. May cause harm to breast-fed children. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Chlorine compounds, Metal oxides, Sulphur 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.

Specific 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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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

Handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust
ventilation.

Advice on safe handling:
- Avoid contact during pregnancy and while nursing.
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
- Oxidizing agents

Storage:
- Conditions for safe storage:
  - Keep in properly labelled containers.
  - Store locked up.
  - 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

Packaging material:
- Unsuitable material: None known.

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>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>PC-TWA (Fumes)</td>
<td>2 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-STEL (Fumes)</td>
<td>4 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fumes)</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>TWA</td>
<td>1 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN, OTO</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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>
</tbody>
</table>
**SAFETY DATA SHEET**

according to GB/T 16483 and GB/T 17519

**Prednisolone / Neomycin / Tetracycline Formulation**

<table>
<thead>
<tr>
<th>Tetracycline hydrochloride</th>
<th>64-75-5</th>
<th>TWA</th>
<th>0.5 mg/m3 (OEB 2)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<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></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
</tbody>
</table>

**Engineering measures**: 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**: Particulates type

**Eye/face 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.

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**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. Contaminated work clothing should not be allowed out of the workplace. 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**: powder
Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</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>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility (ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Paraffin waxes and Hydrocarbon waxes:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 420

Acute dermal toxicity: LD50 (Rabbit): > 3,600 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Neomycin, sulfate (salt):
Acute oral toxicity: LD50 (Mouse): 2,880 mg/kg
LD50 (Rat): 2,750 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 633 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 116 mg/kg
Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.8</td>
<td>2021/08/27</td>
<td>407508-00015</td>
<td>2020/08/25</td>
<td>2016/01/07</td>
</tr>
</tbody>
</table>

**Application Route:** Intraperitoneal

LD50 (Mouse): 27.6 mg/kg

Application Route: Intravenous

LD50 (Mouse): 275 mg/kg

Application Route: Subcutaneous

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 423</td>
<td></td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

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

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 6,443 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Mouse): 2,759 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity (other routes of administration)</th>
<th>LD50 (Rat): 128 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td>LD50 (Mouse): 157 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
</tbody>
</table>

**prednisolone:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Mouse): 1,680 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Rat): &gt; 3,857 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute inhalation toxicity</th>
<th>Remarks: No data available</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>Remarks: No data available</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity (other routes of administration)</th>
<th>LD50 (Rat): 147 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Subcutaneous</td>
<td></td>
</tr>
<tr>
<td>LD50 (Mouse): 767 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
<td></td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

Paraffin waxes and Hydrocarbon waxes:
**Prednisolone / Neomycin / Tetracycline Formulation**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin, sulfate (salt):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Method</td>
<td>Result</td>
<td>Remarks</td>
</tr>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
</tr>
</tbody>
</table>

**prednisolone:**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Neomycin, sulfate (salt):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
</tr>
</tbody>
</table>

**prednisolone:**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
</tr>
</tbody>
</table>
Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Neomycin, sulfate (salt):
Exposure routes: Dermal
Species: Humans
Result: positive

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Tetracycline hydrochloride:
Remarks: No data available

Prednisolone:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Neomycin, sulfate (salt):
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Test system: Chinese hamster ovary cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: positive
- Test Type: In vitro micronucleus test
  Result: negative

Genotoxicity in vivo:
- Test Type: Cytogenetic assay
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Intravenous injection
  Result: negative

Magnesium stearate:
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials
- 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)
  Result: negative
  Remarks: Based on data from similar materials

Tetracycline hydrochloride:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Cytogenetic assay
  Test system: Chinese hamster ovary cells
  Result: negative
- Test Type: Sister chromatid exchange assay
  Result: negative
- Test Type: Mouse Lymphoma
  Result: negative
Prednisolone / Neomycin / Tetracycline Formulation

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

Carcinogenicity
Not classified based on available information.

Components:
Paraffin waxes and Hydrocarbon waxes:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Neomycin, sulfate (salt):
Species: Rat
Exposure time: 2 Years
Result: negative

Tetracycline hydrochloride:
Species: Rat
Application Route: Oral
Exposure time: 103 W
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 103 W
Result: negative
Prednisolone / Neomycin / Tetracycline Formulation

Version 5.8  Revision Date: 2021/08/27  SDS Number: 407508-00015  Date of last issue: 2020/08/25  Date of first issue: 2016/01/07

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

Reproductive toxicity
May damage the unborn child.
May cause harm to breast-fed children.

Components:
Paraffin waxes and Hydrocarbon waxes:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 25 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development:
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight
Result: No adverse effects, No teratogenic effects

Test Type: Development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 6 mg/kg body weight
Result: positive

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

Magnesium stearate:
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:

Species: Rat
Application Route: Ingestion

Result: negative
Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Effects on fertility:

Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:

Test Type: Development
Result: Embryo-foetal toxicity, Specific developmental abnormalities, Skeletal malformations

Reproductive toxicity - Assessment:

Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

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:**

**Paraffin waxes and Hydrocarbon waxes:**
- Exposure routes: Ingestion
- Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Neomycin, sulfate (salt):**
- Target Organs: Kidney, inner ear
- Assessment: May cause damage to organs through prolonged or repeated exposure.
- Remarks: Based on human experience.

**Tetracycline hydrochloride:**
- Target Organs: Gastrointestinal tract, Nervous system, Skin, Teeth
- Assessment: May cause damage to organs through prolonged or repeated exposure.

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

**Repeated dose toxicity**

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 90 Days
- Method: OECD Test Guideline 408

**Neomycin, sulfate (salt):**
- Species: Mouse
- LOAEL: 30 mg/kg
- Application Route: Subcutaneous
- Exposure time: 14 d
- Target Organs: Kidney
Prednisolone / Neomycin / Tetracycline Formulation

Species: Guinea pig
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Intramuscular
Exposure time: 30 - 60 Weeks
Target Organs: ear

Species: Guinea pig
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Guinea pig
NOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 34 d

Species: Dog
NOAEL: 24 mg/kg
Application Route: Intramuscular
Exposure time: 30 d
Target Organs: Kidney

Species: Rat
NOAEL: 25 mg/kg
Application Route: oral (feed)
Exposure time: 84 Weeks
Target Organs: ear
Symptoms: hearing loss
Remarks: mortality observed

Species: Dog
NOAEL: 20 mg/kg
Application Route: Subcutaneous
Exposure time: 90 d
Target Organs: Kidney

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Tetracycline hydrochloride:
Species: Rat
NOAEL: 625 mg/kg
LOAEL: 1,250 mg/kg
Application Route: oral (feed)
Prednisolone / Neomycin / Tetracycline Formulation

Exposure time: 13 W
Target Organs: Liver
Symptoms: Reduced body weight

Species: Mouse
NOAEL: 3,750 mg/kg
LOAEL: 7,500 mg/kg
Application Route: oral (feed)
Exposure time: 13 W
Symptoms: Reduced body weight

Prednisolone:
Species: Rat
NOAEL: 0.6 mg/kg
LOAEL: 7,500 mg/kg
Application Route: Oral
Exposure time: 63 Days
Target Organs: Bone marrow

Species: Dog
NOAEL: 2.5 mg/kg
LOAEL: 7,500 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Target Organs: Adrenal gland

Species: Rabbit
NOAEL: 1 mg/kg
LOAEL: 7,500 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Target Organs: Liver

Aspiration toxicity
Not classified based on available information.

Components:
Tetracycline hydrochloride:
Not applicable

Experience with human exposure

Components:
Neomycin, sulfate (salt):
Skin contact: Symptoms: Sensitisation
Remarks: May irritate skin.
Eye contact: Remarks: May cause eye irritation.
Ingestion: Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

Tetracycline hydrochloride:
Ingestion: Target Organs: Teeth
Symptoms: Gastrointestinal disturbance, Nausea, Vomiting,
Diarrhoea, Liver effects, skin rash, central nervous system effects
Remarks: May cause sensitisation of susceptible persons.
May cause photosensitisation.
Based on Human Evidence

Prednisolone:
Ingestion:

- Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Paraffin waxes and Hydrocarbon waxes:**

- **Toxicity to fish:**
  - LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 210
  - Remarks: Based on data from similar materials

- **Toxicity to algae/aquatic plants:**
  - NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
  - NOEC (Daphnia magna (Water flea)): 10 mg/l
  - Exposure time: 21 d
  - Remarks: Based on data from similar materials

**Neomycin, sulfate (salt):**

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 72 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

c. LC50 (Americamysis): 39 mg/l
  - Exposure time: 96 h

- **Toxicity to algae/aquatic plants:**
  - EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l
  - Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1,000
M-Factor (Chronic aquatic toxicity): 10

Test Type: Respiration inhibition
Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Magnesium stearate:
Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
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
### Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.8</td>
<td>2021/08/27</td>
<td>407508-00015</td>
<td>2020/08/25</td>
<td>2016/01/07</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC10 (Pseudomonas putida): &gt; 100 mg/l</th>
<th>Exposure time: 16 h</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
</table>

Remarks: Based on data from similar materials

**Tetracycline hydrochloride:**

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l</td>
<td>Exposure time: 7 d</td>
<td></td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity):**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50: 0.08 mg/l</th>
<th>Exposure time: 3 h</th>
</tr>
</thead>
</table>

Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**M-Factor (Chronic aquatic toxicity):**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</th>
<th>Exposure time: 7 d</th>
</tr>
</thead>
</table>

**Prednisolone:**

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 85 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 160 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</th>
<th>Exposure time: 7 d</th>
</tr>
</thead>
</table>
Persistence and degradability

Components:

Paraffin waxes and Hydrocarbon waxes:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Paraffin waxes and Hydrocarbon waxes:
Partition coefficient: n-octanol/water: log Pow: 5.3 - 6.7

Neomycin, sulfate (salt):
Partition coefficient: n-octanol/water: log Pow: < -2

Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4

Tetracycline hydrochloride:
Partition coefficient: n-octanol/water: log Pow: -1.37
pH: 7

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**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
  (Neomycin, sulfate (salt), Tetracycline hydrochloride)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
  (Neomycin, sulfate (salt), Tetracycline hydrochloride)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
  (Neomycin, sulfate (salt), Tetracycline hydrochloride)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

**GB 6944/12268**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)

Class: 9
Packing group: III
Labels: 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average
CN OEL / PC-STEL : Permissible concentration - short term exposure limit

AIIC - 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
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- 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN