SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
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<th>Revision Date:</th>
<th>SDS Number:</th>
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</thead>
<tbody>
<tr>
<td>3.5</td>
<td>25.08.2020</td>
<td>443935-00014</td>
<td>23.03.2020</td>
</tr>
</tbody>
</table>

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline 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
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:
  - P203 Obtain, read and follow all safety instructions before use.
  - P260 Do not breathe dust.
  - P263 Avoid contact during pregnancy and 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.
- P318 IF exposed or concerned, get medical advice.
- P333 + P317 If skin irritation or rash occurs: Get medical help.
- 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.

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

| Substance / Mixture | Mixture |

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
<td>Concentration (% w/w)</td>
</tr>
<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; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</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 ad-
vice 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.

Special protective equipment: In the event of fire, wear self-contained breathing apparatus.
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for firefighters  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

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.
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

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>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>ACGIH</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>
<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>Wipe limit</td>
<td>0.1 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>TWA</td>
<td>0.5 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: DSEN, OTO

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

Hand protection: Chemical-resistant gloves

Material: 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.
- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>powder</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
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Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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 : 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

Information on likely routes of exposure : Inhalation
                                    Skin contact
                                    Ingestion
                                    Eye contact

Acute toxicity
Not classified based on available information.

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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 Application Route: Intraperitoneal
LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous
LD50 (Mouse): 275 mg/kg Application Route: Subcutaneous

Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials

Tetracycline hydrochloride:
Acute oral toxicity: LD50 (Rat): 6,443 mg/kg
LD50 (Mouse): 2,759 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 128 mg/kg Application Route: Intravenous
LD50 (Mouse): 157 mg/kg Application Route: Intravenous
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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:

Paraffin waxes and Hydrocarbon waxes:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Neomycin, sulfate (salt):
Species : Rabbit
Result : Mild skin irritation

Magnesium stearate:
Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Tetracycline hydrochloride:
Remarks : No data available

Remarks : No data available

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

Components:

Paraffin waxes and Hydrocarbon waxes:
Species : Rabbit
Method : OECD Test Guideline 405
Neomycin, sulfate (salt):
Species: Rabbit  
Result: No eye irritation
Remarks: Based on data from similar materials

Magnesium stearate:
Species: Rabbit  
Result: No eye irritation
Remarks: Based on data from similar materials

Tetracycline hydrochloride:
Remarks: No data available

Prednisolone:
Remarks: No data available

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:
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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
Remarks: Based on data from similar materials

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
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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:
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:

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

- **Effects on foetal development:**  
  **Species:** Rat  
  **Application Route:** Ingestion  
  **Test Type:** Embryo-foetal development  
  **Result:** negative  
  **Remarks:** Based on data from similar materials

### Tetracycline hydrochloride:

- **Effects on fertility:**  
  **Species:** Rat  
  **Application Route:** Oral  
  **Fertility:** NOAEL: 400 mg/kg body weight  
  **Result:** No effects on fertility

- **Effects on foetal 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:**  
  **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
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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:
Exposure routes : Oral
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.
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</tr>
</tbody>
</table>

**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
- **Species:** Guinea pig
  - **LOAEL:** 50 mg/kg
  - **NOAEL:** 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
  - **LOAEL:** 100 mg/kg
  - **Application Route:** Subcutaneous
  - **Exposure time:** 34 d
- **Species:** Dog
  - **LOAEL:** 24 mg/kg
  - **Application Route:** Intramuscular
  - **Exposure time:** 30 d
  - **Target Organs:** Kidney
- **Species:** Rat
  - **LOAEL:** 25 mg/kg
  - **Application Route:** oral (feed)
  - **Exposure time:** 84 Weeks
  - **Target Organs:** ear
  - **Symptoms:** hearing loss
  - **Remarks:** mortality observed
- **Species:** Dog
  - **LOAEL:** 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)
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
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.

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

Remarks: May irritate skin.

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
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: 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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
LC50 (Americamysis): 39 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

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

Toxicity to microorganisms:
EC50 (Natural microorganism): 107.6 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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

M-Factor (Chronic aquatic toxicity):
: 10

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:

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)):

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>NOELR</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas putida</td>
<td>&gt; 100 mg/l</td>
<td>16 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena flos-aquae (cyanobacterium)</td>
<td>6.2 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

NOEC (Anabaena flos-aquae (cyanobacterium)):

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena flos-aquae (cyanobacterium)</td>
<td>2.5 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

EC50 (Pseudokirchneriella subcapitata (green algae)):

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>3.31 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)):

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>0.032 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

EC50 (Microcystis aeruginosa (blue-green algae)):

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcystis aeruginosa (blue-green algae)</td>
<td>0.09 mg/l</td>
<td>7 d</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aquatic toxicity</td>
<td>10</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas putida</td>
<td>0.08 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic aquatic toxicity</td>
<td>1</td>
</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: 0.23 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

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**
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 3.5 Revision Date: 25.08.2020 SDS Number: 443935-00014 Date of last issue: 23.03.2020

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 IMO instruments
Not applicable for product as supplied.

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

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
DSL: not determined
IECSC: 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
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.

IN / EN