SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 3.4 Revision Date: 23.03.2020 SDS Number: 443935-00013 Date of last issue: 13.09.2019 Date of first issue: 07.01.2016

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: [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 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.  
P280 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.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</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; 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 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
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.
- 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**

- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- 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.
- Take care to prevent spills, waste and minimize release to the environment.
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>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>Further information: DSEN</td>
<td></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>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: 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

Material: Chemical-resistant gloves

Remarks: Consider double gloving.
Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions,
mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

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: Not applicable
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.

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
    - 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
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

 Prednisolone:
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
Result: No eye irritation
Neomycin, sulfate (salt):
Species: Rabbit
Result: No eye irritation

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:
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
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
  - **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: Test Type: Embryo-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
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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.

Repeated dose toxicity

Components:

Paraffin waxes and Hydrocarbon waxes:
Species: Rat
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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
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
LOAEL: 100 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 cause sensitisation of susceptible persons.
May cause photosensitisation.
Based on Human Evidence

**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

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
<table>
<thead>
<tr>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| NOELR (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 |

| Toxicity to microorganisms: |
| EC10 (Pseudomonas putida): | > 100 mg/l |
| Exposure time: 16 h |
| Test substance: Water Accommodated Fraction |

| Tetracycline hydrochloride: |
| Toxicty to algae/aquatic plants: |
| EC50 (Anabaena flos-aquae (cyanobacterium)): | 6.2 mg/l |
| Exposure time: 72 h |
| NOEC (Anabaena flos-aquae (cyanobacterium)): | 2.5 mg/l |
| Exposure time: 72 h |
| EC50 (Pseudokirchneriella subcapitata (green algae)): | 3.31 mg/l |
| Exposure time: 72 h |
| NOEC (Pseudokirchneriella subcapitata (green algae)): | 0.032 mg/l |
| Exposure time: 72 h |
| EC50 (Microcystis aeruginosa (blue-green algae)): | 0.09 mg/l |
| Exposure time: 7 d |

| M-Factor (Acute aquatic toxicity): | 10 |

| Toxicity to microorganisms: |
| EC50: | 0.08 mg/l |
| Exposure time: 3 h |
| Test Type: Respiration inhibition |
| Method: OECD Test Guideline 209 |

| M-Factor (Chronic aquatic toxicity): | 1 |

| Prednisolone: |
| Toxicty 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
octanol/water  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**

<table>
<thead>
<tr>
<th>UNRTDG</th>
<th>UN number</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)</th>
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</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>UN 3077</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>IATA-DGR</th>
<th>UN number</th>
<th>Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>UN 3077</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)</td>
</tr>
<tr>
<td>Class</td>
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<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
<td></td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>956</td>
<td></td>
</tr>
<tr>
<td>Packing instruction (passenger aircraft)</td>
<td>956</td>
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<tr>
<td>Environmentally hazardous</td>
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</tbody>
</table>

**IMDG-Code**

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<tr>
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<td>9</td>
<td></td>
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<tr>
<td>Subsidiary risk</td>
<td>ENVIRONM.</td>
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</tbody>
</table>
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 3.4  Revision Date: 23.03.2020  SDS Number: 443935-00013  Date of last issue: 13.09.2019

Packing group: III
Labels: 9 (ENVIRONM.)
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

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 x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Cheme-
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.