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: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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.
P280 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

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

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; 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
5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| 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. |

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Sulphur oxides</td>
</tr>
</tbody>
</table>

| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |

| Special protective equipment for firefighters | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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.
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

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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

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

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
### SAFETY DATA SHEET

**Prednisolone / Neomycin / Tetracycline Formulation**

**Version**: 3.6  
**Revision Date**: 27.08.2021  
**SDS Number**: 443935-00015  
**Date of last issue**: 25.08.2020  
**Date of first issue**: 07.01.2016

- **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.
- **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 / Neomycin / Tetracycline Formulation**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>Rabbit</td>
<td></td>
<td>Mild skin irritation</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rabbit</td>
<td></td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td></td>
<td></td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

**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.

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

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>Rabbit</td>
<td></td>
<td>Mild skin irritation</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rabbit</td>
<td></td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td></td>
<td></td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td></td>
<td></td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

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

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

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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
<table>
<thead>
<tr>
<th>Test Type: Development</th>
<th>Species: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Subcutaneous</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 6 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

**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
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
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:
- 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

### 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 202
  - 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
### SAFETY DATA SHEET

**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>3.6</td>
<td>27.08.2021</td>
<td>443935-00015</td>
<td>25.08.2020</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

**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>
<tr>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
Exposure time: 72 h

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

No toxicity at the limit of solubility

<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>
<tr>
<td>EC10 (Pseudomonas putida): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 16 h</td>
</tr>
</tbody>
</table>

Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
Exposure time: 16 h

**Tetracycline hydrochloride:**

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
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</thead>
</table>

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):**

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
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</thead>
</table>

10

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

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

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

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

1

**prednisolone:**

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

EC50 (Daphnia magna (Water flea)): > 85 mg/l
Exposure time: 48 h

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

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  

**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
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 3.6  Revision Date: 27.08.2021  SDS Number: 443935-00015  Date of last issue: 25.08.2020
Date of first issue: 07.01.2016

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 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
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.