SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Skin sensitization : 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 in accordance with ABNT NBR 14725 Standard
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:

**Preparation:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P263 Avoid contact during pregnancy/while nursing.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
- P391 Collect spillage.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td></td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>Acute toxicity (Oral), Skin sensitization, Sub-category 1B, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Kidney, inner ear), Category 2, Short-term (acute) aquatic hazard, Category 1, Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>Reproductive toxicity, Effects on or via lactation, Specific target organ toxicity - repeated exposure (Oral) (Gastrointestinal tract, Nervous system, Skin, Teeth), Category 2</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

**SECTION 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).
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Prednisolone / Neomycin / Tetracycline Formulation

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Date of first issue: 07.01.2016

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting:
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
Sulfur oxides

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

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

SECTION 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
SECTION 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.

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.

Conditions for safe storage: Keep in properly labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Ingredients 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</td>
<td>8002-74-2</td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### Hydrocarbon waxes
- **(Fumes)**
  - **Neomycin, sulfate (salt)**: 1405-10-3, TWA 1 mg/m$^3$ (OEB 1), Internal
  - Further information: DSEN
  - Wipe limit: 0.1 mg/100 cm$^2$, Internal

### Magnesium stearate
- **TWA (Inhalable particulate matter)**: 557-04-0, 10 mg/m$^3$, ACGIH
- **TWA (Respirable particulate matter)**, 3 mg/m$^3$, ACGIH

### Tetracycline hydrochloride
- **TWA**: 64-75-5, 0.5 mg/m$^3$ (OEB 2), Internal

### Prednisolone
- **TWA**: 50-24-8, 30 µg/m$^3$ (OEB 3), Internal
  - Wipe limit: 300 µg/100 cm$^2$, Internal

**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.
**SAFETY DATA SHEET**

**Prednisolone / Neomycin / Tetracycline Formulation**

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

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SECTION 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.

SECTION 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
### Prednisolone / Neomycin / Tetracycline Formulation

**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
Result: No eye irritation
Method: OECD Test Guideline 405

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 sensitization
Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.
SAFETY DATA SHEET
Prednisolone / Neomycin / Tetracycline Formulation

Components:
Paraffin waxes and Hydrocarbon waxes:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Neomycin, sulfate (salt):
- Routes of exposure: Dermal
- Species: Humans
- Result: positive

Magnesium stearate:
- Test Type: Maximization Test
- Routes of exposure: 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 fetal 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 fetal development:** Test Type: Embryo-fetal development  
  Species: Rat  
  Application Route: Oral  
  Embryo-fetal 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 fetal development:** Test Type: Embryo-fetal development  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative
Remarks: Based on data from similar materials

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Species</th>
<th>Route</th>
<th>NOAEL (mg/kg body weight)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>400</td>
<td>No effects on fertility.</td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>0.5</td>
<td>Malformations were observed, Cleft palate</td>
</tr>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td>Mouse</td>
<td>Oral</td>
<td>0.5</td>
<td>Malformations were observed, Cleft palate</td>
</tr>
</tbody>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Species</th>
<th>Route</th>
<th>NOAEL (mg/kg body weight)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>1</td>
<td>No effects on fertility.</td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>30</td>
<td>decreased blood formation</td>
</tr>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>25</td>
<td>No effects on fetal development.</td>
</tr>
</tbody>
</table>

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.
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<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>
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<tr>
<td>5.0</td>
<td>23.03.2020</td>
<td>407504-00013</td>
<td>13.09.2019</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

#### Components:

**Paraffin waxes and Hydrocarbon waxes:**
- Routes of exposure: 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:**
- Routes of exposure: 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
### Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
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<tbody>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>34 d</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
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</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>24 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
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</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>84 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>ear</td>
</tr>
<tr>
<td>Symptoms</td>
<td>hearing loss</td>
</tr>
<tr>
<td>Remarks</td>
<td>mortality observed</td>
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<table>
<thead>
<tr>
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<th>Dog</th>
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<tbody>
<tr>
<td>LOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
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</table>

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
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<table>
<thead>
<tr>
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<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>625 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.250 mg/kg</td>
</tr>
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<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 W</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced body weight</td>
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<tr>
<th>Species</th>
<th>Mouse</th>
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<tbody>
<tr>
<td>NOAEL</td>
<td>3.750 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>7.500 mg/kg</td>
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<td>Application Route</td>
<td>oral (feed)</td>
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<tr>
<td>Exposure time</td>
<td>13 W</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced body weight</td>
</tr>
<tr>
<td>Prednisolone:</td>
<td></td>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.6 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Oral</td>
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<td>Exposure time</td>
<td>63 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow</td>
</tr>
</tbody>
</table>

| 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: Sensitization. Remarks: May irritate skin.
  - Eye contact: Remarks: May cause eye irritation.
  - Ingestion: Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss, Loss of balance

- Tetracycline hydrochloride:

- Prednisolone:
  - Ingestion: Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities
### 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 (Daphnia magna (Water flea)): 10 mg/l
    - Exposure time: 21 d
    - Remarks: Based on data from similar materials

- **Neomycin, sulfate (salt):**
  - Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 72 mg/l
    - Exposure time: 48 h
    - Method: OECD Test Guideline 202
  - LC50 (Americamysis): 39 mg/l
    - Exposure time: 96 h
  - Toxicity to algae/aquatic plants: EC50 (Anabaena flos-aquae (cyanobacterium)): 0,00075 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
  - NOEC (Anabaena flos-aquae (cyanobacterium)): 0,0003 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 0,0099 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0,0022 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
### SAFETY DATA SHEET

**Prednisolone / Neomycin / Tetracycline Formulation**

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<thead>
<tr>
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<td>5.0</td>
<td>23.03.2020</td>
<td>407504-00013</td>
<td>13.09.2019</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

#### M-Factor (Acute aquatic toxicity)

- **Factor:** 1.000

#### M-Factor (Chronic aquatic toxicity)

- **Factor:** 10

#### 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

#### Magnesium stearate:

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

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

- **Toxicity to algae/aquatic plants**
  - **EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
    - Exposure time: 72 h
    - Test substance: Water Accommodated Fraction
    - Method: OECD Test Guideline 201
    - Remarks: Based on data from similar materials
      - No toxicity at the limit of solubility.
      - **NOELR** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
        - Exposure time: 72 h
        - Test substance: Water Accommodated Fraction
        - Method: OECD Test Guideline 201
        - 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
    - Remarks: Based on data from similar materials

#### Tetracycline hydrochloride:

- **Toxicity to algae/aquatic plants**
  - **EC50** (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l
    - Exposure time: 72 h
**SAFETY DATA SHEET**

**Prednisolone / Neomycin / Tetracycline Formulation**

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- **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

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

**Toxicity to microorganisms**:

- **EC50**: 0,08 mg/l  
  Exposure time: 3 h  
  Test Type: Respiration inhibition  
  Method: OECD Test Guideline 209

**Prednisolone**:

- **Toxicity to daphnia and other aquatic invertebrates**:
  - **EC50** (Daphnia magna (Water flea)): > 85 mg/l  
    Exposure time: 48 h

- **Toxicity to algae/aquatic plants**:
  - **NOEC** (Pseudokirchneriella subcapitata (green algae)): 160 mg/l  
    Exposure time: 72 h
  - **EC50** (Pseudokirchneriella subcapitata (green algae)): > 160 mg/l  
    Exposure time: 72 h

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**:
  - **NOEC** (Ceriodaphnia dubia (water flea)): 0,23 mg/l  
    Exposure time: 7 d

**Persistence and degradability**

**Components**:

**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

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG  
UN number: UN 3077  
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

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
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
EmS Code : F-A, S-F
Marine pollutant : yes

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

Domestic regulation

ANTT
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
Hazard Identification Number : 90

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.
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.0  Revision Date: 23.03.2020  SDS Number: 407504-00013  Date of last issue: 13.09.2019  Date of first issue: 07.01.2016

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:

- AICS : not determined
- DSL : not determined
- IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information


Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA : 8-hour, time-weighted average

Abbreviations:

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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median
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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

BR / Z8