SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.5  
Revision Date: 25.08.2020  
SDS Number: 407516-00013  
Date of last issue: 23.03.2020  
Date of first issue: 07.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Prednisolone / Neomycin / Tetracycline Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

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

Effects on or via lactation
Specific target organ toxicity - repeated exposure: Category 2 (Kidney, inner ear)
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)

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.
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read
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SECTION 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;= 1 - &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; 5</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

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.
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.
May cause damage to organs through prolonged or repeated exposure.
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.

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:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.

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

If sufficient ventilation is unavailable, use with local exhaust ventilation.

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.

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 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/PERSONAL 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 Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>VLE-PPT (Fumes)</td>
<td>2 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: DSEN, OTO</td>
<td></td>
<td></td>
<td></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>Magnesium stearate</td>
<td>557-04-0</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></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>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>

**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**.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: powder
- **Color**: No data available
- **Odor**: No data available
- **Odor 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
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Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor 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
Autoignition 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

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
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<thead>
<tr>
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<tr>
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<td>23.03.2020</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

**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
administration)  
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.

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
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**Components:**

### Paraffin waxes and Hydrocarbon waxes:
- **Genotoxicity in vitro**: Test Type: Chromosome aberration test in vitro  
  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  
  Species: Mouse  
  Cell type: Bone marrow  
  Application Route: Intravenous injection  
  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.

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<table>
<thead>
<tr>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

---

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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.

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:
- 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 fetal development:
  - Test Type: Development
  - Result: Embryo-fetal 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 fetal development:
- Test Type: Embryo-fetal development
  - Species: Mouse
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
  - Result: Malformations were observed, Cleft palate

- Test Type: Embryo-fetal 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 fetal 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
May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

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
  - Remarks: No significant adverse effects were reported
- Species: Guinea pig
  - NOAEL: 10 mg/kg
  - Application Route: Oral
  - Exposure time: 90 d
- Species: Dog
  - LOAEL: 100 mg/kg
  - Application Route: Subcutaneous
  - Exposure time: 34 d
- Species: Rat
  - LOAEL: 25 mg/kg
  - Application Route: oral (feed)
  - Exposure time: 84 Weeks
  - Target Organs: ear
  - Symptoms: hearing loss
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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: Sensitization
Remarks: May irritate skin.

Eye contact: Remarks: May cause eye irritation.

Ingestion: Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss, Loss of balance
Remarks: May cause sensitization of susceptible persons.
May cause photosensitization.
Based on Human Evidence

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

**Prednisolone:**
Ingestion: Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

**SECTION 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 (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

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

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:

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

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

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:
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Date of first issue: 07.01.2016

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, N.O.S.
(Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class: 9
Packing group: III
Labels: 9

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

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

**Domestic regulation**

**NOM-002-SCT**
- **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

**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.

### SECTION 15. REGULATORY INFORMATION

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

- **Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills**: Not applicable

**The ingredients of this product are reported in the following inventories:**
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **NOM-010-STPS-2014**: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **NOM-010-STPS-2014 / VLE-PPT**: Time weighted average limit value

**AIIC** - Australian Inventory of Industrial Chemicals; **ANTT** - National Agency for Transport by Land of Brazil; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with
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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 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


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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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