SAFETY DATA SHEET
Prednisolone / Neomycin / Tetracycline Formulation

Version 5.4  Revision Date: 23.03.2020  SDS Number: 407516-00012  Date of last issue: 13.09.2019
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
and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</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.
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 and personal protective equipment recommendations.

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.

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.

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.

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,
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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.

SECTON 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></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>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>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or
exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type
Hand protection

Material

Remarks

Eye protection

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
Color
Odor
Odor Threshold
pH
Melting point/freezing point
Initial boiling point and boiling range
Flash point
Evaporation rate
Flammability (solid, gas)
Flammability (liquids)
Upper explosion limit / Upper flammability limit
Lower explosion limit / Lower flammability limit
Vapor pressure
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

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
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Prednisolone:
Acute oral toxicity : LD50 (Mouse): 1,680 mg/kg
LD50 (Rat): > 3,857 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available
Acute toxicity (other routes of administration) : LD50 (Rat): 147 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 767 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation
Not classified based on available information.

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

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

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

Tetracycline hydrochloride:
Remarks : No data available

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
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
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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

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

Species: Guinea pig
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Intramuscular
Exposure time: 30 - 60 Weeks
Target Organs: Kidney

Species: Guinea pig
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Guinea pig
LOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 34 d

Species: Dog
LOAEL: 24 mg/kg
Application Route: Intramuscular
Exposure time: 30 d
Target Organs: Kidney

Species: Rat
LOAEL: 25 mg/kg
Application Route: oral (feed)
Exposure time: 84 Weeks
Target Organs: ear
Symptoms: hearing loss
Remarks: mortality observed

Species: Dog
LOAEL: 20 mg/kg
Application Route: Subcutaneous
Exposure time: 90 d
Target Organs: Kidney

**Magnesium stearate:**
- **Species:** Rat
- **NOAEL:** > 100 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Remarks:** Based on data from similar materials

**Tetracycline hydrochloride:**
- **Species:** Rat
- **NOAEL:** 625 mg/kg
- **LOAEL:** 1,250 mg/kg
- **Application Route:** oral (feed)
- **Exposure time:** 13 W
- **Target Organs:** Liver
- **Symptoms:** Reduced body weight

Species: Mouse
- **NOAEL:** 3,750 mg/kg
- **LOAEL:** 7,500 mg/kg
- **Application Route:** oral (feed)
- **Exposure time:** 13 W
- **Symptoms:** Reduced body weight

**Prednisolone:**
- **Species:** Rat
- **LOAEL:** 0.6 mg/kg
- **Application Route:** Oral
- **Exposure time:** 63 Days
- **Target Organs:** Bone marrow

Species: Dog
- **LOAEL:** 2.5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 6 Weeks
- **Target Organs:** Adrenal gland

Species: Rabbit
- **LOAEL:** 1 mg/kg
- **Application Route:** Oral
- **Exposure time:** 24 Weeks
- **Target Organs:** Liver

Aspiration toxicity
Not classified based on available information.

**Components:**

**Tetracycline hydrochloride:**
Not applicable
Experience with human exposure

**Components:**

**Neomycin, sulfate (salt):**
- **Skin contact:** Symptoms: 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 irritate skin.

**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):**
### Toxocicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna</td>
<td>&gt; 72 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Americamysis</td>
<td>39 mg/l</td>
<td>96 h</td>
<td>US-EPA OPPTS 850.1035</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena flos-aquae</td>
<td>0.00075 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium))</td>
<td>0.0003 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata</td>
<td>0.0099 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>0.0022 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural microorganism</td>
<td>107.6 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC10</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

#### Toxicity to fish

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuciscus idus</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>DIN 38412</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials.

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EL50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
</table>

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

#### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EL50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td></td>
</tr>
</tbody>
</table>

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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:
NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l
aquatic invertebrates (Chronic toxicity)

**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, 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

NOM-002-SCT
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.4  Revision Date: 23.03.2020  SDS Number: 407516-00012  Date of last issue: 13.09.2019

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

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
# 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>5.4</td>
<td>23.03.2020</td>
<td>407516-00012</td>
<td>13.09.2019</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

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

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 23.03.2020

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.

MX / Z8