SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version    Revision Date:    SDS Number:    Date of last issue:
5.0        2021/08/27        407514-00014    2020/08/25

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Prednisolone / Neomycin / Tetracycline Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Effects on or via lactation
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms : ![Pictogram]
Signal word : Danger
Hazard statements : H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification:
Important symptoms and outlines of the emergency assumed:

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>&gt;= 80 - &lt; 90</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction. May damage the unborn child. May cause harm to breast-fed children. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Chlorine compounds
Metal oxides
Sulphur oxides

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

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

**Environmental precautions**
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

**Handling**

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

**Local/Total ventilation**
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Advice on safe handling**
- Avoid contact during pregnancy and while nursing.
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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

Storage
Conditions for safe storage: Keep in properly labelled 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
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>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>Wipe limit</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>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>
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Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

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

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

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

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit: No data available

Upper explosion limit / Upper: No data available
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7. Flammability Limit

Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Decomposition temperature: No data available
pH: No data available
Evaporation rate: Not applicable
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: Not applicable
Density and / or relative density
Relative density: No data available
Density: No data available
Relative vapour density: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

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
No hazardous decomposition products are known.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

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

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

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

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

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

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

**Tetracycline hydrochloride:**
- **Remarks:** No data available

**Prednisolone:**
- **Remarks:** No data available
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**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

**Magnesium stearate:**

- **Species**: Rabbit
- **Result**: No eye irritation
- **Remarks**: Based on data from similar materials

**Neomycin, sulfate (salt):**

- **Species**: Rabbit
- **Result**: No eye irritation

**Tetracycline hydrochloride:**

- **Remarks**: No data available

**Prednisolone:**

- **Remarks**: No data available

**Respiratory or skin sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative

**Magnesium stearate:**

- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative
- **Remarks**: Based on data from similar materials
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Neomycin, sulfate (salt):
- Exposure routes: Dermal
- Species: Humans
- Result: positive

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

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

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
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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

Tetracycline hydrochloride:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Cytogenetic assay
Test system: Chinese hamster ovary cells
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Prednisolone:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: sister chromatid exchange assay
Species: Humans
Result: negative

Carcinogenicity
Not classified based on available information.
Components:

Paraffin waxes and Hydrocarbon waxes:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Neomycin, sulfate (salt):
Species: Rat
Exposure time: 2 Years
Result: negative

Tetracycline hydrochloride:
Species: Rat
Application Route: Oral
Exposure time: 103 W
Result: negative
Species: Mouse
Application Route: Oral
Exposure time: 103 W
Result: negative

Prednisolone:
Species: Rat
Application Route: Oral
Exposure time: 18 Months
Result: negative

Reproductive toxicity
May damage the unborn child.
May cause harm to breast-fed children.

Components:

Paraffin waxes and Hydrocarbon waxes:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:
Effects on fertility:
: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Effects on fertility:
: Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 25 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development:
: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight
Result: No adverse effects, No teratogenic effects

Reproductive toxicity - Assessment:
: Some evidence of adverse effects on development, based on animal experiments.

Tetracycline hydrochloride:

Effects on fertility:
: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
: Test Type: Development
Result: Embryo-foetal toxicity, Specific developmental abnormalities, Skeletal malformations

Reproductive toxicity - Assessment:
: Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

prednisolone:
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</table>

### Effects on fertility

- **Test Type:** Fertility/early embryonic development
- **Species:** Rat
- **Application Route:** Subcutaneous
- **Fertility:** NOAEL: 1 mg/kg body weight
- **Result:** No effects on fertility

### Effects on foetal development

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

- **Test Type:** Embryo-foetal development
- **Species:** Rat
- **Application Route:** Oral
- **Developmental Toxicity:** LOAEL: 30 mg/kg body weight
- **Result:** decreased blood formation

- **Species:** Rat
- **Application Route:** Subcutaneous
- **Developmental Toxicity:** NOAEL: 25 mg/kg body weight
- **Result:** No effects on foetal development

### Reproductive toxicity - Assessment

Some evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### Paraffin waxes and Hydrocarbon waxes:

- **Exposure routes:** Ingestion
- **Assessment:** No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

#### Neomycin, sulfate (salt):

- **Target Organs:** Kidney, inner ear
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.
- **Remarks:** Based on human experience.

#### Tetracycline hydrochloride:

- **Exposure routes:** Oral
- **Target Organs:** Gastrointestinal tract, Nervous system, Skin, Teeth
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.
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**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

**Magnesium stearate:**

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

**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
- **Application Route**: Oral
- **Exposure time**: 90 d
- **Remarks**: No significant adverse effects were reported

- **Species**: Guinea pig
- **NOAEL**: 100 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 34 d

- **Species**: Dog
- **NOAEL**: 24 mg/kg
- **Application Route**: Intramuscular
- **Exposure time**: 30 d
- **Target Organs**: Kidney
<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>Application Route: oral (feed)</th>
<th>Exposure time: 84 Weeks</th>
<th>Target Organs: ear</th>
<th>Symptoms: hearing loss</th>
<th>Remarks: mortality observed</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
<th>Application Route: Subcutaneous</th>
<th>Exposure time: 90 d</th>
<th>Target Organs: Kidney</th>
</tr>
</thead>
</table>

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>Application Route: oral (feed)</th>
<th>Exposure time: 13 W</th>
<th>Target Organs: Liver</th>
<th>Symptoms: Reduced body weight</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
<th>Application Route: oral (feed)</th>
<th>Exposure time: 13 W</th>
<th>Symptoms: Reduced body weight</th>
</tr>
</thead>
</table>

**Prednisolone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>Application Route: Oral</th>
<th>Exposure time: 63 Days</th>
<th>Target Organs: Bone marrow</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
<th>Application Route: Oral</th>
<th>Exposure time: 6 Weeks</th>
<th>Target Organs: Adrenal gland</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
<th>Application Route: Oral</th>
<th>Exposure time: 24 Weeks</th>
<th>Target Organs: Liver</th>
</tr>
</thead>
</table>
Aspiration toxicity
Not classified based on available information.

Components:

Tetracycline hydrochloride:
Not applicable

Experience with human exposure

Components:

Neomycin, sulfate (salt):
- **Skin contact**: Symptoms: Sensitisation
  Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.
- **Ingestion**: Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

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

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin waxes and Hydrocarbon waxes:
- **Toxicity to fish**: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials
| **Toxicity to algae/aquatic plants** | NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials |
| --- | --- |
| **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** | NOEC (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials |

**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 |

**Neomycin, sulfate (salt):**

| **Toxicity to daphnia and other aquatic invertebrates** | EC50 (Daphnia magna (Water flea)): > 72 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
LC50 (Americamysis): 39 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035 |
Toxicity to algae/aquatic plants:

- EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1,000
M-Factor (Chronic aquatic toxicity): 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

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

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

Magnesium stearate:
Biodegradability: Result: Not biodegradable
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

Bioaccumulative potential

Components:

Paraffin waxes and Hydrocarbon waxes:
Partition coefficient: n-octanol/water: log Pow: 5.3 - 6.7

Magnesium stearate:
12. PHYSICAL AND CHEMICAL PROPERTIES

**Partition coefficient:** n-octanol/water

- **Neomycin, sulfate (salt):**
  - log Pow: > 4

- **Tetracycline hydrochloride:**
  - log Pow: -1.37
  - pH: 7

- **Prednisolone:**
  - log Pow: 1.46

**Mobility in soil:**
No data available

**Hazardous to the ozone layer:**
Not applicable

**Other adverse effects:**
No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues:** Dispose of in accordance with local regulations.
- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- **UN number:** UN 3077
- **Proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
  (Neomycin, sulfate (salt), Tetracycline hydrochloride)

  - **Class:** 9
  - **Packing group:** III
  - **Labels:** Miscellaneous

**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
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.0
Revision Date: 2021/08/27
SDS Number: 407514-00014
Date of last issue: 2020/08/25
Date of first issue: 2016/01/07

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.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 5.0  Revision Date: 2021/08/27  SDS Number: 407514-00014  Date of last issue: 2020/08/25  Date of first issue: 2016/01/07

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid paraffin</td>
<td>170</td>
<td>&gt;=80 - &lt;90</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid paraffin</td>
<td>170</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

24 / 26
Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

16. OTHER INFORMATION

Further information

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

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AllIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 Develop-
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<tr>
<td>5.0</td>
<td>2021/08/27</td>
<td>407514-00014</td>
<td>2020/08/25</td>
</tr>
</tbody>
</table>

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.

JP / EN