SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version: 3.4  Revision Date: 23.03.2020  SDS Number: 407521-00013  Date of last issue: 13.09.2019  Date of first issue: 07.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Prednisolone / Neomycin / Tetracycline Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone: +27119239300
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
   Reproductive toxicity, Category 1A: H360D: May damage the unborn child.
   Effects on or via lactation: H362: May cause harm to breast-fed children.
   Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:

   Signal word: Danger
   Hazard statements: H317  May cause an allergic skin reaction.
   H360D  May damage the unborn child.
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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.
P260  Do not breathe dust.
P263  Avoid contact during pregnancy and while nursing.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P391  Collect spillage.

Hazardous components which must be listed on the label:
Neomycin, sulfate (salt)
Tetracycline hydrochloride

2.3 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

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>Skin Sens.1B; H317; Repr.2; H361d STOT RE2; H373 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 3 - &lt; 10</td>
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<tr>
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<td>215-773-1</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 1.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
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<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>Repr.1A; H360D Lact.H362 STOT RE2; H373 Aquatic Acute1; H400 Aquatic Chronic1;</td>
<td>&gt;= 1 - &lt; 2,5</td>
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<tr>
<td></td>
<td>200-593-8</td>
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</tbody>
</table>
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<table>
<thead>
<tr>
<th>Version</th>
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<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

H410
M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 1

Prednisolone  50-24-8  200-021-7  Acute Tox.4; H302 Repr.2; H361d STOT RE1; H372 Aquatic Chronic2; H411

>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.
4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages...
6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the
7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>TWA OEL-RL (Fumes)</td>
<td>2 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL (Fumes)</td>
<td>6 mg/m³</td>
<td>ZA OEL</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></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>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>

8.2 Exposure controls

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
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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

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

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour density: Not applicable

Relative density: No data available
9.2 Other information

Density : No data available
Solubility(ies)
  Water solubility : No data available
  Partition coefficient: n-octanol/water : Not applicable
  Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**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:

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

Tetracycline hydrochloride:
Remarks: No data available

Prednisolone:
Remarks: No data available

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

Components:

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:

Neomycin, sulfate (salt):
Exposure routes: Dermal
Species: Humans
Result: positive

Tetracycline hydrochloride:
Remarks: No data available

Prednisolone:
### Germ cell mutagenicity
Not classified based on available information.

### Components:

**Neomycin, sulfate (salt):**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

  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:**

<table>
<thead>
<tr>
<th>Test Type: Cytogenetic assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td>Application Route: Intravenous injection</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

  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:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

  Test Type: Mouse Lymphoma  
  Result: negative

  Test Type: sister chromatid exchange assay  
  Result: negative
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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:

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:

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

Test Type: Development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 6 mg/kg body weight
Result: positive

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

Tetracycline hydrochloride:

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

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

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

Prednisolone:

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

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

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

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

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Neomycin, sulfate (salt):**

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

**Tetracycline hydrochloride:**

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

**Prednisolone:**

Target Organs: Bone marrow, Adrenal gland, Liver
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**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
<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
<th>Guinea pig</th>
<th>Dog</th>
<th>Dog</th>
<th>Rat</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
<td>24 mg/kg</td>
<td>25 mg/kg</td>
<td>20 mg/kg</td>
<td>25 mg/kg</td>
<td>25 mg/kg</td>
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<td>Application Route</td>
<td>Subcutaneous</td>
<td>Intramuscular</td>
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<td>Subcutaneous</td>
<td>oral (feed)</td>
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<tr>
<td>Exposure time</td>
<td>34 d</td>
<td>30 d</td>
<td>84 Weeks</td>
<td>90 d</td>
<td>13 W</td>
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<table>
<thead>
<tr>
<th>Symptoms</th>
<th>hearing loss</th>
<th>Reduced body weight</th>
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<table>
<thead>
<tr>
<th>Remarks</th>
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</table>

<table>
<thead>
<tr>
<th>Prednisolone:</th>
<th>Rat</th>
<th>Rat</th>
<th>Dog</th>
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</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.6 mg/kg</td>
<td>2.5 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Oral</td>
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<tr>
<td>Exposure time</td>
<td>63 Days</td>
<td>6 Weeks</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow</td>
<td>Bone marrow</td>
<td>Bone marrow</td>
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<table>
<thead>
<tr>
<th>Tetracycline hydrochloride:</th>
<th>Rat</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>625 mg/kg</td>
<td>3.750 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.250 mg/kg</td>
<td>7.500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
<td>oral (feed)</td>
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<tr>
<td>Exposure time</td>
<td>13 W</td>
<td>13 W</td>
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<tr>
<td>Target Organs</td>
<td>Liver</td>
<td>Reduced body weight</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced body weight</td>
<td>Reduced body weight</td>
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<table>
<thead>
<tr>
<th>Remarks</th>
<th>mortality observed</th>
<th>mortality observed</th>
<th>mortality observed</th>
</tr>
</thead>
</table>
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Target Organ(s): Adrenal gland
Species: Rabbit
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Target Organs: Liver

Aspiration toxicity
Not classified based on available information.

Components:

Tetracycline hydrochloride:
Not applicable

Experience with human exposure

Components:

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

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

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
Toxicity to algae/aquatic plants:
- EC50 (Anabaena flos-aquae (cyanobacterium)): 0,00075 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Anabaena flos-aquae (cyanobacterium)): 0,0003 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0,0099 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0,0022 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1.000

Toxicity to microorganisms:
- EC50 (Natural microorganism): 107,6 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- EC10 (Natural microorganism): 2,8 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity): 10

**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
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M-Factor (Acute aquatic toxicity): 10

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

M-Factor (Chronic aquatic toxicity): 1

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: 0.23 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

12.2 Persistence and degradability

Components:

Neomycin, sulfate (salt):
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

Components:

Neomycin, sulfate (salt):
Partition coefficient: n-octanol/water: log Pow: < -2

Tetracycline hydrochloride:
Partition coefficient: n-octanol/water: log Pow: -1.37
pH: 7

Prednisolone:
Partition coefficient: n-octanol/water: log Pow: 1.46
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12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
IATA : Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)

14.3 Transport hazard class(es)
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14.4 Packing group

ADN
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)

ADR
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)
Tunnel restriction code: (-)

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)

IMDG
Packing group: III
Labels: 9 (ENVIRONM.)
EmS Code: F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes
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IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H360D : May damage the unborn child.
H361d : Suspected of damaging the unborn child.
H362 : May cause harm to breast-fed children.
H372 : Causes damage to organs through prolonged or repeated exposure.
H373 : May cause damage to organs through prolonged or repeated exposure.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
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H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Lact. : Effects on or via lactation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; KECl - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
</tr>
<tr>
<td>Lact.</td>
<td>H362</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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.

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