SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Prednisolone / Neomycin / Tetracycline Formulation

Version 3.7   Revision Date: 27.08.2021   SDS Number: 443934-00016   Date of last issue: 09.04.2021

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
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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 : [Images of pictograms]
   Signal word : Danger
   Hazard statements : H317 May cause an allergic skin reaction.
   H360D May damage the unborn child.
   H362 May cause harm to breast-fed children.
   H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td></td>
<td></td>
<td>Skin Sens. 1B; H317 Repr. 2; H361d STOT RE 2; H373 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tr>
<td>3.7</td>
<td>27.08.2021</td>
<td>443934-00016</td>
<td>09.04.2021</td>
<td>07.01.2016</td>
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<table>
<thead>
<tr>
<th>General advice</th>
<th>Aquatic toxicity:</th>
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</thead>
<tbody>
<tr>
<td>General advice</td>
<td>1,000</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>M-Factor (Acute aquatic toxicity):</td>
</tr>
<tr>
<td>64-75-5 200-593-8</td>
<td>&gt;= 1 - &lt; 2.5</td>
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<tr>
<td>prednisolone</td>
<td>Acute Tox. 4; H302</td>
</tr>
<tr>
<td>50-24-8 200-021-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td></td>
<td>Repr. 1A; H360D</td>
</tr>
<tr>
<td></td>
<td>Lact. H362</td>
</tr>
<tr>
<td></td>
<td>STOT RE 2; H373</td>
</tr>
<tr>
<td></td>
<td>(Gastrointestinal tract, Nervous system, Skin, Teeth)</td>
</tr>
<tr>
<td></td>
<td>Aquatic Acute 1; H400</td>
</tr>
<tr>
<td></td>
<td>Aquatic Chronic 1; H410</td>
</tr>
<tr>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
</tr>
</tbody>
</table>

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 cir-
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cumstances 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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: 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.

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.

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

<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 wax-es</td>
<td>8002-74-2</td>
<td>OELV - 8 hrs (TWA) (Fumes)</td>
<td>2 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>


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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. Equipment should conform to I.S. EN 143

Filter type
Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state
powder
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Colour: No data available
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
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
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: 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
Relative density: No data available
Density: No data available
Relative vapour density: Not applicable
Particle characteristics
Particle size: No data available

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: Not applicable
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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 hazard classes as defined in Regulation (EC) No 1272/2008
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
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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.
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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:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

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
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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:
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
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:
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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.
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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

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)
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<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>Dog</td>
<td>20 mg/kg</td>
<td>Subcutaneous</td>
<td>84 Weeks</td>
<td>ear</td>
<td>hearing loss</td>
<td>mortality observed</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>Rat</td>
<td>625 mg/kg</td>
<td>oral (feed)</td>
<td>13 W</td>
<td>Kidney</td>
<td>Reduced body weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>3,750 mg/kg</td>
<td>oral (feed)</td>
<td>13 W</td>
<td>Liver</td>
<td>Reduced body weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7,500 mg/kg</td>
<td>oral (feed)</td>
<td>13 W</td>
<td>Liver</td>
<td>Reduced body weight</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>0.6 mg/kg</td>
<td>Oral</td>
<td>63 Days</td>
<td>Bone marrow</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>2.5 mg/kg</td>
<td>Oral</td>
<td>6 Weeks</td>
<td>Adrenal gland</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>1 mg/kg</td>
<td>Oral</td>
<td>24 Weeks</td>
<td>Liver</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.
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Components:

Tetracycline hydrochloride: Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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  
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

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
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<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcystis aeruginosa (blue-green algae)</td>
<td>0.09 mg/l</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 209</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50 : 0.08 mg/l</td>
<td>3 h</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 160 mg/l</td>
<td>72 h</td>
<td></td>
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</tr>
<tr>
<td>Species: Ceriodaphnia dubia (water flea)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC: 0.23 mg/l</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>Biodegradability</td>
<td>Result: rapidly degradable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biodegradation</td>
<td>50 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>1.2 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 314</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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 / Neomycin / Tetracycline Formulation

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product: Assessment
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product: Assessment
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number

ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077
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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)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

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

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
14.4 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

14.5 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.

14.6 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parlia-
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ment and the Council concerning the export and import of dangerous chemicals
REACH - List of substances subject to authorisation: Not applicable
(Annex XIV)

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.
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
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</tr>
</tbody>
</table>

| Lact.   | : Effects on or via lactation |
| Repr.   | : Reproductive toxicity      |
| Skin Sens. | : Skin sensitisation |
| STOT RE | : Specific target organ toxicity - repeated exposure |
| IE OEL | : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1 |

| IE OEL / OELV - 8 hrs (TWA) | : Occupational exposure limit value (8-hour reference period) |
| IE OEL / OELV - 15 min (STEL) | : Occupational exposure limit value (15-minute reference period) |

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; AIIC - Australian Inventory of Industrial Chemicals; 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; IC0 - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information
Sources of key data used to compile the Safety Data Sheet:

### Classification of the mixture:
| Skin Sens. 1 | H317 |
| Repr. 1A     | H360D |

### Classification procedure:
- Calculation method
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<table>
<thead>
<tr>
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<tbody>
<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>

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.

IE / EN