

### Prednisolone / Neomycin / Tetracycline Formulation

Date of last issue: 16.12.2022 Version Revision Date: SDS Number: 5.0 04.04.2023 407521-00022 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 Sub-: Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company

20 Spartan Road

1619 Spartan, South Africa

Telephone +27119239300

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, Cate-

gory 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



H400: Very toxic to aquatic life.

Signal word Danger

Hazard statements H317 May cause an allergic skin reaction.



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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 protec-

tion/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.

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Neomycin, sulfate (salt)	1405-10-3 215-773-1	Skin Sens. 1B; H317 Repr. 2; H361d STOT RE 2; H373 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1.000 M-Factor (Chronic aquatic toxicity): 10	>= 3 - < 10
tetracycline hydrochloride	64-75-5	Repr. 1A; H360D	>= 1 - < 2,5



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	200-593-8	Lact.H362 STOT RE 2; H373 (Gastrointestinal tract, Nervous system, Skin, Teeth) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1
prednisolone	50-24-8 200-021-7	Acute Tox. 4; H302 >= 0,1 - < 0,25 Repr. 2; H361d STOT RE 1; H372 (Bone marrow, Adrenal gland, Liver) Aquatic Chronic 2; H411

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

4.1 Description of first aid measu	ures
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General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting.

Get medical attention.



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Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

May cause an allergic skin reaction. May damage the unborn child.

May cause harm to breast-fed children.

#### 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 fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

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.



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#### 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 pro-

tective 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

Sweep up or vacuum up spillage and collect in suitable con-Methods for cleaning up

tainer 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 deter-

mine 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 as-



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sessment

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

Self-reactive substances and mixtures

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**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin waxes and Hydrocarbon wax- es	8002-74-2	OEL-RL (Fumes)	4 mg/m3	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For			
	Hazardous Chemical Agents			
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal



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tetracycline hydro- chloride	64-75-5	TWA	0.9 mg/m3 (OEB 2)	Internal
prednisolone	50-24-8	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Neomycin, sulfate (salt)	Water	0,00004 mg/l

#### 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/face 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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



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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, han-

dling 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

Density : No data available

Solubility(ies)

Water solubility
Partition coefficient: n-

Auto-ignition temperature

octanol/water

No data availableNot applicable

: 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.

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.



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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling 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



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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):  $> 3.857 \,\text{mg/kg}$ 

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



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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

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:



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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



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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 develop-

ment were detected.

Effects on foetal develop-

ment

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 - As-

sessment

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 develop-

ment

Test Type: Development

Result: Embryo-foetal toxicity, Specific developmental abnor-

malities, Skeletal malformations

Reproductive toxicity - As-

sessment

Studies indicating a hazard to babies during the lactation peri-

od, May damage the unborn child.



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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 develop-

ment

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 - As-

sessment

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.



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#### 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: RatLOAEL: 25 mg/kgApplication Route: oral (feed)Exposure time: 84 Weeks

Target Organs : ear

Symptoms : hearing loss
Remarks : mortality observed

Species : Dog LOAEL : 20 mg/kg Application Route : Subcutaneous

Exposure time : 90 d
Target Organs : Kidney

#### tetracycline hydrochloride:

 Species
 : Rat

 NOAEL
 : 625 mg/kg

 LOAEL
 : 1.250 mg/kg



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Application Route : oral (feed)
Exposure time : 13 W
Target Organs : Liver

Symptoms : Reduced body weight

Species: MouseNOAEL: 3.750 mg/kgLOAEL: 7.500 mg/kgApplication Route: oral (feed)

Exposure time : 13 W

Symptoms : Reduced body weight

prednisolone:

Species : Rat

LOAEL : 0,6 mg/kg
Application Route : Oral
Exposure time : 63 Days
Target Organs : Bone marrow

Species : Dog
LOAEL : 2,5 mg/kg
Application Route : Oral
Exposure time : 6 Weeks
Target Organs : Adrenal gland

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

#### **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

#### tetracycline hydrochloride:

Not applicable

#### Experience with human exposure

#### **Components:**

Neomycin, sulfate (salt):

Skin contact : Symptoms: 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,



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Diarrhoea, Liver effects, skin rash, central nervous system

effects

Remarks: May cause sensitisation of susceptible persons.

May cause photosensitisation. Based on Human Evidence

prednisolone:

Symptoms: sodium retention, Headache, Vertigo, fluid reten-Ingestion

tion, 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/aguatic

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 tox-:

icity)

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



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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/I

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 tox-:

icity)

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

ma/l

Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160

mg/l

Exposure time: 72 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,23 mg/l

Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)



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#### 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-

log Pow: -1,37

octanol/water

pH: 7

prednisolone:

Partition coefficient: n-

octanol/water

: log Pow: 1,46

#### 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 Other adverse effects

#### **Product:**

Endocrine disrupting poten-

tial

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.

#### **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



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are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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,

NOS

(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



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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)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

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

**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.



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#### 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.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. The Regulations for Hazardous Chemical

Agents, Occupational Exposure Limits

ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour expo-



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#### sure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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; ARC - International Agency for Research on Cancer; ATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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; 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**

Sources of key data used to : compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

Sheet cy, http://echa.europa.eu

#### Classification of the mixture: Classification procedure:

Skin Sens. 1 H317 Calculation method
Repr. 1A H360D Calculation method
Lact. H362 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

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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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