

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
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 / Bacitracin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
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, 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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	:	<p>Prevention:</p> <p>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.</p> <p>Response:</p> <p>P391 Collect spillage.</p>

Hazardous components which must be listed on the label:

Neomycin, sulfate (salt)
tetracycline hydrochloride
Bacitracin

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	>= 3 - < 10

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version
6.0Revision Date:
26.09.2023SDS Number:
407521-00023Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

tetracycline hydrochloride	64-75-5 200-593-8	M-Factor (Chronic aquatic toxicity): 10 Repr. 1A; H360D Lact.H362 STOT RE 2; H373 (Gastrointestinal tract, Nervous system, Skin, Teeth) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1	$\geq 1 - < 2,5$
Bacitracin	1405-87-4 215-786-2	Skin Sens. 1; H317 Aquatic Chronic 2; H411	$\geq 0,25 - < 1$
prednisolone	50-24-8 200-021-7	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow, Adrenal gland, Liver) Aquatic Chronic 2; H411	$\geq 0,1 - < 0,25$

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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.0	26.09.2023	407521-00023	Date of first issue: 07.01.2016

- 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 fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0	Revision Date: 26.09.2023	SDS Number: 407521-00023	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
----------------	------------------------------	-----------------------------	---

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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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
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 waxes	8002-74-2	OEL-RL (Fumes)	4 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m ³ (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm ²	Internal
tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m ³ (OEB 2)	Internal
Bacitracin	1405-87-4	TWA	4 mg/m ³ (OEB 1)	Internal
	Further information: DSEN, RSEN			
		Wipe limit	0.1 mg/100 cm ²	Internal
prednisolone	50-24-8	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	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 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0	Revision Date: 26.09.2023	SDS Number: 407521-00023	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
----------------	------------------------------	-----------------------------	---

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
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.

9.2 Other information

Flammability (liquids)	:	Not applicable
Molecular weight	:	No data available
Particle size	:	No data available

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

Bacitracin:

Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg
 Remarks: Based on data from similar materials

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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

Bacitracin:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

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)

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

Genotoxicity in vivo : 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

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

Bacitracin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative
 Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
 Result: negative
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
 Result: negative
 Remarks: Based on data from similar materials

prednisolone:

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

Test Type: Mouse Lymphoma

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

Genotoxicity in vivo	Result: negative
	Test Type: sister chromatid exchange assay Result: negative
	: 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
----------------------	--

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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:

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.

Bacitracin:

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

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

prednisolone:

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Subcutaneous
 Fertility: NOAEL: 1 mg/kg body weight

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

Effects on foetal development	<p>Result: No effects on fertility</p> <p>: 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</p> <p>Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: decreased blood formation</p> <p>Species: Rat Application Route: Subcutaneous Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: No effects on foetal development</p>
Reproductive toxicity - Assessment	<p>: Some evidence of adverse effects on development, based on animal experiments.</p>

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.

Bacitracin:

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

prednisolone:

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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)
 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

Application Route : oral (feed)
 Exposure time : 13 W
 Target Organs : Liver
 Symptoms : Reduced body weight

Species : Mouse
 NOAEL : 3.750 mg/kg
 LOAEL : 7.500 mg/kg
 Application Route : oral (feed)
 Exposure time : 13 W
 Symptoms : Reduced body weight

Bacitracin:

Species : Rat
 LOAEL : > 10 mg/kg
 Application Route : Ingestion
 Exposure time : 13 Weeks
 Remarks : Based on data from similar materials

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

Eye contact : Remarks: May irritate skin.
Ingestion : Remarks: May cause eye irritation.
: 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

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

Bacitracin:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Artemia salina (brine shrimp)): 21,8 mg/l
 Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 10 mg/l
 Exposure time: 10 d
 Method: OECD Test Guideline 201

prednisolone:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 85 mg/l

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

aquatic invertebrates	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
--	---------------------------

Bacitracin:

Partition coefficient: n-octanol/water	: log Pow: -0,8
--	-----------------

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
------------	--

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0	Revision Date: 26.09.2023	SDS Number: 407521-00023	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
----------------	------------------------------	-----------------------------	---

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : 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 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 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)

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 407521-00023 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

IATA : Environmentally hazardous substance, solid, n.o.s.
(Neomycin, sulfate (salt), tetracycline hydrochloride)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
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)
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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0	Revision Date: 26.09.2023	SDS Number: 407521-00023	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
----------------	------------------------------	-----------------------------	---

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.

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0	Revision Date: 26.09.2023	SDS Number: 407521-00023	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
----------------	------------------------------	-----------------------------	---

- H373 : exposure.
: 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 exposure 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; AIIIC - 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; 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.0	26.09.2023	407521-00023	Date of first issue: 07.01.2016

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

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

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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

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.

ZA / EN