

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
11.1	24.02.2025	407518-00025	Date of first issue: 07.01.2016

Section 1: Identification

Product name : Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification**GHS Classification**

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

Effects on or via lactation

Specific target organ toxicity - : Category 2 (Kidney, inner ear)
repeated exposure

Specific target organ toxicity - : Category 2 (Gastrointestinal tract, Nervous system, Skin,
repeated exposure (Oral) Teeth)


Hazardous to the aquatic : Category 1
environment - acute hazard

Hazardous to the aquatic : Category 1
environment - chronic hazard

GHS label elements

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- Hazard 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.
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe mist or vapours.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.
- Storage:**
P405 Store locked up.
- Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

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Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	≥ 70 -< 90
Magnesium stearate	557-04-0	≥ 1 -< 10
Neomycin, sulfate (salt)	1405-10-3	≥ 2.5 -< 10
tetracycline hydrochloride	64-75-5	≥ 1 -< 2.5
Bacitracin	1405-87-4	≥ 0.25 -< 1
prednisolone	50-24-8	≥ 0.1 -< 0.25

Section 4: First-aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
May damage the unborn child.
May cause harm to breast-fed children.
May cause damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

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

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

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

Hazchem Code : 3Z

Section 6: Accidental release measures

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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.

Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE

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- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
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 mist or vapours.
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.
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.
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	WES-TWA (Mist)	5 mg/m ³	NZ OEL
		WES-STEL (Mist)	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
Neomycin, sulfate (salt)	1405-10-3	TWA	1.5 mg/m ³ (OEB)	Internal

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	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm ²	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
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

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

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

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

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posable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance	:	oily, suspension
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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
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

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Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

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Magnesium stearate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Acute oral toxicity	:	LD50 (Mouse): 2,880 mg/kg LD50 (Rat): 2,750 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 633 mg/kg Application Route: Subcutaneous LD50 (Mouse): 116 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous LD50 (Mouse): 275 mg/kg Application Route: Subcutaneous

tetracycline hydrochloride:

Acute oral toxicity	:	LD50 (Rat): 6,443 mg/kg LD50 (Mouse): 2,759 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 128 mg/kg Application Route: Intravenous LD50 (Mouse): 157 mg/kg Application Route: Intravenous

Bacitracin:

Acute oral toxicity	:	LD50 (Mouse): > 2,000 mg/kg Remarks: Based on data from similar materials
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prednisolone:

Acute oral toxicity	:	LD50 (Mouse): 1,680 mg/kg LD50 (Rat): > 3,857 mg/kg
Acute inhalation toxicity	:	Remarks: No data available

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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:**White mineral oil (petroleum):**

Species : Rabbit
Result : No skin irritation

Magnesium stearate:

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Neomycin, sulfate (salt):

Species : Rabbit
Result : Mild skin irritation

tetracycline hydrochloride:

Remarks : No data available

prednisolone:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species : Rabbit
Result : No eye irritation

Magnesium stearate:

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

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Neomycin, sulfate (salt):

Species	:	Rabbit
Result	:	No eye irritation

tetracycline hydrochloride:

Remarks	:	No data available
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prednisolone:

Remarks	:	No data available
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Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Neomycin, sulfate (salt):

Exposure routes	:	Dermal
Species	:	Humans
Result	:	positive

tetracycline hydrochloride:

Remarks	:	No data available
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Bacitracin:

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

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Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

prednisolone:

Remarks : No data available

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

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

Neomycin, sulfate (salt):

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Chromosomal aberration

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Test system: Human lymphocytes
Result: positive

Test Type: in vitro micronucleus test
Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay
Species: Mouse
Cell type: Bone marrow
Application Route: Intravenous injection
Result: negative

tetracycline hydrochloride:

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

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

Test Type: sister chromatid exchange assay
Result: negative

Test Type: Mouse Lymphoma
Result: negative

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
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

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

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

Carcinogenicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

Neomycin, sulfate (salt):

Species : Rat
Exposure time : 2 Years
Result : negative

tetracycline hydrochloride:

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

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

prednisolone:

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

Reproductive toxicity

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

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Components:**White mineral oil (petroleum):**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Magnesium stearate:

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

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

Neomycin, sulfate (salt):

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

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

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

Reproductive toxicity - As- : Some evidence of adverse effects on development, based on

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assessment

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
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

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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

May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

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.

Repeated dose toxicity**Components:****White mineral oil (petroleum):**

Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

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Species : Rat
LOAEL : ≥ 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

Magnesium stearate:

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

Neomycin, sulfate (salt):

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Subcutaneous
Exposure time : 14 d
Target Organs : Kidney

Species : Guinea pig
NOAEL : 50 mg/kg
LOAEL : 100 mg/kg
Application Route : Intramuscular
Exposure time : 30 - 60 Weeks
Target Organs : ear

Species : Guinea pig
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 90 d
Remarks : No significant adverse effects were reported

Species : Guinea pig
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

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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
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

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Target Organs : Liver

Aspiration toxicity

Not classified based on available information.

Components:**tetracycline hydrochloride:**

Not applicable

Experience with human exposure**Components:****Neomycin, sulfate (salt):**

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

tetracycline hydrochloride:

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

Ingestion	:	Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities
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Section 12: Ecological information**Ecotoxicity****Components:****White mineral oil (petroleum):**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100

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plants

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 21 d

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 72 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

LC50 (Americamysis): 39 mg/l

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Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

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

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

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

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

M-Factor (Acute aquatic toxicity) : 1,000
M-Factor (Chronic aquatic toxicity) : 10
Toxicity to microorganisms : EC50 (Natural microorganism): 107.6 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

tetracycline hydrochloride:

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l
Exposure time: 72 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l
Exposure time: 72 h

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EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l
Exposure time: 7 d

M-Factor (Acute aquatic toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 1
Toxicity to microorganisms : EC50: 0.08 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 85 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l
Exposure time: 7 d

Persistence and degradability**Components:****White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

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Neomycin, sulfate (salt):

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

Bioaccumulative potential**Components:****Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

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

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

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

Section 14: Transport information**International Regulations**

UNRTDG

**Prednisolone / Neomycin / Tetracycline / Baci-
tracin Formulation**

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UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Neomycin, sulfate (salt), tetracycline hydrochloride)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Neomycin, sulfate (salt), tetracycline hydrochloride)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Neomycin, sulfate (salt), tetracycline hydrochloride)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**NZS 5433**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Neomycin, sulfate (salt), tetracycline hydrochloride)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : yes

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

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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 24.02.2025

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/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

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AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

NZ / EN