

## Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 8.0      Revision Date: 26.09.2023      SDS Number: 407518-00021      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

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### 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

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### Section 2: Hazard identification

#### GHS Classification

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

Effects on or via lactation

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

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




Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

#### GHS label elements

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Hazard pictograms	:	  
Signal word	:	Danger
Hazard statements	:	<p>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.</p>
Precautionary statements	:	<p><b>Prevention:</b>          P201 Obtain special instructions before use.          P260 Do not breathe dust.          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.</p> <p><b>Response:</b>          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.</p> <p><b>Storage:</b>          P405 Store locked up.</p> <p><b>Disposal:</b>          P501 Dispose of contents/ container to an approved waste disposal plant.</p>

### Other hazards which do not result in classification

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

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Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Paraffin waxes and Hydrocarbon waxes	8002-74-2	>= 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 : 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.

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.  
 Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.

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 (CO<sub>2</sub>)  
 Dry chemical

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Unsuitable extinguishing media	:	None known.
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 <sub>x</sub> ) Chlorine compounds Metal oxides Sulphur 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	:	2Z

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### 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. 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	:	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.

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### Section 7: Handling and storage

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- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Avoid contact during pregnancy and while nursing.  
 Do not get on skin or clothing.  
 Do not breathe dust.  
 Do not swallow.  
 Avoid contact with eyes.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Minimize dust generation and accumulation.  
 Keep container closed when not in use.  
 Keep away from heat and sources of ignition.  
 Take precautionary measures against static discharges.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 When using do not eat, drink or smoke.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wash contaminated clothing before re-use.  
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 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
Paraffin waxes and Hydrocar-	8002-74-2	WES-TWA	2 mg/m3	NZ OEL

# SAFETY DATA SHEET



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bon waxes		(Fumes)		
		TWA (Fumes)	2 mg/m3	ACGIH
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
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m3 (OEB 2)	Internal
Bacitracin	1405-87-4	TWA	4 mg/m3 (OEB 1)	Internal
Further information: DSEN, RSEN				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal
prednisolone	50-24-8	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**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

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  
 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.

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**Section 9: Physical and chemical properties**

Appearance	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
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

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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.

Molecular weight : No data available

Particle size : No data available

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**Section 10: Stability and reactivity**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

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

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Paraffin waxes and Hydrocarbon waxes:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 420

Acute dermal toxicity : LD50 (Rabbit): > 3,600 mg/kg  
Method: OECD Test Guideline 402  
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

### 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:****Paraffin waxes and Hydrocarbon waxes:**

Species : Rabbit  
Method : OECD Test Guideline 404  
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:****Paraffin waxes and Hydrocarbon waxes:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Magnesium stearate:**

Species : Rabbit

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

**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:****Paraffin waxes and Hydrocarbon waxes:**

|| Test Type : Maximisation Test  
|| Exposure routes : Skin contact  
|| Species : Guinea pig  
|| Method : OECD Test Guideline 406  
|| 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  
 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:

### Paraffin waxes and Hydrocarbon waxes:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Intraperitoneal injection  
 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

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Genotoxicity in vivo : 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  
 Result: negative

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Genotoxicity in vivo	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:

#### Paraffin waxes and Hydrocarbon waxes:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 2 Years
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.

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May cause harm to breast-fed children.

## Components:

### **Paraffin waxes and Hydrocarbon waxes:**

Effects on fertility	:	Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Skin contact Result: negative Remarks: Based on data from similar materials

### **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

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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  
 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



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

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

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:

#### Paraffin waxes and Hydrocarbon waxes:

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

#### 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.
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#### 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:

##### Paraffin waxes and Hydrocarbon waxes:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 90 Days
Method	: OECD Test Guideline 408

##### 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

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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  
 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

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

**Aspiration toxicity**

Not classified based on available information.

**Components:****tetracycline hydrochloride:**

|| Not applicable

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

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

**tetracycline hydrochloride:**

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

**prednisolone:**

|| Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

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**Section 12: Ecological information****Ecotoxicity****Components:****Paraffin waxes and Hydrocarbon waxes:**

|| Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials  
|| Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

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aquatic invertebrates	Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Remarks: Based on data from similar materials

### 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
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		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
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
<b>tetracycline hydrochloride:</b>		
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

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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  
 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:

#### Paraffin waxes and Hydrocarbon waxes:

Biodegradability : Result: Not readily biodegradable.  
 Biodegradation: 31 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 301F  
 Remarks: Based on data from similar materials

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**Magnesium stearate:**

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

**Neomycin, sulfate (salt):**

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

**Bioaccumulative potential****Components:****Paraffin waxes and Hydrocarbon waxes:**

Partition coefficient: n-octanol/water : log Pow: 5.3 - 6.7

**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

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**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 han-



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ding site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## Section 14: Transport information

### International Regulations

#### UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

#### IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

#### IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, 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 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt), tetracycline hydrochloride)
Class	:	9
Packing group	:	III

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Labels	:	9
Hazchem Code	:	2Z
Marine pollutant	:	no

**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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**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

**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

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**Section 16: Other information**

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**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/>

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

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

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ACGIH / TWA : 8-hour, time-weighted average  
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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