

## Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0      Revision Date: 26.09.2023      SDS Number: 407504-00022      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Effects on or via lactation

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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.  
H410 Very toxic to aquatic life with long lasting effects.

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Precautionary Statements : **Prevention:**  
 P201 Obtain special instructions before use.  
 P260 Do not breathe dust.  
 P263 Avoid contact during pregnancy/ while nursing.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P391 Collect spillage.

### 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

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Paraffin waxes and Hydrocarbon waxes	8002-74-2		>= 70 -< 90
Neomycin, sulfate (salt)	1405-10-3	Acute toxicity (Oral), Category 5 Skin sensitization, Sub-category 1B Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Kidney, inner ear), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 3 -< 5
Magnesium stearate	557-04-0		>= 1 -< 5
Tetracycline hydrochloride	64-75-5	Reproductive toxicity, Category 1A Effects on or via lactation, Specific target organ toxicity - repeated exposure (Oral) (Gastrointestinal tract, Nervous system, Skin,	>= 1 -< 2,5

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		Teeth), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	
Bacitracin	1405-87-4	Skin sensitization, Category 1 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 2	$\geq 0,25$ - $< 1$
prednisolone	50-24-8	Acute toxicity (Oral), Category 4 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Bone mar- row, Adrenal gland, Liver), Category 1 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 2	$\geq 0,1$ - $< 0,25$

### 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.

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Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. 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.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
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 Sulfur 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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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.

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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

- |                             |   |   |
|-----------------------------|---|---|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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 labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |

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Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin waxes and Hydrocarbon waxes	8002-74-2	TWA (Fumes)	2 mg/m <sup>3</sup>	ACGIH
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m <sup>3</sup> (OEB 2)	Internal
Bacitracin	1405-87-4	TWA	4 mg/m <sup>3</sup> (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/m <sup>3</sup> (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

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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, disposable 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
Color	:	No data available
Odor	:	No data available
Odor 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
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available

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Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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.
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**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
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## 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

### 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

### 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

### 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

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

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Neomycin, sulfate (salt):**

Species : Rabbit  
Result : Mild skin irritation

**Magnesium stearate:**

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

**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

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Result	: No eye irritation
Method	: OECD Test Guideline 405

### Neomycin, sulfate (salt):

Species	: Rabbit
Result	: No eye irritation

### Magnesium stearate:

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

### Tetracycline hydrochloride:

Remarks	: No data available
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### prednisolone:

Remarks	: No data available
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### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Paraffin waxes and Hydrocarbon waxes:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

#### Neomycin, sulfate (salt):

Routes of exposure	: Dermal
Species	: Humans
Result	: positive

#### Magnesium stearate:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

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### Tetracycline hydrochloride:

||Remarks : No data available

### Bacitracin:

||Test Type : Human repeat insult patch test (HRIPT)  
||Routes of exposure : Skin contact  
||Result : positive  
  
||Assessment : Probability or evidence of skin sensitization in humans

### prednisolone:

||Remarks : No data available

### 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

#### Neomycin, sulfate (salt):

||Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Result: negative  
  
Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: positive  
  
Test Type: in vitro micronucleus test  
Result: negative  
  
||Genotoxicity in vivo : Test Type: Cytogenetic assay  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Intravenous injection  
Result: negative

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**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

**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:****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.  
May cause harm to breast-fed children.

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

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

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test  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Skin contact  
 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 fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Embryo-fetal 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.

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

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Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 400 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
Result: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0,5 mg/kg body weight  
Result: Malformations were observed., Cleft palate

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Result: decreased blood formation

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: No effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.



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### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Components:

#### Paraffin waxes and Hydrocarbon waxes:

Routes of exposure	:	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:

Routes of exposure	:	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.

### Repeated dose toxicity

### Components:

#### Paraffin waxes and Hydrocarbon waxes:

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

#### Neomycin, sulfate (salt):

Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Subcutaneous

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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
<b>Magnesium stearate:</b>	
Species	: Rat
NOAEL	: > 100 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Remarks	: Based on data from similar materials
<b>Tetracycline hydrochloride:</b>	
Species	: Rat
NOAEL	: 625 mg/kg
LOAEL	: 1.250 mg/kg

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

Species : 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: Sensitization

## Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

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

### Tetracycline hydrochloride:

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

### prednisolone:

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

## 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l  
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

#### 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

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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

### 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.

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		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

### 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
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
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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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##### Neomycin, sulfate (salt):

Biodegradability	:	Result: rapidly degradable Biodegradation: 50 % Exposure time: 1,2 d Method: OECD Test Guideline 314
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##### Magnesium stearate:

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

#### Components:

##### Paraffin waxes and Hydrocarbon waxes:

Partition coefficient: n-octanol/water	:	log Pow: 5,3 - 6,7
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##### Neomycin, sulfate (salt):

Partition coefficient: n-octanol/water	:	log Pow: < -2
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##### Magnesium stearate:

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

Partition coefficient: n-octanol/water	:	log Pow: -1,37 pH: 7
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## II

### 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

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,



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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.

### Domestic regulation

#### ANTT

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  
Hazard Identification Number : 90

### 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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

### The ingredients 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

Revision Date : 26.09.2023  
Date format : dd.mm.yyyy

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### Further information

Sources of key data used to compile the Material 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.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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; TECl - 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.

# SAFETY DATA SHEET



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