

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 6.0 Revision Date: 26.09.2023 SDS Number: 443922-00022 Date of last issue: 04.04.2023
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 : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

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.
 - P202 Do not handle until all safety precautions have been read and understood.
 - 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.
- 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.
 - P362 + P364 Take off contaminated clothing and wash it before reuse.
 - 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

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.	Concentration (% w/w)
Paraffin waxes and Hydrocarbon waxes	8002-74-2	>= 70 -< 90
Neomycin, sulfate (salt)	1405-10-3	>= 3 -< 5
Magnesium stearate	557-04-0	>= 1 -< 5
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

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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. 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 ₂) 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 _x) 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.

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

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.

SECTION 7. HANDLING AND STORAGE

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

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- environment.
- Conditions for safe storage : Keep in properly labeled 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
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	CMP (Fumes)	2 mg/m ³	AR OEL
		TWA (Fumes)	2 mg/m ³	ACGIH
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m ³ (OEB 1)	Internal
		Further information: DSEN, OTO		
		Wipe limit	0.1 mg/100 cm ²	Internal
Magnesium stearate	557-04-0	CMP	10 mg/m ³	AR OEL
		Further information: A4 - Not classifiable as a human carcinogen		
		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** : 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).

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

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 |

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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
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

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.

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Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Product:

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

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 tox-
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icity
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
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

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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
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

prednisolone:

Remarks : No data available

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

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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

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

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Genotoxicity in vivo : 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

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

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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

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

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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 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.

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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

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 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

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		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.

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

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|| 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
 || 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

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Application Route : Subcutaneous
 Exposure time : 90 d
 Target Organs : Kidney

Magnesium stearate:

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

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: Sensitization
 Remarks: May irritate skin.
 Eye contact : Remarks: May cause eye irritation.
 Ingestion : 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 ef-
 fects
 Remarks: May cause sensitization of susceptible persons.
 May cause photosensitization.
 Based on Human Evidence

prednisolone:

|| Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid reten-
 tion, 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 : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
 aquatic invertebrates Exposure time: 48 h
 Remarks: Based on data from similar materials
 Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): > 100
 plants mg/l

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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

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

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		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

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

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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

Neomycin, sulfate (salt):

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

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

Neomycin, sulfate (salt):

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

Magnesium stearate:

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

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

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
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.

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents Registry : Not applicable

Control of precursors and essential chemicals for the preparation of drugs : 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

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)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

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

SAFETY DATA SHEET



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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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