

# Prednisolone / Neomycin / Tetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 16.12.2022 6.0 04.04.2023 407504-00021 Date of first issue: 07.01.2016

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Prednisolone / Neomycin / Tetracycline 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

#### **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 :

(!)

¥2

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.



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H410 Very toxic to aquatic life with long lasting effects.

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 protec-

tion/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 lacta- tion, Specific target organ toxicity - repeated exposure (Oral) (Gas- trointestinal tract,	>= 1 -< 2,5



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			Nervous system, Skin, Teeth), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	
predn	isolone	50-24-8	Acute toxicity (Oral), Category 4 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Bone marrow, Adrenal gland, Liver), Category 1 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 2	>= 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. 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

In case of eye contact

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

May cause an allergic skin reaction. May damage the unborn child.

May cause harm to breast-fed children.

Protection of first-aiders First Aid responders should pay attention to self-protection,



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and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Chlorine compounds

Metal oxides Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec-: tive equipment and emer-

gency 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



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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

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 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



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#### **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/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	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
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

Hand protection

Particulates type

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,



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disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **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

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



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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 reac: :

tions

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

Hazardous decomposition

products

Oxidizing agentsNo 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



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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-

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

prednisolone:

Acute oral toxicity : LD50 (Mouse): 1.680 mg/kg

LD50 (Rat):  $> 3.857 \,\text{mg/kg}$ 

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



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#### 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

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

#### 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

#### Tetracycline hydrochloride:

Remarks : No data available

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)



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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

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



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Test Type: Mouse Lymphoma

Result: negative

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: RatApplication Route: IngestionExposure time: 2 YearsResult: negative

#### Neomycin, sulfate (salt):

Species: RatExposure time: 2 YearsResult: 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



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**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 - As-

sessment

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



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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 - As-

sessment

Studies indicating a hazard to babies during the lactation

period, May damage the unborn child.

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 - As-

sessment

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 concentra-

tions 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.

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

Exposure time : 14 d
Target Organs : Kidney

Species : Guinea pig NOAEL : 50 mg/kg



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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

#### 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



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Species : Mouse

NOAEL : 3.750 mg/kg

LOAEL : 7.500 mg/kg

Application Route : oral (feed)

Exposure time : 13 W

Symptoms : Reduced body weight

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Species : Rat

LOAEL : 0,6 mg/kg
Application Route : Oral
Exposure time : 63 Days
Target Organs : Bone marrow

Species: DogLOAEL: 2,5 mg/kgApplication Route: OralExposure time: 6 WeeksTarget 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

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



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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:

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 (Chron-

ic 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:

EC50 (Daphnia magna (Water flea)): > 72 mg/l aquatic invertebrates

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



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NOEC (Pseudokirchneriella subcapitata (green algae)):

 $0.0022 \, \text{mg/l}$ 

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 1.000

icity)

M-Factor (Chronic aquatic

toxicity)

city)

Toxicity to microorganisms : EC50 (Natural microorganism): 107,6 mg/l

10

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.

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



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Tetracycline hydrochloride:

Toxicity to algae/aguatic

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

10

1

Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0,09 mg/l

Exposure time: 7 d

M-Factor (Acute aquatic tox- :

icity)

M-Factor (Chronic aquatic

toxicity)

dation (Chiloriic aquatic .

Toxicity to microorganisms : EC50: 0,08 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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/I

Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160

mg/l

Exposure time: 72 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

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-

: log Pow: > 4

octanol/water

Tetracycline hydrochloride:

Partition coefficient: n-

log Pow: -1,37

octanol/water

рЙ: 7

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 : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



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#### **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**

**UNRTDG** 

UN 3077 **UN** number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Neomycin, sulfate (salt), tetracycline hydrochloride)

Class Ш Packing group Labels 9

IATA-DGR

UN 3077 UN/ID No.

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Neomycin, sulfate (salt), Tetracycline hydrochloride)

Class 9 Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(Neomycin, sulfate (salt), Tetracycline hydrochloride)

Class 9 Packing group Ш 9 Labels **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 Ш 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



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

#### **SECTION 15. REGULATORY INFORMATION**

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

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

#### **SECTION 16. OTHER INFORMATION**

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#### **Further information**

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, 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 Chemi-



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cal 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.

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