

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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
Specific target organ toxicity : Category 2 (Kidney, inner ear)
- repeated exposure
Specific target organ toxicity : Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)
- repeated exposure (Oral)

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.
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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.
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.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

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 | >= 1 -< 5 |
| Magnesium stearate | 557-04-0 | >= 1 -< 5 |
| Tetracycline hydrochloride | 64-75-5 | >= 1 -< 5 |
| Bacitracin | 1405-87-4 | >= 0.1 -< 1 |
| prednisolone | 50-24-8 | >= 0.1 -< 1 |

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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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

SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO 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. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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 environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

- 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

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 | VLE-PPT (Fumes) | 2 mg/m ³ | NOM-010-STPS-2014 |
| | | 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 | VLE-PPT | 10 mg/m ³ | NOM-010-STPS-2014 |
| | | 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 |

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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|----|--|------------|----------------------------|----------|
| II | | 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). 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.

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

| | | |
|----------------------------------|---|--|
| 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- |
|---------------------|---|---|

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

| | | |
|--------------------|---|-------------------------|
| 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 |
|---------|---|-------------------|

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) |
|-----------------------|---|--|

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

Genotoxicity in vivo : 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

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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 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- : Some evidence of adverse effects on development, based on

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

Assessment 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

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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

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

Components:

Paraffin waxes and Hydrocarbon waxes:

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.

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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
 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

|| 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
 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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

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

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

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:

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version 7.0 Revision Date: 26.09.2023 SDS Number: 407516-00021 Date of last issue: 04.04.2023
 Date of first issue: 07.01.2016

| | |
|---|--|
| 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 |

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 |
| Toxicity to microorganisms | : EC50: 0.08 mg/l Exposure time: 3 h Test Type: Respiration inhibition |

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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 |
|------------------|---|--|

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

Packing group : III
 Labels : 9
 Environmentally hazardous : yes

IATA-DGR

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

IMDG-Code

UN number : UN 3077
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
 N.O.S.
 (Neomycin, sulfate (salt), Tetracycline hydrochloride)
 Class : 9
 Packing group : III
 Labels : 9
 EmS Code : F-A, S-F
 Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

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

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

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

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16. OTHER INFORMATION

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

Full text of other abbreviations

| | | |
|--------------------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NOM-010-STPS-2014 | : | Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NOM-010-STPS-2014 / VLE- | : | Time weighted average limit value |
| PPT | : | |

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 Recom-

Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 7.0 | 26.09.2023 | 407516-00021 | Date of first issue: 07.01.2016 |

recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8