

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07/06/2024
12.1	09/28/2024	407520-00025	Date of first issue: 01/07/2016

### SECTION 1. IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
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@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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.

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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 mist or vapors.  
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 must not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P363 Wash contaminated clothing before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	87.7
Neomycin, sulfate (salt)	1405-10-3	4.6
Magnesium stearate	557-04-0	4.6
Tetracycline hydrochloride	64-75-5	2.43
Bacitracin	1405-87-4	0.365
prednisolone	50-24-8	0.126

## 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.

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In case of skin contact	: Get medical attention. 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	: Flush eyes with water as a precaution. 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.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Chlorine compounds Metal oxides
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.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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- |   |   |
|---|---|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | : Soak up with inert absorbent material.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### SECTION 7. HANDLING AND STORAGE

- |                             |   |
|-----------------------------|---|
| Technical measures          | : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.   |
| Local/Total ventilation     | : If sufficient ventilation is unavailable, use with local exhaust ventilation.   |
| Advice on safe handling     | : Avoid contact during pregnancy and while nursing.<br>Do not get on skin or clothing.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : Do not store with the following product types:<br>Strong oxidizing agents   |

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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
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Mist)	5 mg/m <sup>3</sup>	NIOSH REL
		ST (Mist)	10 mg/m <sup>3</sup>	NIOSH REL
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: DSEN, OTO				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m <sup>3</sup> (OEB 2)	Internal
Bacitracin	1405-87-4	TWA	4 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: DSEN, RSEN				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal
prednisolone	50-24-8	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where

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concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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 : oily, suspension

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
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	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	Not applicable

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.

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Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
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:

##### **White mineral oil (petroleum):**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
  
Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity  
  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
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



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LD50 (Mouse): 275 mg/kg  
Application Route: Subcutaneous

### Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### Tetracycline hydrochloride:

Acute oral toxicity : LD50 (Rat): 6,443 mg/kg  
LD50 (Mouse): 2,759 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 128 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 157 mg/kg  
Application Route: Intravenous

### Bacitracin:

Acute oral toxicity : LD50 (Mouse): > 2,000 mg/kg  
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:

**White mineral oil (petroleum):**

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Species : Rabbit  
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:

#### White mineral oil (petroleum):

Species : Rabbit  
Result : No eye irritation

#### 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

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### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### White mineral oil (petroleum):

Test Type	: Buehler Test
Routes of exposure	: Skin contact
Species	: Guinea pig
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
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##### 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
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##### prednisolone:

Remarks	: No data available
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### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### White mineral oil (petroleum):

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test
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Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
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

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Test system: Chinese hamster ovary cells  
Result: negative

Test Type: sister chromatid exchange assay  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative

### Bacitracin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

### prednisolone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative

Test Type: sister chromatid exchange assay  
Result: negative

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:

#### White mineral oil (petroleum):

Species : Rat  
Application Route : Ingestion  
Exposure time : 24 Months

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Result : negative

### Neomycin, sulfate (salt):

Species : Rat  
Exposure time : 2 Years  
Result : negative

### Tetracycline hydrochloride:

Species : Rat  
Application Route : Oral  
Exposure time : 103 W  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 103 W  
Result : negative

### prednisolone:

Species : Rat  
Application Route : Oral  
Exposure time : 18 Months  
Result : negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child.  
May cause harm to breast-fed children.

### Components:

#### White mineral oil (petroleum):

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

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### Neomycin, sulfate (salt):

Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity Parent: NOAEL: 25 mg/kg body weight  
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 275 mg/kg body weight  
Result: No adverse effects., No teratogenic effects.

Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 6 mg/kg body weight  
Result: positive

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

### Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

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

### 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.

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### Bacitracin:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

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

### prednisolone:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 1 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight  
Result: Malformations were observed., Cleft palate

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

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

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

### 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.



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## Prednisolone / Neomycin / Tetracycline / Bacitracin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07/06/2024
12.1	09/28/2024	407520-00025	Date of first issue: 01/07/2016

### Components:

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

Target Organs	:	Kidney, inner ear
Assessment	:	May cause damage to organs through prolonged or repeated exposure.
Remarks	:	Based on human experience.

#### **Tetracycline hydrochloride:**

Routes of exposure	:	Oral
Target Organs	:	Gastrointestinal tract, Nervous system, Skin, Teeth
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

#### **Bacitracin:**

Assessment	:	No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
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#### **prednisolone:**

Target Organs	:	Bone marrow, Adrenal gland, Liver
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### Components:

#### **White mineral oil (petroleum):**

Species	:	Rat
LOAEL	:	160 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Species	:	Rat
LOAEL	:	>= 1 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

#### **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

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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

### Bacitracin:

Species	: Rat
LOAEL	: > 10 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks
Remarks	: Based on data from similar materials

### prednisolone:

Species	: Rat
LOAEL	: 0.6 mg/kg
Application Route	: Oral
Exposure time	: 63 Days
Target Organs	: Bone marrow

Species	: Dog
LOAEL	: 2.5 mg/kg
Application Route	: Oral
Exposure time	: 6 Weeks
Target Organs	: Adrenal gland

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

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Tetracycline hydrochloride:

Not applicable

### Experience with human exposure

### Components:

#### Neomycin, sulfate (salt):

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

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Loss of balance

### **Tetracycline hydrochloride:**

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

### **prednisolone:**

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

## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

##### **White mineral oil (petroleum):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d

##### **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 : EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l

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plants

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:

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

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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  
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

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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:

##### **White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

##### **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:

##### **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

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### 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.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Neomycin, sulfate (salt), tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

#### IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

#### IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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.



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### Domestic regulation

#### 49 CFR

UN/ID/NA number	: UN 3082
Proper shipping name	: Environmentally hazardous substance, liquid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Neomycin, sulfate (salt), Tetracycline hydrochloride)
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	: Respiratory or skin sensitization Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
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<b>SARA 313</b>	: The following components are subject to reporting levels established by SARA Title III, Section 313:
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Tetracycline hydrochloride	64-75-5	2.43 %
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### US State Regulations

#### Pennsylvania Right To Know

White mineral oil (petroleum)	8042-47-5
Magnesium stearate	557-04-0
Neomycin, sulfate (salt)	1405-10-3

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### California Prop. 65

WARNING: This product can expose you to chemicals including Neomycin, sulfate (salt), which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California List of Hazardous Substances

White mineral oil (petroleum)	8042-47-5
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### California Permissible Exposure Limits for Chemical Contaminants

White mineral oil (petroleum)	8042-47-5
Magnesium stearate	557-04-0

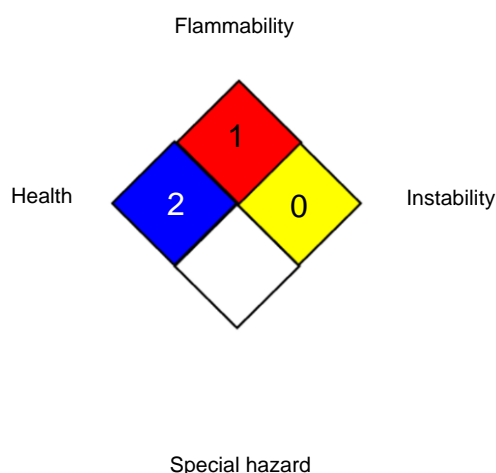
### The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	4
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour

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NIOSH REL / ST	:	workday during a 40-hour workweek STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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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

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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.

US / Z8