

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Benzylpenicillin / Neomycin Formulation

Version 1.4      Revision Date: 09/28/2024      SDS Number: 11119511-00005      Date of last issue: 09/30/2023  
Date of first issue: 12/07/2022

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### SECTION 1. IDENTIFICATION

Product name : Benzylpenicillin / Neomycin Formulation  
Other means of identification : No data available

#### 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


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Respiratory sensitization : Sub-category 1A  
Skin sensitization : Sub-category 1B  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Kidney, inner ear)  
- repeated exposure

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.

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 vapors.

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P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
P284 Wear respiratory protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
P362 + P364 Take off contaminated clothing and wash it 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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	Paraffinum liquidum	8042-47-5	74.5
Benzylpenicillin	No data available	61-33-6	14.7
Neomycin, sulfate (salt)	No data available	1405-10-3	8.2
Aluminum tristearate	Octadecanoic acid, aluminum salt (3:1)	637-12-7	2.5

## 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.  
If not breathing, give artificial respiration.

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- In case of skin contact : If breathing is difficult, give oxygen.  
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 cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure.  
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
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.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapors.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:

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Strong oxidizing agents  
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>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist - Inhalable dust)	5 mg/m <sup>3</sup>	CA QC OEL
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Benzylpenicillin	61-33-6	TWA	600 µg/m <sup>3</sup> (OEB 2)	Internal
		Further information: RSEN, DSEN		
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
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
Aluminum tristearate	637-12-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Respirable)	1 mg/m <sup>3</sup> (Aluminum)	CA BC OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (respirable dust)	5 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

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**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.  
Laboratory operations do not require special containment.

### 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 : Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

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.

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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream

Color : white

Odor : No data available

Odor Threshold : No data available

pH : 7

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

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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	:	0.9 g/cm <sup>3</sup>
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

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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

##### **Benzylpenicillin:**

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg  
LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 3,500 mg/kg  
Application Route: Intraperitoneal  
LD50 (Mouse): 329 mg/kg  
Application Route: Intravenous

##### **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



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LD50 (Mouse): 27.6 mg/kg  
Application Route: Intravenous

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

### Aluminum tristearate:

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

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

Species : Rabbit  
Result : No skin irritation

#### Neomycin, sulfate (salt):

Species : Rabbit  
Result : Mild skin irritation

#### Aluminum tristearate:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials

Result : No skin irritation

### 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

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### Aluminum tristearate:

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Components:

#### White mineral oil (petroleum):

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Benzylpenicillin:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Dermal  
Species : Mouse  
Result : Weak sensitizer

Test Type : Maximization Test  
Routes of exposure : Dermal  
Species : Guinea pig  
Result : positive  
Remarks : Based on data from similar materials

Result : Strong sensitizer  
Remarks : Based on human experience.

#### Neomycin, sulfate (salt):

Routes of exposure : Dermal  
Species : Humans  
Result : positive

#### Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

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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  
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

#### **Benzylpenicillin:**

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

#### **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

#### **Aluminum tristearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

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

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

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

Species : Rat  
Exposure time : 2 Years  
Result : negative

### **Reproductive toxicity**

Suspected of damaging the unborn child.

### **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

#### **Benzylpenicillin:**

Effects on fertility : Test Type: Fertility  
Species: Mouse  
Result: No effects on fertility.

Test Type: Fertility  
Species: Rat  
Result: No effects on fertility.

Test Type: Fertility  
Species: Rabbit

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Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
Species: Mouse  
Result: No effects on fetal development.

Test Type: Development  
Species: Rat  
Result: No effects on fetal development.

Test Type: Development  
Species: Rabbit  
Result: No effects on fetal development.

### 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.

### Aluminum tristearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

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

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### 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.

### 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.

### Repeated dose toxicity

### Components:

#### White mineral oil (petroleum):

Species : Rat  
LOAEL : 160 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

Species : Rat  
LOAEL :  $\geq 1$  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  
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

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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

### Aluminum tristearate:

Species : Rat  
NOAEL :  $\geq 5,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Benzylpenicillin:**

Inhalation : Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

#### **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

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### 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

##### **Benzylpenicillin:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 hrs  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.6 mg/l  
Exposure time: 48 hrs  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201
- NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201
- EC50 (blue-green algae): 0.74 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201
- NOEC (blue-green algae): 0.14 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201



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Toxicity to microorganisms : EC50: > 500 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 5 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### 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

### Aluminum tristearate:

#### Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

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### Persistence and degradability

#### Components:

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

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

##### **Benzylpenicillin:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 70.10 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

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

Biodegradability : Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 1.2 d  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

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

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

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### **UNRTDG**

UN number : UN 3082

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Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Neomycin, sulfate (salt), Benzylpenicillin)

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), Benzylpenicillin)

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), Benzylpenicillin)

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

#### TDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Neomycin, sulfate (salt), Benzylpenicillin)

Class : 9  
Packing group : III  
Labels : 9  
ERG Code : 171  
Marine pollutant : yes(Neomycin, sulfate (salt), Benzylpenicillin)

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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### SECTION 15. REGULATORY INFORMATION

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

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

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA AB OEL / STEL	:	15-minute occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA	:	Time-weighted average exposure value

AIC - 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 Tempera-

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ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/>

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Date format : mm/dd/yyyy

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

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