

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue:             |
| 2.1     | 2023/09/30     | 11119515-00004 | 2023/04/04                      |
|         |                |                | Date of first issue: 2022/12/07 |

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Benzylpenicillin / Neomycin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361d Suspected of damaging the unborn child.

## Benzylpenicillin / Neomycin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

H410 Very toxic to aquatic life with long lasting effects.

## Precautionary statements

:

**Prevention:**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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 advice/ attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P362 + P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.5 %

**Other hazards which do not result in classification**

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name                 | CAS-No.   | Concentration (% w/w) |
|-------------------------------|-----------|-----------------------|
| White mineral oil (petroleum) | 8042-47-5 | >= 60 -<= 100         |
| Benzylpenicillin              | 61-33-6   | >= 10 -< 25           |
| Neomycin, sulfate (salt)      | 1405-10-3 | >= 3 -< 10            |
| Aluminum tristearate          | 637-12-7  | < 10                  |

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

**4. FIRST AID MEASURES**

- |                                                             |   |                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                                                                                                                    |
| If inhaled                                                  | : | If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                                                                                                                                                                   |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                                                                                                     |
| In case of eye contact                                      | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                                                                                                                      |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                                                                                                                     |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>Suspected of damaging the unborn child.<br>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.                                                                                                                                                                                                                                                                                   |

**5. FIREFIGHTING MEASURES**

- |                                       |   |                                                                                                                                                                                                                           |
|---------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media          | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Metal oxides                                                                                                                                                                                             |
| Specific extinguishing methods        | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do |

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

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

**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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

**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 vapours.  
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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.

## Benzylpenicillin / Neomycin Formulation

Version 2.1      Revision Date: 2023/09/30      SDS Number: 11119515-00004      Date of last issue: 2023/04/04  
 Date of first issue: 2022/12/07

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components                                                                                                                                      | CAS-No.   | Value type<br>(Form of exposure)    | Control parameters / Permissible concentration | Basis    |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------------------------------------|------------------------------------------------|----------|
| White mineral oil (petroleum)                                                                                                                   | 8042-47-5 | NAB (Mist)                          | 5 mg/m <sup>3</sup>                            | ID OEL   |
|                                                                                                                                                 |           | PSD (Mist)                          | 10 mg/m <sup>3</sup>                           | ID 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  | NAB                                 | 10 mg/m <sup>3</sup>                           | ID OEL   |
| Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |           |                                     |                                                |          |
|                                                                                                                                                 |           | NAB (Respirable particulate matter) | 1 mg/m <sup>3</sup> (Aluminium)                | ID OEL   |
| Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |           |                                     |                                                |          |
|                                                                                                                                                 |           | 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> (Aluminium)                | ACGIH    |

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

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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 vapour type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Hand protection          | : |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Eye protection           | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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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**9. PHYSICAL AND CHEMICAL PROPERTIES**

- |                                         |   |                   |
|-----------------------------------------|---|-------------------|
| Appearance                              | : | cream             |
| Colour                                  | : | white             |
| Odour                                   | : | No data available |
| Odour 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 |

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| 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                                        |
| Vapour pressure                                  | : | No data available                                        |
| Relative vapour 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                                           |
| Auto-ignition 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 size                                    | : | Not applicable                                           |

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**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            | : | No hazardous decomposition products are known. |

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

products

**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

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

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

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

**Aluminum tristearate:**

Species : Rabbit

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

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

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

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

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

|                 |   |              |
|-----------------|---|--------------|
| Test Type       | : | Buehler Test |
| Exposure routes | : | Skin contact |
| Species         | : | Guinea pig   |
| Result          | : | negative     |

**Benzylpenicillin:**

|                 |   |                               |
|-----------------|---|-------------------------------|
| Test Type       | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Dermal                        |
| Species         | : | Mouse                         |
| Result          | : | Weak sensitizer               |

|                 |   |                                      |
|-----------------|---|--------------------------------------|
| Test Type       | : | Maximisation Test                    |
| Exposure routes | : | Dermal                               |
| Species         | : | Guinea pig                           |
| Result          | : | positive                             |
| Remarks         | : | Based on data from similar materials |

|         |   |                            |
|---------|---|----------------------------|
| Result  | : | Strong sensitizer          |
| Remarks | : | Based on human experience. |

**Neomycin, sulfate (salt):**

|                 |   |          |
|-----------------|---|----------|
| Exposure routes | : | Dermal   |
| Species         | : | Humans   |
| Result          | : | positive |

**Aluminum tristearate:**

|                 |   |                                      |
|-----------------|---|--------------------------------------|
| Test Type       | : | Local lymph node assay (LLNA)        |
| Exposure routes | : | Skin contact                         |
| Species         | : | Mouse                                |
| Method          | : | OECD Test Guideline 429              |
| Result          | : | negative                             |
| Remarks         | : | Based on data from similar materials |

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

**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<br>Result: negative                                                                                                                                                                                |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Method: OECD Test Guideline 474<br>Result: negative<br>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)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: Chinese hamster ovary cells<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: positive<br><br>Test Type: in vitro micronucleus test<br>Result: negative |
| Genotoxicity in vivo  | : | Test Type: Cytogenetic assay<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Intravenous injection<br>Result: negative                                                                                                                                                                                                                            |

**Aluminum tristearate:**

|                       |   |                                                                                                                                                                                                                                                            |
|-----------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471 |
|-----------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

Result: negative  
Remarks: Based on data from similar materials

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 foetal development : Test Type: Embryo-foetal 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

## Benzylpenicillin / Neomycin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

Result: No effects on fertility

Test Type: Fertility  
Species: Rabbit  
Result: No effects on fertility

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

Test Type: Development  
Species: Rat  
Result: No effects on foetal development

Test Type: Development  
Species: Rabbit  
Result: No effects on foetal 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 foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal 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 foetal development : Test Type: Fertility/early embryonic development  
Species: Rat

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**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             | : | >= 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          |

## Benzylpenicillin / Neomycin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

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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

**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: Sensitisation  
Remarks: May irritate skin.  
Eye contact : Remarks: May cause eye irritation.  
Ingestion : Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue:             |
| 2.1     | 2023/09/30     | 11119515-00004 | 2023/04/04                      |
|         |                |                | Date of first issue: 2022/12/07 |

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****White mineral oil (petroleum):**

- |                                                                        |   |                                                                                                                          |
|------------------------------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203         |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                  |
| Toxicity to algae/aquatic plants                                       | : | NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l<br>Exposure time: 28 d                                            |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1,000 mg/l<br>Exposure time: 21 d                                                     |

**Benzylpenicillin:**

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

## Benzylpenicillin / Neomycin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

---

Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

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

M-Factor (Acute aquatic toxicity) : 1,000

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms : EC50 (Natural microorganism): 107.6 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l  
 Exposure time: 3 h

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

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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

**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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**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

Contaminated packaging : Dispose of in accordance with local regulations.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

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  
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.

**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.

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

**15. REGULATORY INFORMATION**

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

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**16. OTHER INFORMATION**

Revision Date : 2023/09/30

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

**Full text of other abbreviations**

**Benzylpenicillin / Neomycin Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 11119515-00004 | Date of first issue: 2022/12/07 |

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ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
ID OEL / NAB : Long term exposure limit  
ID OEL / PSD : Short term exposure limit

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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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