

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Benzylpenicillin / Neomycin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 2.4     | 28.09.2024     | 11119567-00006 | Date of first issue: 07.12.2022 |

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Benzylpenicillin / Neomycin Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                                                  |
|------------------------------------------------|----------------------------------------------------------------------------------|
| Respiratory sensitisation, Category 1          | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Skin sensitisation, Category 1                 | H317: May cause an allergic skin reaction.                                       |
| Reproductive toxicity, Category 2              | H361d: Suspected of damaging the unborn child.                                   |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                                                |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects.                      |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Hazard statements        | : | H317 May cause an allergic skin reaction.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>H361d Suspected of damaging the unborn child.<br>H410 Very toxic to aquatic life with long lasting effects.                                                                                                                                                                                       |
| Precautionary statements | : | <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br><br><b>Response:</b><br>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.<br>P391 Collect spillage. |

### Hazardous components which must be listed on the label:

Benzylpenicillin  
Neomycin, sulfate (salt)

### Additional Labelling

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

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

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| Chemical name            | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                                                                                | Concentration<br>(% w/w) |
|--------------------------|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Benzylpenicillin         | 61-33-6<br>200-506-3                                  | Resp. Sens. 1A;<br>H334<br>Skin Sens. 1B; H317<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 3;<br>H412<br><br>M-Factor (Acute<br>aquatic toxicity): 1                                                                                       | $\geq 10$ - $< 20$       |
| Neomycin, sulfate (salt) | 1405-10-3<br>215-773-1                                | Skin Sens. 1B; H317<br>Repr. 2; H361d<br>STOT RE 2; H373<br>(Kidney, inner ear)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity):<br>1,000<br>M-Factor (Chronic<br>aquatic toxicity): 10 | $\geq 3$ - $< 10$        |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.

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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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Suspected of damaging the unborn child.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for 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.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

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

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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.

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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components                      | CAS-No.   | Value type (Form of exposure)           | Control parameters            | Basis    |
|---------------------------------|-----------|-----------------------------------------|-------------------------------|----------|
| White mineral oil (petroleum)   | 8042-47-5 | OELV - 8 hrs (TWA) (inhalable fraction) | 5 mg/m <sup>3</sup>           | IE OEL   |
| 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 tri-                   | 637-12-7  | OELV - 8 hrs                            | 10 mg/m <sup>3</sup>          | IE OEL   |

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|          |  |       |  |  |
|----------|--|-------|--|--|
| stearate |  | (TWA) |  |  |
|----------|--|-------|--|--|

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name           | Environmental Compartment | Value        |
|--------------------------|---------------------------|--------------|
| Benzylpenicillin         | Water                     | 0.014 mg/l   |
| Neomycin, sulfate (salt) | Water                     | 0.00004 mg/l |

## 8.2 Exposure controls

### 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

Eye/face 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.

Hand protection :  
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : cream

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

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Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

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

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **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

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

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

|         |   |                      |
|---------|---|----------------------|
| Species | : | Rabbit               |
| Result  | : | Mild skin irritation |

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

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

|         |   |                   |
|---------|---|-------------------|
| Species | : | Rabbit            |
| Result  | : | No eye irritation |

### 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:

##### 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 |

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Result : positive

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **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

### Carcinogenicity

Not classified based on available information.

#### Components:

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

Species : Rat  
Exposure time : 2 Years  
Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

#### Components:

##### **Benzylpenicillin:**

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

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|                                    |   |                                                                                                                                                                                                                                                |
|------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    |   | Test Type: Fertility<br>Species: Rat<br>Result: No effects on fertility                                                                                                                                                                        |
|                                    |   | Test Type: Fertility<br>Species: Rabbit<br>Result: No effects on fertility                                                                                                                                                                     |
| Effects on foetal development      | : | Test Type: Development<br>Species: Mouse<br>Result: No effects on foetal development                                                                                                                                                           |
|                                    |   | Test Type: Development<br>Species: Rat<br>Result: No effects on foetal development                                                                                                                                                             |
|                                    |   | Test Type: Development<br>Species: Rabbit<br>Result: No effects on foetal development                                                                                                                                                          |
| <b>Neomycin, sulfate (salt):</b>   |   |                                                                                                                                                                                                                                                |
| Effects on fertility               | : | Test Type: Three-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>General Toxicity - Parent: NOAEL: 25 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected. |
| Effects on foetal development      | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight<br>Result: No adverse effects, No teratogenic effects                                                  |
|                                    |   | Test Type: Development<br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 6 mg/kg body weight<br>Result: positive                                                                                            |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments.                                                                                                                                                                  |

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

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### 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:

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

|                   |   |              |
|-------------------|---|--------------|
| Species           | : | Mouse        |
| LOAEL             | : | 30 mg/kg     |
| Application Route | : | Subcutaneous |
| Exposure time     | : | 14 d         |
| Target Organs     | : | Kidney       |

|                   |   |               |
|-------------------|---|---------------|
| Species           | : | Guinea pig    |
| NOAEL             | : | 50 mg/kg      |
| LOAEL             | : | 100 mg/kg     |
| Application Route | : | Intramuscular |
| Exposure time     | : | 30 - 60 Weeks |
| Target Organs     | : | ear           |

|                   |   |                                              |
|-------------------|---|----------------------------------------------|
| Species           | : | Guinea pig                                   |
| NOAEL             | : | 10 mg/kg                                     |
| Application Route | : | Oral                                         |
| Exposure time     | : | 90 d                                         |
| Remarks           | : | No significant adverse effects were reported |

|                   |   |              |
|-------------------|---|--------------|
| Species           | : | Guinea pig   |
| LOAEL             | : | 100 mg/kg    |
| Application Route | : | Subcutaneous |
| Exposure time     | : | 34 d         |

|                   |   |               |
|-------------------|---|---------------|
| Species           | : | Dog           |
| LOAEL             | : | 24 mg/kg      |
| Application Route | : | Intramuscular |
| Exposure time     | : | 30 d          |
| Target Organs     | : | Kidney        |

|                   |   |                    |
|-------------------|---|--------------------|
| Species           | : | Rat                |
| LOAEL             | : | 25 mg/kg           |
| Application Route | : | oral (feed)        |
| Exposure time     | : | 84 Weeks           |
| Target Organs     | : | ear                |
| Symptoms          | : | hearing loss       |
| Remarks           | : | mortality observed |

|         |   |          |
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| Species | : | Dog      |
| LOAEL   | : | 20 mg/kg |

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|                   |   |              |
|-------------------|---|--------------|
| Application Route | : | Subcutaneous |
| Exposure time     | : | 90 d         |
| Target Organs     | : | Kidney       |

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

|            |   |                                                                                                                                                                                                                                                             |
|------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
|------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Experience with human exposure

#### Components:

##### **Benzylpenicillin:**

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

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

|              |   |                                                                                |
|--------------|---|--------------------------------------------------------------------------------|
| Skin contact | : | Symptoms: Sensitisation<br>Remarks: May irritate skin.                         |
| Eye contact  | : | Remarks: May cause eye irritation.                                             |
| Ingestion    | : | Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance |

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **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 |
|----------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------|

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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

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

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

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

M-Factor (Chronic aquatic toxicity) : 10

### 12.2 Persistence and degradability

#### Components:

##### **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

### 12.3 Bioaccumulative potential

#### Components:

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

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

## SECTION 14: Transport information

### 14.1 UN number or ID number

|      |           |
|------|-----------|
| ADN  | : UN 3082 |
| ADR  | : UN 3082 |
| RID  | : UN 3082 |
| IMDG | : UN 3082 |
| IATA | : UN 3082 |

### 14.2 UN proper shipping name

|      |                                                                                                       |
|------|-------------------------------------------------------------------------------------------------------|
| ADN  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Neomycin, sulfate (salt), Benzylpenicillin) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Neomycin, sulfate (salt), Benzylpenicillin) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Neomycin, sulfate (salt), Benzylpenicillin) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.                                                 |

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**IATA** : (Neomycin, sulfate (salt), Benzylpenicillin)  
: Environmentally hazardous substance, liquid, n.o.s.  
(Neomycin, sulfate (salt), Benzylpenicillin)

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | : 9   |                  |
| <b>ADR</b>  | : 9   |                  |
| <b>RID</b>  | : 9   |                  |
| <b>IMDG</b> | : 9   |                  |
| <b>IATA</b> | : 9   |                  |

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**ADR**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

**RID**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**IMDG**  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

**IATA (Cargo)**  
Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

**IATA (Passenger)**  
Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

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### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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REACH - List of substances subject to authorisation : Not applicable  
(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |                          |                     |                     |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL<br>HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|--------------------------|---------------------|---------------------|

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-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 through prolonged or repeated exposure.         |
| H400  | : Very toxic to aquatic life.                                                |
| H410  | : Very toxic to aquatic life with long lasting effects.                      |
| H412  | : Harmful to aquatic life with long lasting effects.                         |

### Full text of other abbreviations

|                 |                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------|
| Aquatic Acute   | : Short-term (acute) aquatic hazard                                                                                             |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard                                                                                            |
| Repr.           | : Reproductive toxicity                                                                                                         |
| Resp. Sens.     | : Respiratory sensitisation                                                                                                     |
| Skin Sens.      | : Skin sensitisation                                                                                                            |
| STOT RE         | : Specific target organ toxicity - repeated exposure                                                                            |
| IE OEL          | : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |

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IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

|                   |       |
|-------------------|-------|
| Resp. Sens. 1     | H334  |
| Skin Sens. 1      | H317  |
| Repr. 2           | H361d |
| Aquatic Acute 1   | H400  |
| Aquatic Chronic 1 | H410  |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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

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IE / EN