SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

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

1.1 Product identifier
   Trade name : Benzylpenicillin / Streptomycin Sulphate Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Acute toxicity, Category 4 : H302: Harmful if swallowed.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   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 1A : H360D: May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.
   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)
   Hazard pictograms : 
   Signal word : Danger
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Formulation

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Date of first issue: 13.02.2018

Hazard statements:
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Benzylpenicillin
Streptomycin sulphate

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.

Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

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Formulation

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<table>
<thead>
<tr>
<th>Registration number</th>
<th>Benzylpenicillin</th>
<th>Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412</th>
</tr>
</thead>
<tbody>
<tr>
<td>61-33-6</td>
<td></td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>200-506-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
</tr>
<tr>
<td>223-286-0</td>
<td></td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

| M-Factor (Acute aquatic toxicity): 100 | M-Factor (Chronic aquatic toxicity): 100 |

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.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks
Harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
Contact with dust can cause mechanical irritation or drying of the skin.

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 (CO2)
Dry chemical

Unsuitable extinguishing media
None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a
potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, 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. 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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye 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 Organic peroxides Explosives 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**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: RSEN, DSEN</td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1,000 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

- **Eye protection** : Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

- **Hand protection** : 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 NS EN 143

  - **Filter type** : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Physical state** : powder
- **Colour** : white
- **Odour** : odourless
- **Odour Threshold** : No data available
- **Melting point/freezing point** : No data available
- **Initial boiling point and boiling** : No data available
## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>6.0 - 7.5 (aqueous suspension)</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>slightly soluble</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>&gt; 0.3 g/cm³</td>
</tr>
<tr>
<td><strong>Relative vapour density</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Particle size</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 9.2 Other information

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: Not applicable
- **Molecular weight**: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

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
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1.030 mg/kg
Method: Calculation method

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
**Streptomycin sulphate:**

**Acute oral toxicity**
- LD50 (Hamster): 400 mg/kg
- LD50 (Rat): 430 mg/kg
- LD50 (Mouse): 25,000 mg/kg

**Acute toxicity (other routes of administration)**
- LD50 (Mouse): 85 - 111 mg/kg  
  Application Route: Intravenous
- LD50 (Mouse): 575 - 610 mg/kg  
  Application Route: Intraperitoneal
- LD50 (Mouse): 500 - 600 mg/kg  
  Application Route: Subcutaneous
- TDLo (Dog): 220 - 440 mg/kg  
  Application Route: Intravenous  
  Symptoms: Lowered blood pressure
- LDLo (Monkey): 110 mg/kg  
  Application Route: Intravenous
- TDLo (Monkey): 30 - 70 mg/kg  
  Application Route: Subcutaneous  
  Symptoms: respiratory depression

**Skin corrosion/irritation**
Not classified based on available information.

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**
**Streptomycin sulphate:**
- Result: Mild 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.

Streptomycin sulphate:

Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Dermal
Species: Humans
Result: Weak sensitizer

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.

Streptomycin sulphate:

Genotoxicity in vitro: Test Type: Chromosomal aberration
Result: equivocal
Genotoxicity in vivo: Test Type: Chromosomal aberration
Cell type: Human lymphocytes
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Streptomycin sulphate:

Species: Rat
Application Route: Oral
NOAEL: 5 mg/kg body weight
Result: negative
Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen
Reproductive toxicity
May damage the unborn child.

Components:

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

Species: Rat
Result: No effects on fertility

Species: Rabbit
Result: No effects on fertility

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

Species: Rat
Result: No effects on foetal development

Species: Rabbit
Result: No effects on foetal development

Streptomycin sulphate:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Intraperitoneal
Fertility: LOAEL: 40 mg/kg body weight
Symptoms: male reproductive effects

Effects on foetal development:
Test Type: Development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 250 mg/kg body weight
Symptoms: fetal deafness, Embryo-foetal toxicity

Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects

Reproductive toxicity - Assessment: May damage the unborn child.
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STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Components:
Streptomycin sulphate:
Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Streptomycin sulphate:
Species: Rat
NOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 72 Days
Remarks: No significant adverse effects were reported

Species: Cat
LOAEL: 200 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: inner ear

Species: Dog
LOAEL: 44 mg/kg
Application Route: Intramuscular
Exposure time: 14 Days
Target Organs: inner ear

Species: Dog
LOAEL: 50 - 100 mg/kg
Application Route: Intramuscular
Exposure time: 20 Days
Target Organs: inner ear, Kidney
Symptoms: ataxia

Species: Monkey
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Intramuscular
Exposure time: 5 Days
Target Organs: Liver, Kidney

Species: Rat
NOAEL: 5 mg/kg
Application Route: Oral
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

Streptomycin sulphate:
Inhalation: Target Organs: inner ear
Symptoms: hearing loss
Target Organs: Kidney
Symptoms: hearing loss
Skin contact: Symptoms: skin rash

SECTION 12: Ecological information

12.1 Toxicity

Components:

Benzylpenicillin:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): 3.6 mg/l
aqueous invertebrates

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.10</td>
<td>27.08.2021</td>
<td>2456277-00017</td>
<td>09.04.2021</td>
<td>13.02.2018</td>
</tr>
</tbody>
</table>

Exposure time: 48 hrs
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants

Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC50 (blue-green algae): 0.74 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (blue-green algae): 0.14 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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
Remarks: Based on data from similar materials

NOEC: 5 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Streptomycin sulphate:

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 487 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

EC50 (Microcystis aeruginosa (blue-green algae)): 0.007 mg/l
Exposure time: 72 h
Method: ISO 8692

EC50 (Selenastrum capricornutum (green algae)): 0.133 mg/l
Exposure time: 72 h
M-Factor (Acute aquatic toxicity): 100
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 32 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity): 100

12.2 Persistence and degradability

Components:

Benzylpenicillin:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 70,10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Benzylpenicillin:
Partition coefficient: n-octanol/water: log Pow: 1,83
Streptomycin sulphate:
Partition coefficient: n-octanol/water: log Pow: -3,2

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.

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
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(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.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

SECTION 14: Transport information

14.1 UN number or ID number

ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Streptomycin sulphate, Benzylpenicillin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Streptomycin sulphate, Benzylpenicillin)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Streptomycin sulphate, Benzylpenicillin)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Streptomycin sulphate, Benzylpenicillin)
IATA: Environmentally hazardous substance, solid, n.o.s. (Streptomycin sulphate, Benzylpenicillin)

14.3 Transport hazard class(es)
## 14.4 Packing group

### ADN
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

### ADR
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

### RID
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

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

### IATA (Cargo)
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

### IATA (Passenger)
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

## 14.5 Environmental hazards

### ADN
- Environmentally hazardous: yes

### ADR
- Environmentally hazardous: yes

### RID
### Environmentally hazardous
- IMDG
- Marine pollutant
- IATA (Passenger)
- Environmentally hazardous
- IATA (Cargo)
- Environmentally hazardous

### 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.

### 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, preparations and articles (Annex XVII): Not applicable
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
- REACH - List of substances subject to authorisation (Annex XIV): Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
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<tbody>
<tr>
<td>100 t</td>
<td>200 t</td>
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</table>

#### Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

#### The components of this product are reported in the following inventories:
- AICS: not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 5.10  Revision Date: 27.08.2021  SDS Number: 2456277-00017  Date of last issue: 09.04.2021
Date of first issue: 13.02.2018

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

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D : May damage the unborn child.
H372 : Causes 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

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 Stand-
Benzylpenicillin / Streptomycin Sulphate Solid Formulation

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<thead>
<tr>
<th>Version</th>
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Further information

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

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<thead>
<tr>
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<th>Eye Irrit. 2</th>
<th>Resp. Sens. 1</th>
<th>Skin Sens. 1</th>
<th>Repr. 1A</th>
<th>STOT RE 1</th>
<th>Aquatic Acute 1</th>
<th>Aquatic Chronic 1</th>
</tr>
</thead>
<tbody>
<tr>
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<td>H360D</td>
<td>H372</td>
<td>H400</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:
- 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 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.

NO / EN