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
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone: 44 1 670 59 30 00
   Telefax: 908-735-1496
   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)
Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Hazard pictograms:

Signal word: Danger

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
- 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>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>200-506-3</td>
<td></td>
<td></td>
<td>Resp. Sens.1A; H334</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1B; H317</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute1;</td>
<td></td>
</tr>
</tbody>
</table>
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H400 Aquatic Chronic3; H412

M-Factor (Acute aquatic toxicity): 1

Streptomycin sulphate 3810-74-0 223-286-0

Acute Tox.4; H302 Eye Irrit.2; H319 Skin Sens.1B; H317 Repr.1A; H360D STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410

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

>= 30 - < 50

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

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. 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.

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.
- 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.
- 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. 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>
</tbody>
</table>

Further information: RSEN, DSEN
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
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 NS EN 143
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder
Colour : white
Odour : odourless
Odour Threshold : No data available

pH : 6,0 - 7,5
(aqueous suspension)

Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
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</tr>
</tbody>
</table>

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour density: Not applicable

Relative density: No data available

Density: > 0.3 g/cm³

Solubility(ies):
- Water solubility: slightly soluble
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity:
- Viscosity, kinematic: Not applicable

Explosive properties: Not explosive

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

**9.2 Other information**

- Flammability (liquids): Not applicable
- Molecular weight: No data available
- Particle size: 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 toxicological effects

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

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

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

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

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

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

Repeated dose toxicity
Components:
Streptomycin sulphate:
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<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
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<tr>
<td>Exposure time</td>
<td>72 Days</td>
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<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
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<tbody>
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<td>Application Route</td>
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<tr>
<td>Exposure time</td>
<td>90 Days</td>
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<tr>
<td>Target Organs</td>
<td>inner ear</td>
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<thead>
<tr>
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<th>Dog</th>
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</thead>
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<tr>
<td>Application Route</td>
<td>Intramuscular</td>
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<td>Exposure time</td>
<td>14 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>inner ear</td>
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</tbody>
</table>

<table>
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<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
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<td>Intramuscular</td>
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<tr>
<td>Exposure time</td>
<td>20 Days</td>
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<tr>
<td>Target Organs</td>
<td>inner ear, Kidney</td>
</tr>
<tr>
<td>Symptoms</td>
<td>ataxia</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
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<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
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<tr>
<td>Remarks</td>
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<th>Monkey</th>
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<td>Application Route</td>
<td>Intramuscular</td>
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<tr>
<td>Target Organs</td>
<td>Liver, Kidney</td>
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<tr>
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</table>

<table>
<thead>
<tr>
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<th>Monkey</th>
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</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
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<tr>
<td>Exposure time</td>
<td>66 Days</td>
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<tr>
<td>Target Organs</td>
<td>Blood, Liver, Kidney</td>
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<tr>
<td>Symptoms</td>
<td>anemia</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**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 aquatic invertebrates:
  EC50 (Daphnia magna (Water flea)): 3.6 mg/l
  Exposure time: 48 hrs
  Method: OECD Test Guideline 202
  Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
  EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
  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
Method: OECD Test Guideline 201

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- log Pow: 1,83
octanol/water

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
Not relevant

12.6 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

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

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IATA

| (Streptomycin sulphate, Benzylpenicillin) |

14.3 Transport hazard class(es)

| ADN  | 9 |
| ADR  | 9 |
| RID  | 9 |
| IMDG | 9 |
| IATA | 9 |

14.4 Packing group

| ADN  | Packing group: III |
|      | Classification Code: M7 |
|      | Hazard Identification Number: 90 |
|      | Labels: 9 (ENVIRONM.) |
| ADR  | Packing group: III |
|      | Classification Code: M7 |
|      | Hazard Identification Number: 90 |
|      | Labels: 9 (ENVIRONM.) |
|      | Tunnel restriction code: (-) |
| RID  | Packing group: III |
|      | Classification Code: M7 |
|      | Hazard Identification Number: 90 |
|      | Labels: 9 (ENVIRONM.) |
| IMDG | Packing group: III |
|      | Labels: 9 (ENVIRONM.) |
|      | 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  |

| (Streptomycin sulphate, Benzylpenicillin) | Environmentally hazardous substance, solid, n.o.s. | (Streptomycin sulphate, Benzylpenicillin) |
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

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 Transport in bulk according to Annex II of Marpol and the IBC Code
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

E1 ENVIRONMENTAL HAZARDS
Quantity 1 100 t
Quantity 2 200 t

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
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**

- **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; AICS - Australian Inventory of Chemical Substances; 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 - In-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 5.7 Revision Date: 25.06.2020 SDS Number: 2456277-00014 Date of last issue: 09.06.2020
Date of first issue: 13.02.2018

Further information:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
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<tbody>
<tr>
<td>Calculation method</td>
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</table>

Acute Tox. 4 H302
Eye Irrit. 2 H319
Resp. Sens. 1 H334
Skin Sens. 1 H317
Repr. 1A H360D
STOT RE 1 H372
Aquatic Acute 1 H400
Aquatic Chronic 1 H410

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.