

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

### 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 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

### 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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

### 2.2 Label elements

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

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:

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

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Benzylpenicillin	61-33-6 200-506-3	Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412  M-Factor (Acute aquatic toxicity): 1	>= 50 - < 70
Streptomycin sulphate	3810-74-0 223-286-0	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  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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

- 
- 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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

### 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 : 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 : Surround spill with absorbents and place a damp covering

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

over the area to minimise entry of the material into the air.  
Add excess liquid to allow the material to enter into solution.  
Soak up with inert absorbent material.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces  
with compressed air).  
Dust deposits should not be allowed to accumulate on surfac-  
es, as these may form an explosive mixture if they are re-  
leased into the atmosphere in sufficient concentration.  
Clean up remaining materials from spill with suitable absor-  
bent.  
Local or national regulations may apply to releases and dis-  
posal of this material, as well as those materials and items  
employed in the cleanup of releases. You will need to deter-  
mine 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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-<br>sessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-<br>tory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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  |

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

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  
Self-reactive substances and mixtures  
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

Dust      5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable dust)  
Basis: FOR-2011-12-06-1358

10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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
Streptomycin sulphate	3810-74-0	TWA	OEB 2 (>= 100 < 1,000 µg/m <sup>3</sup> )	Internal
		Further information: DSEN		

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

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0,014 mg/l

### 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/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 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 range : No data available
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : Not applicable
- Upper explosion limit / Upper flammability limit : No data available



# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

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

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : slightly soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : > 0,3 g/cm<sup>3</sup>

Relative vapour density : Not applicable

Particle characteristics  
Particle size : No data available

### 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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

### 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

---

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

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

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

---

### 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

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

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

Test Type: Development  
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.

#### **STOT - single exposure**

Not classified based on available information.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1      Revision Date: 30.09.2023      SDS Number: 2456277-00024      Date of last issue: 04.04.2023  
Date of first issue: 13.02.2018

---

### 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  
Exposure time : 2 yr  
Remarks : No significant adverse effects were reported

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

Species	:	Monkey
LOAEL	:	25 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	66 Days
Target Organs	:	Blood, Liver, Kidney
Symptoms	:	anemia

### 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

##### **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

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

---

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201

EC50 (blue-green algae): 0,74 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201

NOEC (blue-green algae): 0,14 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201

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

### **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)



# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

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

### 12.3 Bioaccumulative potential

#### Components:

##### **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 (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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

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.  
Do not dispose of waste into sewer.  
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)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

#### 14.4 Packing group

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

---

### 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 : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

### 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)	:	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
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 HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

#### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### 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.

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

### 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  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 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;

# SAFETY DATA SHEET

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



## Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2456277-00024	Date of first issue: 13.02.2018

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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### 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:

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

### Classification procedure:

Calculation method
Calculation method
Calculation method
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 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