

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

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

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

- 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.

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

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	>= 50 - < 70

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

		Aquatic Acute 1; H400 Aquatic Chronic 3; 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 RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 30 - < 50
		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.

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

- 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 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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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 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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1	Revision Date: 30.09.2023	SDS Number: 2444738-00024	Date of last issue: 04.04.2023 Date of first issue: 13.02.2018
----------------	------------------------------	------------------------------	---

- 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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, 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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

- Specific use(s) : No data available

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Benzylpenicillin	61-33-6	TWA	600 µg/m ³ (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm ²	Internal
Streptomycin sulphate	3810-74-0	TWA	OEB 2 (>= 100 < 1,000 µg/m ³)	Internal
	Further information: DSEN			

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

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.
- 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)

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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.
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/cm ³
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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

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

TDL_o (Dog): 220 - 440 mg/kg
Application Route: Intravenous
Symptoms: Lowered blood pressure

LDLo (Monkey): 110 mg/kg
Application Route: Intravenous

TDL_o (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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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.

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 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.

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 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

Species : Monkey

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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.

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
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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

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)
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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

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 Other adverse effects

Product:

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

SECTION 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. 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

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

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
 Date of first issue: 13.02.2018

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

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)

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	2444738-00024	Date of first issue: 13.02.2018

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 - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

Version 8.1 Revision Date: 30.09.2023 SDS Number: 2444738-00024 Date of last issue: 04.04.2023
Date of first issue: 13.02.2018

Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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.

ZA / EN