SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.2	30.09.2023	2449591-00023	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 / Procaine Hydrochloride / Piroxicam Liquid 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)

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 - single exposure, Category 2	H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :

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.
H371 May cause damage to organs.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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
Procaine hydrochloride

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3 %

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.

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	>= 10 - < 20
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	>= 10 - < 20
Procaine hydrochloride	51-05-8 200-077-2	Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Sens. 1; H317 Repr. 1A; H360D STOT SE 1; H370 (Nervous system, Heart)	>= 1 - < 10
Piroxicam	36322-90-4 252-974-3	Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372 (Gastrointestinal tract)	>= 1 - < 3

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 : 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.
May cause damage to organs.
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).

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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Oxides of phosphorus
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.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
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.
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

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/m3 (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm2	Internal
Streptomycin sulphate	3810-74-0	TWA	OEB 2 (>= 100 < 1,000 µg/m3)	Internal
	Further information: DSEN			
Procaine hydrochloride	51-05-8	TWA	60 µg/m3 (OEB 3)	Internal
		Wipe limit	600 µg/100 cm²	Internal
Piroxicam	36322-90-4	TWA	100 µg/m3 (OEB 2)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Potassium dihydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	14,82 mg/m3
	Consumers	Inhalation	Long-term systemic effects	6,35 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day
Dipotassium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	19,1 mg/m3

	Consumers	Inhalation	Long-term systemic effects	8,17 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day

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 appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

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

Hand protection
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

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

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	:	Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 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

Procaine hydrochloride:

Acute oral toxicity	:	LD50 (Rat): 200 mg/kg
		LD50 (Mouse): 350 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 43 mg/kg Application Route: Intravenous
		LD50 (Mouse): 33 mg/kg Application Route: Intravenous
		LD50 (Dog): 33 mg/kg Application Route: Intravenous

Piroxicam:

Acute oral toxicity	:	LD50 (Rat): 216 mg/kg
		LD50 (Dog): 108 mg/kg
		LD50 (Hamster): 170 mg/kg
		LD50 (Guinea pig): 388 mg/kg
		LD50 (Monkey): 1.000 mg/kg
Acute dermal toxicity	:	LD50 (Rat): > 5.000 mg/kg

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

Procaine hydrochloride:

Result : Moderate eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Benzylpenicillin:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Dermal
Species	:	Mouse
Result	:	Weak sensitizer

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	positive
Remarks	:	Based on data from similar materials

Result	:	Strong sensitizer
Remarks	:	Based on human experience.

Streptomycin sulphate:

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

Procaine hydrochloride:

Exposure routes	:	Dermal
Result	:	Sensitiser
Remarks	:	Based on human experience. Based on data from similar materials

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

Procaine hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: equivocal

Piroxicam:

Genotoxicity in vivo : Test Type: sister chromatid exchange assay
Species: Humans
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

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.

Procaine hydrochloride:

Reproductive toxicity - Assessment : May damage the unborn child.

Piroxicam:

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight

Symptoms: foetal mortality
Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,4 - 4 mg/kg body weight
Result: Effects on foetal development

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: No embryo-foetal toxicity

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

May cause damage to organs.

Components:

Procaine hydrochloride:

Target Organs : Nervous system, Heart
Assessment : Causes damage to organs.

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.

Piroxicam:

Target Organs : Gastrointestinal tract
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
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

Procaine hydrochloride:

Inhalation : Target Organs: Central nervous system
Symptoms: nervousness, Dizziness, Convulsions, Breathing difficulties, Rash, Swelling of tissue, irregular heart beat
Remarks: May cause harm to the unborn child.
Based on clinical use
Target Organs: Heart
Symptoms: nervousness, Dizziness, Convulsions, Breathing difficulties, Rash, Swelling of tissue, irregular heart beat
Remarks: May cause harm to the unborn child.
Based on clinical use

Piroxicam:

Ingestion : Target Organs: Gastrointestinal tract
Symptoms: Diarrhoea, constipation, flatulence, Headache, Dizziness, tinnitus, skin rash, Ulceration, chest pain, Abdominal pain

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
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

Procaine hydrochloride:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Piroxicam:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

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

Procaine hydrochloride:

Partition coefficient: n-octanol/water	:	log Pow: 2,14

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 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

14.2 UN proper shipping name

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

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	:	M6
Hazard Identification Number	:	90
Labels	:	9

ADR

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

RID

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

IMDG

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

IATA (Cargo)

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

IATA (Passenger)

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

14.5 Environmental hazards

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

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

H301 : Toxic if swallowed.
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.
H361 : Suspected of damaging fertility or the unborn child.
H370 : Causes damage to organs.
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
STOT SE	:	Specific target organ toxicity - single 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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: **Classification procedure:**

Eye Irrit. 2	H319	Calculation method
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360D	Calculation method
STOT SE 2	H371	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	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.

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