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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid **Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2456209-00025 6.4 28.09.2024 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 Hydrochlo-

ride / Piroxicam Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-: Veterinary product

stance/Mixture

Recommended restrictions Not applicable

on use

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)

Eye irritation, Category 2 H319: Causes serious eye irritation.

H334: May cause allergy or asthma symptoms or Respiratory sensitisation, Category 1

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 ex-H371: May cause damage to organs.

posure, Category 2

Specific target organ toxicity - repeated

exposure, Category 1

Short-term (acute) aguatic hazard, Cate-

gory 1

H372: Causes damage to organs through pro-

longed or repeated exposure.

H400: Very toxic to aquatic life.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

¥2

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 breath-

ing 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.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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.

### **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,	>= 1 - < 10

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

	1	Heart)	
Piroxicam	36322-90-4	Acute Tox. 3; H301	>= 1 - < 3
	252-974-3	Repr. 2; H361	
		STOT RE 1; H372	
		(Gastrointestinal	
		tract)	

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 ad-

vice 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 difficul-

ties if inhaled.

May damage the unborn child.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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, reac-

tive 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 prod- :

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

#### **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 pro-

tective 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 absor-

bent.

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 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 : 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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

practice, based on the results of the workplace exposure as-

sessment

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 respira-

tory 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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

	Further information: DSEN			
Procaine hydro- chloride	51-05-8	TWA	60 μg/m3 (OEB 3)	Internal
		Wipe limit	600 μg/100 cm <sup>2</sup>	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 dihy- drogenorthophos- phate	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 hy- drogenorthophos- phate	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 expo-

sure assessment demonstrates exposures outside the rec-

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

### **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

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 : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

# **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure Skin contact

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

**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.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

### 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- As-

sessment

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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

**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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

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 develop-

ment

Test Type: Development

Species: Mouse

Result: No effects on foetal development

Test Type: Development

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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 develop-

ment

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 - As-

sessment

May damage the unborn child.

**Procaine hydrochloride:** 

Reproductive toxicity - As-

sessment

May damage the unborn child.

Piroxicam:

Effects on foetal develop-

ment

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.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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 - As-

sessment

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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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.

### 11.2 Information on other hazards

### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

(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, bron-

chospasm, skin rash

Streptomycin sulphate:

Inhalation : Target Organs: inner ear

Symptoms: hearing loss Target Organs: Kidney Symptoms: hearing loss Symptoms: skin rash

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, Ab-

dominal 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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid **Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 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 tox- :

icity)

1

EC50 : > 500 mg/l Toxicity to microorganisms 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 tox- :

icity)

100

Toxicity to daphnia and other : aquatic invertebrates (Chron-

NOEC: 32 mg/l Exposure time: 21 d

19/26

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

ic toxicity) 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-

: log Pow: 2.14

octanol/water

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

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

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 consid-

ered 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.

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 han-

dling 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 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)

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

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)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

22 / 26

964

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.4
 28.09.2024
 2456209-00025
 Date of first issue: 13.02.2018

IATA (Passenger)

Packing instruction (passen- : 964

ger aircraft)

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 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) Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is appli-

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

cable to the placing on the market or

not.

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

: Not applicable

Regulation (EC) on substances that deplete the ozone

layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

ianis (recasi)

: Not applicable

Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

: Not applicable

REACH - List of substances subject to authorisation

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1

Quantity 2

E1 ENVIRONMENTAL

**HAZARDS** 

100 t 200 t

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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 difficul-

ties if inhaled.

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 6.4	Revision Date: 28.09.2024	SDS Numbe 2456209-00	
H360E	)	: May dar	nage the unborn child.
H361		: Suspect	ed of damaging fertility or the unborn child.
H370		: Causes	damage to organs.
H372		: Causes	damage to organs through prolonged or repeated
		exposur	e.
H400		: Very tox	ic to aquatic life.
H410		: Very tox	ic to aquatic life with long lasting effects.

Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

H412

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; TRGS - Technical Rule for Hazardous Substances; TSCA

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



# Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.4 28.09.2024 2456209-00025 Date of first issue: 13.02.2018

- Toxic Substances Control Act (United States); UN - United Nations; 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 Agen-

cy, 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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