

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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**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

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**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.                      |

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| 7.0     | 14.04.2025     | 2449591-00024 | 30.09.2023                      |
|         |                |               | Date of first issue: 13.02.2018 |

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

Hazard statements :

- 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

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**

**Benzylpenicillin / Streptomycin Sulphate /  
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Version 7.0      Revision Date: 14.04.2025      SDS Number: 2449591-00024      Date of last issue: 30.09.2023  
Date of first issue: 13.02.2018

| Chemical name          | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification  | Concentration<br>(% w/w) |
|------------------------|---|---|--------------------------|
| Benzylpenicillin       | 61-33-6<br>200-506-3                                  | Resp. Sens. 1A;<br>H334<br>Skin Sens. 1B;<br>H317<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 3;<br>H412<br><br>M-Factor (Acute<br>aquatic toxicity): 1  | >= 10 - < 20             |
| Streptomycin sulphate  | 3810-74-0<br>223-286-0                                | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B;<br>H317<br>Repr. 1A; H360D<br>STOT RE 1; H372<br>(Kidney, inner ear)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity):<br>100<br>M-Factor (Chronic<br>aquatic toxicity):<br>100 | >= 10 - < 20             |
| Procaine hydrochloride | 51-05-8<br>200-077-2                                  | Acute Tox. 3; H301<br>Eye Irrit. 2; H319<br>Skin Sens. 1; H317<br>Repr. 1A; H360D<br>STOT SE 1; H370<br>(Nervous system,<br>Heart)  | >= 1 - < 10              |
| Piroxicam              | 36322-90-4<br>252-974-3                               | Acute Tox. 3; H301<br>Repr. 2; H361<br>STOT RE 1; H372<br>(Gastrointestinal<br>tract)   | >= 1 - < 3               |

For explanation of abbreviations see section 16.

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|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**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.<br>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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.   |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.   |

**4.2 Most important symptoms and effects, both acute and delayed**

- |       |   |  |
|-------|---|--|
| Risks | : | Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br><br>May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>May damage the unborn child.<br>May cause damage to organs.<br>Causes damage to organs through prolonged or repeated exposure. |
|-------|---|--|

**4.3 Indication of any immediate medical attention and special treatment needed**

- |           |   |   |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

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Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
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.

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**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.

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|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

---

## 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.

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## 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.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures        | : If exposure to chemical is likely during typical use, provide eye 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.<br>Wash contaminated clothing before re-use.<br>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  |

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|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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/m <sup>3</sup> (OEB 2)             | Internal |
| Further information: RSEN, DSEN |            |                               |   |          |
|                                 |            | Wipe limit                    | 100 µg/100 cm <sup>2</sup>                | Internal |
| Streptomycin sulphate           | 3810-74-0  | TWA                           | OEB 2 (>= 100 < 1,000 µg/m <sup>3</sup> ) | Internal |
| Further information: DSEN       |            |                               |   |          |
| Procaine hydrochloride          | 51-05-8    | TWA                           | 60 µg/m <sup>3</sup> (OEB 3)              | Internal |
|                                 |            | Wipe limit                    | 600 µg/100 cm <sup>2</sup>                | Internal |
| Piroxicam                       | 36322-90-4 | TWA                           | 100 µg/m <sup>3</sup> (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/m <sup>3</sup> |
|                                    | Consumers | Inhalation      | Long-term systemic effects | 6,35 mg/m <sup>3</sup>  |
|                                    | Consumers | Ingestion       | Long-term systemic effects | 70 mg/kg bw/day         |
| Dipotassium hydrogenorthophosphate | Workers   | Inhalation      | Long-term systemic effects | 19,1 mg/m <sup>3</sup>  |

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

Version 7.0      Revision Date: 14.04.2025      SDS Number: 2449591-00024      Date of last issue: 30.09.2023  
Date of first issue: 13.02.2018

|  |           |            |                            |                        |
|--|-----------|------------|----------------------------|------------------------|
|  | Consumers | Inhalation | Long-term systemic effects | 8,17 mg/m <sup>3</sup> |
|  | 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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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 |



**Benzylpenicillin / Streptomycin Sulphate /  
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Formulation**

|                |                              |                              |   |
|----------------|------------------------------|------------------------------|---|
| Version<br>7.0 | Revision Date:<br>14.04.2025 | SDS Number:<br>2449591-00024 | Date of last issue: 30.09.2023<br>Date of first issue: 13.02.2018 |
|----------------|------------------------------|------------------------------|---|

|  |  |
|--|--|
| 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  |
| 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**

|                  |                     |
|------------------|---------------------|
| Molecular weight | : No data available |
| Particle size    | : Not applicable    |

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**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. |
|---------------------|---|

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**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

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue:             |
| 7.0     | 14.04.2025     | 2449591-00024 | 30.09.2023                      |
|         |                |               | Date of first issue: 13.02.2018 |

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:**

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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|| 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.

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**II****Streptomycin sulphate:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Chromosomal aberration<br>Result: equivocal |
|-----------------------|---|--|

|                      |   |   |
|----------------------|---|---|
| Genotoxicity in vivo | : | Test Type: Chromosomal aberration<br>Cell type: Human lymphocytes<br>Result: negative |
|----------------------|---|---|

**Procaine hydrochloride:**

|                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: equivocal |
|-----------------------|---|---|

**Piroxicam:**

|                      |   |   |
|----------------------|---|---|
| Genotoxicity in vivo | : | Test Type: sister chromatid exchange assay<br>Species: Humans<br>Cell type: Human lymphocytes<br>Result: negative |
|----------------------|---|---|

**Carcinogenicity****II** 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****II** May damage the unborn child.**Components:****Benzylpenicillin:**

|                      |   |   |
|----------------------|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Mouse<br>Result: No effects on fertility |
|----------------------|---|---|

|  |   |   |
|--|---|---|
|  | : | Test Type: Fertility<br>Species: Rat<br>Result: No effects on fertility |
|--|---|---|

|  |   |   |
|--|---|---|
|  | : | Test Type: Fertility<br>Species: Rabbit |
|--|---|---|

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

|                               |  |
|-------------------------------|--|
| Effects on foetal development | Result: No effects on fertility  |
|                               | : Test Type: Development<br>Species: Mouse<br>Result: No effects on foetal development |
|                               | Test Type: Development<br>Species: Rat<br>Result: No effects on foetal development     |
|                               | Test Type: Development<br>Species: Rabbit<br>Result: No effects on foetal development  |

## **Streptomycin sulphate:**

|                                    |  |
|------------------------------------|--|
| Effects on fertility               | : Test Type: Fertility<br>Species: Rat<br>Application Route: Intraperitoneal<br>Fertility: LOAEL: 40 mg/kg body weight<br>Symptoms: male reproductive effects                                |
| Effects on foetal development      | : Test Type: Development<br>Species: Mouse<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 250 mg/kg body weight<br>Symptoms: fetal deafness, Embryo-foetal toxicity |
|                                    | Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 10 mg/kg body weight<br>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<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation |
|                               | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 30 mg/kg body weight   |

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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



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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**Streptomycin sulphate:**

|              |   |   |
|--------------|---|---|
| Inhalation   | : | Target Organs: inner ear<br>Symptoms: hearing loss<br>Target Organs: Kidney<br>Symptoms: hearing loss |
| Skin contact | : | Symptoms: skin rash   |

**Procaine hydrochloride:**

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

**Piroxicam:**

|           |   |  |
|-----------|---|--|
| Ingestion | : | Target Organs: Gastrointestinal tract<br>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<br>Exposure time: 96 hrs<br>Method: OECD Test Guideline 203   |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 3,6 mg/l<br>Exposure time: 48 hrs<br>Method: OECD Test Guideline 202  |
| Toxicity to algae/aquatic plants                    | : | EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201<br><br>NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201<br><br>EC50 (blue-green algae): 0,74 mg/l<br>Exposure time: 72 hrs |

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

|                                   |                                    |
|-----------------------------------|------------------------------------|
|                                   | 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 |

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**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.<br>Biodegradation: 70,10 %<br>Exposure time: 28 d<br>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. |
|--------------------------------|---|

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

|                        |   |  |
|------------------------|---|--|
| Product                | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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.<br>(Benzylpenicillin, Streptomycin sulphate) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Benzylpenicillin, Streptomycin sulphate) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Benzylpenicillin, Streptomycin sulphate) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Benzylpenicillin, Streptomycin sulphate) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Benzylpenicillin, Streptomycin sulphate) |

**14.3 Transport hazard class(es)**

|     | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | :     | 9                |
| ADR | :     | 9                |
| RID | :     | 9                |

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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**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 |
|------------------|-------|

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

**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.                      |

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

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; 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 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:**

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 7.0     | 14.04.2025     | 2449591-00024 | Date of first issue: 13.02.2018 |

|                   |       |                    |
|-------------------|-------|--------------------|
| 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 |

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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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