SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone: +27119239300
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   - Eye irritation, Category 2
     H319: Causes serious eye irritation.
   - Respiratory sensitisation, Category 1
     H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   - Skin sensitisation, Category 1
     H317: May cause an allergic skin reaction.
   - Reproductive toxicity, Category 1A
     H360D: May damage the unborn child.
   - Specific target organ toxicity - single exposure, Category 2
     H371: May cause damage to organs.
   - Specific target organ toxicity - repeated exposure, Category 1
     H372: Causes damage to organs through prolonged or repeated exposure.
   - Short-term (acute) aquatic hazard, Category 1
     H400: Very toxic to aquatic life.
   - Long-term (chronic) aquatic hazard, Category 1
     H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms : 

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D May damage the unborn child.
H371 May cause damage to organs.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P311 IF exposed or concerned: 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
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

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### SECTION 4: First aid measures

**4.1 Description of first aid measures**

**General advice**: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
<th>Health Hazards</th>
<th>Aquatic Hazard</th>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200-506-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>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</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>223-286-0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Sens. 1; H317 Repr. 1A; H360D STOT SE 1; H370 (Nervous system, Heart)</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200-077-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372 (Gastrointestinal tract)</td>
<td></td>
<td>&gt;= 1 - &lt; 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>252-974-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May cause an allergic skin reaction.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage the unborn child.
May cause damage to organs.
Causes damage to organs through prolonged or repeated exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Oxides of phosphorus, Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Technical measures : See Engineering measures under EXPOSURE
CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
SAFETY DATA SHEET
Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 4.8 Revision Date: 28.09.2020 SDS Number: 2449591-00014 Date of last issue: 04.07.2020
Date of first issue: 13.02.2018

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: RSEN, DSEN</td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>TWA</td>
<td>OEB 2 (≥ 100 &lt; 1,000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>TWA</td>
<td>60 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Internal</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium dihydrogenorthophosphate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.82 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6.35 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>70 mg/kg bw/day</td>
</tr>
<tr>
<td>Dipotassium hydrogenorthophosphate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>19.1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>8.17 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>70 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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 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**: 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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

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

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

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure : Inhalation, Skin contact
SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Benzylpenicillin:
Acute oral toxicity : LD50 (Rat): 8.000 mg/kg
LD50 (Mouse): > 5.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 3.500 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 329 mg/kg
Application Route: Intravenous

Streptomycin sulphate:
Acute oral toxicity : LD50 (Hamster): 400 mg/kg
LD50 (Rat): 430 mg/kg
LD50 (Mouse): 25.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 85 - 111 mg/kg
Application Route: Intravenous
LD50 (Mouse): 575 - 610 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 500 - 600 mg/kg
Application Route: Subcutaneous

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

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

TDLo (Monkey): 30 - 70 mg/kg
Application Route: Subcutaneous
Symptoms: respiratory depression

Procaine hydrochloride:
SAFETY DATA SHEET

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Acute oral toxicity
: LD50 (Rat): 200 mg/kg
LD50 (Mouse): 350 mg/kg

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

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

Acute dermal toxicity
: LD50 (Rat): > 5.000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
Streptomycin sulphate:
Result : Mild eye irritation

Procaine hydrochloride:
Result : Moderate eye irritation

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

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

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

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

Result: Strong sensitizer
Remarks: Based on human experience.

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

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

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Benzylpenicillin:**
Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Streptomycin sulphate:**
Genotoxicity in vitro: Test Type: Chromosomal aberration
Result: equivocal

Genotoxicity in vivo: Test Type: Chromosomal aberration
Cell type: Human lymphocytes
Result: negative

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

**Piroxicam:**
### Genotoxicity in vivo
- **Test Type**: sister chromatid exchange assay
- **Species**: Humans
- **Cell type**: Human lymphocytes
- **Result**: negative

### Carcinogenicity
Not classified based on available information.

### Components:

**Streptomycin sulphate:**
- **Species**: Rat
- **Application Route**: Oral
- **NOAEL**: 5 mg/kg body weight
- **Result**: negative
- **Carcinogenicity - Assessment**: Weight of evidence does not support classification as a carcinogen

### Reproductive toxicity
May damage the unborn child.

### Components:

**Benzylpenicillin:**
- **Effects on fertility**
  - **Test Type**: Fertility
  - **Species**: Mouse
  - **Result**: No effects on fertility
  - **Test Type**: Fertility
  - **Species**: Rat
  - **Result**: No effects on fertility
  - **Test Type**: Fertility
  - **Species**: Rabbit
  - **Result**: No effects on fertility

- **Effects on foetal development**
  - **Test Type**: Development
  - **Species**: Mouse
  - **Result**: No effects on foetal development
  - **Test Type**: Development
  - **Species**: Rat
  - **Result**: No effects on foetal development
  - **Test Type**: Development
  - **Species**: Rabbit
  - **Result**: No effects on foetal development

**Streptomycin sulphate:**
- **Effects on fertility**
  - **Test Type**: Fertility
Species: Rat  
Application Route: Intraperitoneal  
Fertility: LOAEL: 40 mg/kg body weight  
Symptoms: male reproductive effects

**Effects on foetal development**

Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 250 mg/kg body weight  
Symptoms: fetal deafness, Embryo-foetal toxicity

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects

**Reproductive toxicity - Assessment**

May damage the unborn child.

**Procaine hydrochloride:**

**Reproductive toxicity - Assessment**

May damage the unborn child.

**Piroxicam:**

**Effects on foetal development**

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

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Symptoms: foetal mortality  
Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation  
Remarks: Maternal toxicity observed.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.4 - 4 mg/kg body weight  
Result: Effects on foetal development

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

STOT - single exposure
May cause damage to organs.

Components:

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

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Components:

Streptomycin sulphate:
Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.

Piroxicam:
Target Organs: Gastrointestinal tract
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Streptomycin sulphate:
Species: Rat
NOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 72 Days
Remarks: No significant adverse effects were reported

Species: Cat
LOAEL: 200 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: inner ear

Species: Dog
LOAEL: 44 mg/kg
Application Route: Intramuscular
Exposure time: 14 Days
Target Organs: inner ear

Species: Dog
LOAEL: 50 - 100 mg/kg
**Application Route:** Intramuscular  
**Exposure time:** 20 Days  
**Target Organs:** inner ear, Kidney  
**Symptoms:** ataxia

**Species:** Monkey  
**NOAEL:** 50 mg/kg  
**LOAEL:** 100 mg/kg  
**Application Route:** Intramuscular  
**Exposure time:** 5 Days  
**Target Organs:** Liver, Kidney

**Species:** Rat  
**NOAEL:** 5 mg/kg  
**Application Route:** Oral  
**Exposure time:** 2 yr  
**Remarks:** No significant adverse effects were reported

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

**Aspiration toxicity**  
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Benzylpenicillin:**  
**Inhalation:** Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

**Streptomycin sulphate:**  
**Inhalation:** Target Organs: inner ear  
Symptoms: hearing loss  
Target Organs: Kidney  
Symptoms: hearing loss  
**Skin contact:** Symptoms: skin rash

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

**Piroxicam:**

**Ingestion**

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

### SECTION 12: Ecological information

#### 12.1 Toxicity: Ecological information

**Components:**

**Benzylpenicillin:**

**Toxicity to fish**

LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

**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
Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants**

EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC50 (blue-green algae): 0,74 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (blue-green algae): 0,14 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

**M-Factor (Acute aquatic toxicity)**

1

**Toxicity to microorganisms**

EC50: > 500 mg/l
Exposure time: 3 h
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Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

NOEC : 5 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Streptomycin sulphate:
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 487 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Microcystis aeruginosa (blue-green algae)): 0.007 mg/l
Exposure time: 72 h
Method: ISO 8692

EC50 (Selenastrum capricornutum (green algae)): 0.133 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 32 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 100

Procaine hydrochloride:

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

Piroxicam:

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded
12.2 Persistence and degradability

**Components:**

**Benzylpenicillin:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 70.10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

**Components:**

**Benzylpenicillin:**
Partition coefficient: n-octanol/water: log Pow: 1.83

**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
Not relevant

12.6 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.

**Contaminated packaging:**
Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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
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Date of first issue: 13.02.2018

Hazard Identification Number : 90
Labels : 9

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

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

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

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-statements**

- **H301**: Toxic if swallowed.
- **H302**: Harmful if swallowed.
- **H317**: May cause an allergic skin reaction.
- **H319**: Causes serious eye irritation.
- **H334**: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **H360D**: May damage the unborn child.
- **H361**: Suspected of damaging fertility or the unborn child.
- **H370**: Causes damage to organs.
- **H372**: Causes damage to organs through prolonged or repeated exposure.
- **H400**: Very toxic to aquatic life.
- **H410**: Very toxic to aquatic life with long lasting effects.
- **H412**: Harmful to aquatic life with long lasting effects.

**Full text of other abbreviations**

- **Acute Tox.**: Acute toxicity
- **Aquatic Acute**: Short-term (acute) aquatic hazard
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Irrit.**: Eye irritation
- **Repr.**: Reproductive toxicity
- **Resp. Sens.**: Respiratory sensitisation
- **Skin Sens.**: Skin sensitisation
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **STOT SE**: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; **ADR** - European Agreement concerning the International Carriage of Dangerous Goods by Road; **AIIC** - Australian Inventory of Industrial Chemicals; **ASTM** - American Society for
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Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
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<tr>
<td>STOT SE 2</td>
<td>H371</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:
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
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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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