SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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
   Walton Manor, Walton
   MK7 7AJ Milton Keynes - United Kingdom
   Telephone: 908-740-4000
   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
   Respiratory sensitisation, Category 1
   Skin sensitisation, Category 1
   Reproductive toxicity, Category 1A
   Specific target organ toxicity - single exposure, Category 2
   Specific target organ toxicity - repeated exposure, Category 1
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1

   H319: Causes serious eye irritation.
   H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   H317: May cause an allergic skin reaction.
   H360D: May damage the unborn child.
   H371: May cause 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.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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:
- 6-(2-Phenylacetamido)penicillanic acid
- 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>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

2 / 24
### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

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

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

---

<table>
<thead>
<tr>
<th>Substance</th>
<th>Registration number</th>
<th>M-Factor (Acute aquatic toxicity):</th>
<th>M-Factor (Chronic aquatic toxicity):</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6 200-506-3</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0 223-286-0</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 Repr. 1A; H360D STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8 200-077-2</td>
<td>Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Sens. 1; H317 Repr. 1A; H360D STOT SE 1; H370</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4 252-974-3</td>
<td>Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
If inhaled:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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

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

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

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

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

SECTION 5: Firefighting measures

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

Unsuitable extinguishing:
None known.
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 and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and dis-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 4.3 Revision Date: 08/14/2019 SDS Number: 2456210-00009 Date of last issue: 19.02.2019
Date of first issue: 13.02.2018

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

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Do not get in eyes. 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. Take care to prevent spills, waste and minimize release to the environment.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>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. 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.</td>
</tr>
</tbody>
</table>

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 Explosives Gases |

7.3 Specific end use(s)
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version: 4.3    Revision Date: 08/14/2019    SDS Number: 2456210-00009    Date of last issue: 19.02.2019

Specific use(s): No data available

No data available
No data available
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>Further information</td>
<td>DSEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>RSEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1,000 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>DSEN</td>
<td></td>
<td></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 600 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 700 µg/100 cm²</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>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6.35 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>70 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Dipotassium dihydrogenorthophosphate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>19.1 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>8.17 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>70 mg/kg</td>
<td></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

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
Flammmability (solid, gas): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 4.3
Revision Date: 08/14/2019
SDS Number: 2456210-00009
Date of last issue: 19.02.2019
Date of first issue: 13.02.2018

9.1 Flammability limit
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available

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

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity
Not classified based on available information.

Product:
- Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:

6-(2-Phenylacetamido)penicillanic acid:
- 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
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006  

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

---  

**Application Route**: Intravenous  
**Symptoms**: Lowered blood pressure  

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

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

---  

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

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

---  

**Piroxicam**:  
**Acute oral toxicity**  
: LD50 (Rat): 216 mg/kg  
: LD50 (Dog): 108 mg/kg  
: LD50 (Hamster): 170 mg/kg  
: LD50 (Guinea pig): 388 mg/kg  
: LD50 (Monkey): 1,000 mg/kg  

**Acute dermal toxicity**  
: LD50 (Rat): > 5,000 mg/kg  

---  

**Skin corrosion/irritation**  
Not classified based on available information.  

**Serious eye damage/eye irritation**  
Causes serious eye irritation.  

---  

**Components**:  

**Streptomycin sulphate**:  
**Result**: Mild eye irritation  

---  

**Procaine hydrochloride**:  

---  

**Note**:  
This document provides a summary of the safety data sheet for the specified compounds. For detailed information, please refer to the complete safety data sheet.  

---  

**Date of last issue**: 19.02.2019  
**Date of first issue**: 13.02.2018  

---  

**MSD**
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:

6-(2-Phenylacetamido)penicillanic acid:
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:

6-(2-Phenylacetamido)penicillanic acid:
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

Procam 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:

6-(2-Phenylacetamido)penicillanic acid:
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
Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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

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

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

  Reproductive toxicity - Assessment: May damage the unborn child.

Procaine hydrochloride:
- Reproductive toxicity - Assessment: May damage the unborn child.

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

  Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: LOAEL: 30 mg/kg body weight
  Symptoms: foetal mortality
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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

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

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

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

STOT - single exposure
May cause damage to organs.

Components:

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

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

Components:

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

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

Repeated dose toxicity

Components:

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

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

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

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

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

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

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

6-(2-Phenylacetamido)penicillanic acid:
Inhalation: Symptoms: Allergic reactions, Abdominal pain, bron-
chospasm, skin rash

**Streptomycin sulphate:**

**Inhalation**

Target Organs: inner ear
Symptoms: hearing loss

**Skin contact**

Target Organs: Kidney
Symptoms: hearing loss

**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

**Skin contact**

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

**Piroxicam:**

**Ingestion**

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

---

### SECTION 12: Ecological information

**12.1 Toxicity**

**Components:**

**6-(2-Phenylacetamido)penicillanic acid:**

**Toxicity to fish**

LC50 (Oryzias latipes (Japanese medaka)): 1,000 mg/l
Exposure time: 96 hrs
Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**

EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 hrs
Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants**

EC50 (Anabaena flos-aquae): 0.006 mg/l
Exposure time: 96 hrs
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 hrs
Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-): 100
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid
Formulation

Version: 4.3
Revision Date: 08/14/2019
SDS Number: 2456210-00009
Date of last issue: 19.02.2019
Date of first issue: 13.02.2018

M-Factor (Chronic aquatic toxicity): 100

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

**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:**

6-(2-Phenylacetamido)penicillanic acid:
Biodegradability: Biodegradation: 27 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
12.3 Bioaccumulative potential

**Components:**

- **6-(2-Phenylacetamido)penicillanic acid:**
  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

- **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. (6-(2-Phenylacetamido)penicillanic acid, Streptomycin sulphate)

**ADR**
- ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid, Streptomycin sulphate)

**RID**
- ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid, Streptomycin sulphate)

**IMDG**
- ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid, Streptomycin sulphate)

**IATA**
- Environmentally hazardous substance, liquid, n.o.s. (6-(2-Phenylacetamido)penicillanic acid, 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
- Hazard Identification Number: 90
- Labels: 9
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation : Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

(Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:
Number on list 3


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity 1</td>
<td>100 t</td>
</tr>
<tr>
<td>Quantity 2</td>
<td>200 t</td>
</tr>
</tbody>
</table>

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 difficulties if inhaled.
H360D: May damage the unborn child.
H361: Suspected of damaging fertility or the unborn child.
H370: Causes damage to organs.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate /
Procaine Hydrochloride / Piroxicam Liquid
Formulation

Version 4.3
Revision Date: 08/14/2019
SDS Number: 2456210-00009
Date of last issue: 19.02.2019
Date of first issue: 13.02.2018

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.

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; AICS - Australian Inventory of Chemical Substances; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 4.3 Revision Date: 08/14/2019 SDS Number: 2456210-00009 Date of last issue: 19.02.2019
Date of first issue: 13.02.2018


Classification of the mixture:

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

STOT SE 2

STOT RE 1

Aquatic Acute 1

Aquatic Chronic 1

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.

GB / EN