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
Kilsheelan
Clonmel Tipperary, IE

Telephone: 353-51-601000

E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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
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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</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>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>200-506-3</td>
<td></td>
<td></td>
<td>Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>223-286-0</td>
<td></td>
<td></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>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>200-077-2</td>
<td></td>
<td></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>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>252-974-3</td>
<td></td>
<td></td>
<td>Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372 (Gastrointestinal tract)</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
4.1 Description of first aid measures

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

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

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child. May cause damage to organs. Causes damage to organs through prolonged or repeated exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
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Benzylpenicillin / Streptomycin Sulphate / 
Procaine Hydrochloride / Piroxicam Liquid 
Formulation

Version 4.10  Revision Date: 27.08.2021  SDS Number: 2456209-00016  Date of last issue: 09.04.2021
Date of first issue: 13.02.2018

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

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during 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
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6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitised individuals 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 barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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
- 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></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: RSEN, DSEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: DSEN</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>Wipe limit</td>
<td>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 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></td>
<td></td>
<td>Long-term systemic effects</td>
<td>19.1 mg/m³</td>
</tr>
</tbody>
</table>
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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
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.
Equipment should conform to I.S. EN 143
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Physical state: liquid
Colour: No data available
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
### 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</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>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosives</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of 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:

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.10</td>
<td>27.08.2021</td>
<td>2456209-00016</td>
<td>09.04.2021</td>
<td>13.02.2018</td>
</tr>
</tbody>
</table>

**Application Route:** Intravenous

**LD50 (Mouse):** 575 - 610 mg/kg

**Application Route:** Intraperitoneal

**LD50 (Mouse):** 500 - 600 mg/kg

**Application Route:** Subcutaneous

**TDLO (Dog):** 220 - 440 mg/kg

**Application Route:** Intravenous

**Symptoms:** Lowered blood pressure

**LDLO (Monkey):** 110 mg/kg

**Application Route:** Intravenous

**TDLO (Monkey):** 30 - 70 mg/kg

**Application Route:** Subcutaneous

**Symptoms:** respiratory depression

### Procaine hydrochloride:

**Acute oral toxicity**

: **LD50 (Rat):** 200 mg/kg

: **LD50 (Mouse):** 350 mg/kg

**Acute toxicity (other routes of administration)**

: **LD50 (Rat):** 43 mg/kg

**Application Route:** Intravenous

: **LD50 (Mouse):** 33 mg/kg

**Application Route:** Intravenous

: **LD50 (Dog):** 33 mg/kg

**Application Route:** Intravenous

### Piroxicam:

**Acute oral toxicity**

: **LD50 (Rat):** 216 mg/kg

: **LD50 (Dog):** 108 mg/kg

: **LD50 (Hamster):** 170 mg/kg

: **LD50 (Guinea pig):** 388 mg/kg

: **LD50 (Monkey):** 1,000 mg/kg

**Acute dermal toxicity**

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

### Skin corrosion/irritation

Not classified based on available information.
**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

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

**Procaine hydrochloride:**
Result : Moderate eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

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

**Components:**

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

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

Result : Strong sensitizer
Remarks : Based on human experience.

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

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

Streptomycin sulphate:
Effects on fertility:

Test Type: Fertility
Species: Rat
Application Route: Intraperitoneal
Fertility: LOAEL: 40 mg/kg body weight
Symptoms: male reproductive effects

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

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

Reproductive toxicity - Assessment:
May damage the unborn child.

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

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

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

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

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.

**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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: 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.

Experience with human exposure

Components:

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

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

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

Piroxicam:
Ingestion: Target Organs: Gastrointestinal tract
Symptoms: Diarrhoea, constipation, flatulence, Headache, Dizziness, tinnitus, skin rash, Ulceration, chest pain, Abdominal pain
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Benzylpenicillin:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 hrs  
Method: OECD Test Guideline 203  
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  
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

M-Factor (Chronic aquatic toxicity): 100

**Procaine hydrochloride:**

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

Chronic aquatic toxicity: Toxic effects cannot be excluded

**Piroxicam:**

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

Chronic aquatic toxicity: Toxic effects cannot be excluded

12.2 Persistence and degradability

**Components:**

**Benzylpenicillin:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 70.10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
12.3 Bioaccumulative potential

Components:

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

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 Endocrine disrupting properties

Product:
Assessment : 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.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste han-
SAFETY DATA SHEET
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Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

SECTION 14: Transport information

14.1 UN number or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 3082</th>
</tr>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
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</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)</th>
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<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)</td>
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<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Benzylpenicillin, Streptomycin sulphate)</td>
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14.3 Transport hazard class(es)

<table>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
<td>9</td>
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<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
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</tbody>
</table>

14.4 Packing group

<table>
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<tr>
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<tbody>
<tr>
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<tr>
<td>Hazard Identification Number</td>
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<tr>
<td>Labels</td>
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<tr>
<td>ADR</td>
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</tbody>
</table>
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

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

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

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

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

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
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Date of first issue: 13.02.2018

14.7 Maritime transport in bulk according to IMO instruments

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:
Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): 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 - List of substances subject to authorisation (Annex XIV): Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
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<tbody>
<tr>
<td></td>
<td>Quantity 1</td>
</tr>
<tr>
<td></td>
<td>100 t</td>
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</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.
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Procaine Hydrochloride / Piroxicam Liquid
Formulation

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; AIC - 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)
SAFETY DATA SHEET
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Further information

Classification of the mixture:

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

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.

IE / EN