SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 4.9
Revision Date: 2021/08/27
SDS Number: 2449561-00015
Date of last issue: 2020/09/28
Date of first issue: 2018/02/13

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation: Category 2B
Respiratory sensitisation: Category 1
Skin sensitisation: Category 1
Reproductive toxicity: Category 1A
Specific target organ toxicity - single exposure: Category 2 (Nervous system, Heart)
Specific target organ toxicity - repeated exposure: Category 1 (Kidney, inner ear)
Specific target organ toxicity - repeated exposure: Category 2 (Gastrointestinal tract)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
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Hazard pictograms:

Signal word: Danger

Hazard statements:
H317 May cause an allergic skin reaction.  
H320 Causes 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 (Nervous system, Heart).  
H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure.  
H373 May cause damage to organs (Gastrointestinal tract) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
P284 Wear respiratory protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3 %

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>&gt;= 10 - &lt; 25</td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>&gt;= 10 - &lt; 25</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

4. 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.

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.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficul-
ties 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).

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).

Notes to physician:
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

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

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.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for:
Soak up with inert absorbent material.
containment and cleaning up

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.

7. HANDLING AND STORAGE

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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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></td>
<td>Further information: RSEN, DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<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>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>

### 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

#### Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Hand protection</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particulates type</td>
<td></td>
<td>Chemical-resistant gloves</td>
</tr>
</tbody>
</table>

#### 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.

#### Skin and body protection
Work uniform or laboratory coat.
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.

### Appearance
liquid

### Colour
No data available

### Odour
No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
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<tr>
<td>pH</td>
<td>No data available</td>
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<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<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>Flammability (liquids)</td>
<td>No data available</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>
<tr>
<td>Solubility(ies)</td>
<td></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>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</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>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity: Not classified based on available information.

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

Components:

Benzylpenicillin:
Acute oral toxicity: LD50 (Rat): 8,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): 3,500 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 329 mg/kg
Application Route: Intravenous

Streptomycin sulphate:
Acute oral toxicity: LD50 (Hamster): 400 mg/kg
LD50 (Rat): 430 mg/kg
LD50 (Mouse): 25,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): 85 - 111 mg/kg
Application Route: Intravenous
LD50 (Mouse): 575 - 610 mg/kg
Application Route: Intraperitoneal
## Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute toxicity (other routes of administration)</th>
<th>Skin corrosion/irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procaine hydrochloride</td>
<td>LD50 (Rat): 200 mg/kg</td>
<td>LD50 (Rat): 43 mg/kg</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 350 mg/kg</td>
<td>LD50 (Mouse): 33 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 (Dog): 33 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td>Piroxicam</td>
<td>LD50 (Rat): 216 mg/kg</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): 108 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Hamster): 170 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Guinea pig): 388 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Monkey): 1,000 mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### LD50

- **Application Route**: Subcutaneous
- **Symptoms**: Lowered blood pressure

### TDLo

- **Application Route**: Intravenous
- **Symptoms**: Respiratory depression

### LDLo

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

### Acute dermal toxicity

**LD50 (Rat):** 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
  - LD50 (Mouse): 33 mg/kg
  - 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 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
Remarks : Maximisation Test
Remarks : Dermal
Remarks : Guinea pig
Remarks : positive
Remarks : Based on data from similar materials
Remarks : 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.
Remarks : 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.
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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:

- 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 mortality
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 (Nervous system, Heart).

**Components:**

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

**STOT - repeated exposure**
Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure.
May cause damage to organs (Gastrointestinal tract) 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
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**Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<th>Date of last issue</th>
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</thead>
<tbody>
<tr>
<td>4.9</td>
<td>2021/08/27</td>
<td>2449561-00015</td>
<td>2020/09/28</td>
<td>2018/02/13</td>
</tr>
</tbody>
</table>

**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:**
**SAFETY DATA SHEET**

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

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**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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

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

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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

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

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

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
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.
14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Benzylpenicillin, Streptomycin sulphate)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Benzylpenicillin, Streptomycin sulphate)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Benzylpenicillin, Streptomycin sulphate)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA
SAFETY DATA SHEET

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- 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; KEIC - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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