SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 5.5  Revision Date: 27.08.2021  SDS Number: 2449588-00015  Date of last issue: 28.09.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier’s details
Company: MSD
Address: Rua Coronel Bento Soares, 530 Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral): Category 5
Eye irritation: Category 2B
Respiratory sensitization: Category 1
Skin sensitization: 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
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GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:

Signal Word: Danger

Hazard Statements:
H303 May be harmful if swallowed.
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.
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.

Additional Labeling
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>Respiratory sensitization, Sub-category 1A Skin sensitization, Sub-category 1B</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
</tbody>
</table>
## SECTION 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute toxicity (Oral), Category</th>
<th>Ocular irritation, Category</th>
<th>Skin sensitization, Sub-category</th>
<th>Reproductive toxicity, Category</th>
<th>Specific target organ toxicity - single exposure (Organ System), Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Streptomycin sulphate</td>
<td>Category 4</td>
<td>Category 2B</td>
<td>Category 1B</td>
<td>Category 1A</td>
<td>Category 1</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>Category 3</td>
<td>Category 2B</td>
<td>Category 1</td>
<td>Category 1A</td>
<td>Category 1</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>Category 3</td>
<td></td>
<td></td>
<td>Category 2</td>
<td>Category 1</td>
</tr>
</tbody>
</table>
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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 be harmful if swallowed. May cause an allergic skin reaction. Causes 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).

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulfur 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 containment and cleaning up: Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOANL 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 vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practices.
practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Already sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

Conditions for safe storage: Keep in properly labeled 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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Wipe limit 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>Wipe limit 600 µg/100 cm²</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></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 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN, DSEN

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-
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.

Filter type: Particulates type
Hand protection Material: Chemical-resistant gloves

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: No data available
Odor: No data available
Odor 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
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET

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Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Density: No data available
Solubility(ies):
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity:
  Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
May be harmful if swallowed.

Product:
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Acute oral toxicity: Acute toxicity estimate: 2.447 mg/kg Method: Calculation method

Components:

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

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

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

Acute toxicity (other routes of administration): LD50 (Mouse): 85 - 111 mg/kg
Application Route: Intravenous
LD50 (Mouse): 575 - 610 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 500 - 600 mg/kg
Application Route: Subcutaneous
TDLo (Dog): 220 - 440 mg/kg
Application Route: Intravenous
Symptoms: Lowered blood pressure

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

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

Procaine hydrochloride:
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 eye irritation.

Components:
Streptomycin sulphate:
Result: Mild eye irritation

Procaine hydrochloride:
Result: Moderate eye irritation

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

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

Components:
Benzylpenicillin:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Dermal
Species: Mouse
Result: Weak sensitizer

: Maximization Test
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Dermal: Guinea pig: 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)
Routes of exposure: Dermal
Species: Humans
Result: Weak sensitizer

Procaine hydrochloride:
Routes of exposure: Dermal
Result: Sensitizer
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.

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 fetal development: Test Type: Development
Species: Mouse
Result: No effects on fetal development.

Test Type: Development
Species: Rat
Result: No effects on fetal development.

Test Type: Development
Species: Rabbit
Result: No effects on fetal 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 fetal development:
- **Test Type:** Development
  - **Species:** Mouse
  - **Application Route:** Intraperitoneal
  - **Developmental Toxicity:** LOAEL: 250 mg/kg body weight
  - **Symptoms:** fetal deafness, Embryo-fetal 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 fetal development:
- **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 10 mg/kg body weight
  - **Result:** Embryo-fetal toxicity., No teratogenic effects., Fetal growth retardation

  **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 30 mg/kg body weight
  - **Symptoms:** Fetal mortality.
  - **Result:** Embryo-fetal 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 fetal development.

  **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: 10 mg/kg body weight
  - **Result:** No embryo-fetal 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
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
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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 y
Remarks: No significant adverse effects were reported

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

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

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

Piroxicam:
Ingestion: Target Organs: Gastrointestinal tract
SECTION 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

- **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
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</tr>
</tbody>
</table>

- **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

SECTION 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.

SECTION 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
SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 5.5  Revision Date: 27.08.2021  SDS Number: 2449588-00015  Date of last issue: 28.09.2020
Date of first issue: 13.02.2018

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.

Domestic regulation

ANTT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
Further information
Sources of key data used to compile the Material Safety Data Sheet:

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
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ERG - Emergency Response Guide
- 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
- I50 - Half maximal inhibitory concentration
- ICAO - International Civil Aviation Organization
- IECSC - Inventory of Existing Chemical Substances in China
- IC50 - Half maximal inhibitory concentration
- IC50 - Lethal Concentration to 50% of a test population
- 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
- 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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