SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation: Category 2B
Respiratory sensitization: Category 1
Skin sensitization: Category 1
Reproductive toxicity: Category 1A
Specific target organ toxicity - single exposure: Category 1 (Nervous system, Heart)
Specific target organ toxicity - repeated exposure: Category 1 (Kidney, inner ear, Gastrointestinal tract)

GHS label elements
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.
H360 May damage fertility or the unborn child.
H370 Causes damage to organs (Nervous system, Heart).
H372 Causes damage to organs (Kidney, inner ear, Gastrointestinal tract) through prolonged or repeated exposure.
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 vapors.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves, protective clothing, eye protection and face protection.
- P285 In case of inadequate ventilation wear respiratory protection.

**Response:**
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P304 + P341 IF INHALED: If breathing is difficult, 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.
- P307 + P311 IF exposed: Call a doctor.
- P333 + P313 IF skin irritation or rash occurs: Get medical attention.
- P337 + P313 IF eye irritation persists: Get medical attention.
- P363 Wash contaminated clothing before reuse.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<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>18.33</td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>3810-74-0</td>
<td>10.5</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>2</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES
SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 5.4  Revision Date: 08/27/2021  SDS Number: 2449593-00015  Date of last issue: 09/28/2020  Date of first issue: 02/13/2018

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 difficulties if inhaled. May damage fertility or the unborn child. Causes 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  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 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/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 vapors.
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
SAFETY DATA SHEET

Benzy1penicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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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.

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>Benzy1penicillin</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>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., dripless 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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided
by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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.

**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.

### 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
SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
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
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: 2,446 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
TDL0 (Dog): 220 - 440 mg/kg
Application Route: Intravenous
Symptoms: Lowered blood pressure
LDLo (Monkey): 110 mg/kg
Application Route: Intravenous
SAFETY DATA SHEET

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**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

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

Procaine hydrochloride:
Routes of exposure: Dermal
Result: Sensitizer
Remarks: Based on human experience.

Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Streptomycin sulphate:
Genotoxicity in vitro: Test Type: Chromosomal aberration
Result: equivocal
Genotoxicity in vivo:
Test Type: Chromosomal aberration
Cell type: Human lymphocytes
Result: negative

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

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

Carcinogenicity
Not classified based on available information.

Components:

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage fertility or the unborn child.

Components:

Benzy1penicillin:
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**  
Species: Mouse  
Result: No effects on fetal development.

Species: Rat  
Result: No effects on fetal development.

Species: Rabbit  
Result: No effects on fetal development.

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

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

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**  
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**
Causes 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, 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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>100 mg/kg</td>
<td>Subcutaneous</td>
<td>72 Days</td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat</td>
<td>200 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>inner ear</td>
</tr>
<tr>
<td>Dog</td>
<td>44 mg/kg</td>
<td>Intramuscular</td>
<td>14 Days</td>
<td>inner ear</td>
</tr>
<tr>
<td>Dog</td>
<td>50 - 100 mg/kg</td>
<td>Intramuscular</td>
<td>20 Days</td>
<td>inner ear, Kidney</td>
</tr>
<tr>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Intramuscular</td>
<td>5 Days</td>
<td>Blood, Liver, Kidney</td>
</tr>
<tr>
<td>Rat</td>
<td>5 mg/kg</td>
<td>Oral</td>
<td>2 y</td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td>25 mg/kg</td>
<td>Subcutaneous</td>
<td>66 Days</td>
<td>Blood, Liver, Kidney</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.
Experience with human exposure

**Components:**

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

**Streptomycin sulphate:**
- **Inhalation:***Target Organs:** inner ear
  - **Symptoms:** hearing loss
  - **Target Organs:** Kidney
  - **Symptoms:** hearing loss

- **Skin contact:**
  - **Symptoms:** skin rash

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

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

**Piroxicam:**
- **Ingestion:**
  - **Target Organs:** Gastrointestinal tract
  - **Symptoms:** Diarrhea, constipation, flatulence, Headache, Dizziness, tinnitus, skin rash, Ulceration, chest pain, Abdominal pain

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

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

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
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
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

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Benzylpenicillin, Streptomycin sulphate)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Benzylpenicillin, Streptomycin sulphate)
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Serious eye damage or eye irritation

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Water: 7732-18-5
- Benzylpenicillin: 61-33-6
- Streptomycin sulphate: 3810-74-0

California Prop. 65
WARNING: This product can expose you to chemicals including Streptomycin sulphate, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
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</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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.
SAFETY DATA SHEET

Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 5.4   Revision Date: 08/27/2021   SDS Number: 2449593-00015   Date of last issue: 09/28/2020

Revision Date: 08/27/2021

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.

US / Z8