

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

Version 9.0      Revision Date: 2023/09/30      SDS Number: 2449558-00023      Date of last issue: 2023/04/04  
Date of first issue: 2018/02/13

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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## 2. HAZARDS IDENTIFICATION

### GHS classification of chemical product

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

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Long-term (chronic) aquatic hazard : Category 1

## 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.  
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.

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P337 + P313 If eye irritation persists: Get medical advice/ attention.  
 P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
 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

Substance / Mixture : Mixture

**Components**

| Chemical name          | CAS-No.    | Concentration (% w/w) | ENCS No. |
|------------------------|------------|-----------------------|----------|
| Benzylpenicillin       | 61-33-6    | >= 10 - < 20          |          |
| Streptomycin sulphate  | 3810-74-0  | >= 10 - < 20          |          |
| Procaine hydrochloride | 51-05-8    | >= 1 - < 10           |          |
| Piroxicam              | 36322-90-4 | >= 1 - < 3            |          |

### 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.

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- In case of eye contact : Thoroughly clean shoes before reuse.  
: 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 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 (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)  
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.

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## 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 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

### Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Do not eat, drink or smoke when using this product.

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Avoidance of contact : Take care to prevent spills, waste and minimize release to the environment.  
Hygiene measures : Oxidizing agents  
: 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.

## Storage

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  
Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

| Components             | CAS-No.                         | Value type (Form of exposure) | Control parameters / Reference concentration / Permissible concentration | Basis    |
|------------------------|---------------------------------|-------------------------------|--|----------|
| Benzylpenicillin       | 61-33-6                         | TWA                           | 600 µg/m <sup>3</sup> (OEB 2)  | Internal |
|                        | Further information: RSEN, DSEN |                               |  |          |
|                        |                                 | Wipe limit                    | 100 µg/100 cm <sup>2</sup>   | Internal |
| Streptomycin sulphate  | 3810-74-0                       | TWA                           | OEB 2 (>= 100 < 1,000 µg/m <sup>3</sup> )                                | Internal |
|                        | Further information: DSEN       |                               |  |          |
| Procaine hydrochloride | 51-05-8                         | TWA                           | 60 µg/m <sup>3</sup> (OEB 3)   | Internal |
|                        |                                 | Wipe limit                    | 600 µg/100 cm <sup>2</sup>   | Internal |
| Piroxicam              | 36322-90-4                      | TWA                           | 100 µg/m <sup>3</sup> (OEB 2)  | Internal |

Engineering measures : Use appropriate engineering controls and manufacturing

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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.   |
| Filter type              | : | Particulates type  |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Eye protection           | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.   |

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

- |  |   |                   |
|--|---|-------------------|
| Physical state   | : | liquid            |
| Colour   | : | No data available |
| Odour  | : | No data available |
| Odour Threshold  | : | No data available |
| Melting point/freezing point   | : | No data available |
| Boiling point, initial boiling point and boiling range               | : | No data available |
| Flammability (solid, gas)  | : | Not applicable    |
| Flammability (liquids)   | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : |                   |
| Upper explosion limit / Upper flammability limit                     | : | No data available |
| Lower explosion limit / Lower flammability limit                     | : | No data available |

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|  |   |  |
|--|---|--|
| Flash point                            | : | No data available  |
| Decomposition temperature              | : | No data available  |
| pH                                     | : | No data available  |
| Evaporation rate                       | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Viscosity                              |   |  |
| Viscosity, kinematic                   | : | No data available  |
| Solubility(ies)                        |   |  |
| Water solubility                       | : | No data available  |
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Vapour pressure                        | : | No data available  |
| Density and / or relative density      |   |  |
| Relative density                       | : | No data available  |
| Density                                | : | No data available  |
| Relative vapour density                | : | No data available  |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | No data available  |
| Particle characteristics               |   |  |
| Particle size                          | : | Not applicable   |

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**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. |



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## 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  
 LD50 (Mouse): 500 - 600 mg/kg  
 Application Route: Subcutaneous  
 TDLo (Dog): 220 - 440 mg/kg  
 Application Route: Intravenous  
 Symptoms: Lowered blood pressure

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

TDL<sub>o</sub> (Monkey): 30 - 70 mg/kg  
Application Route: Subcutaneous  
Symptoms: respiratory depression

### Procaine hydrochloride:

Acute oral toxicity : LD<sub>50</sub> (Rat): 200 mg/kg  
LD<sub>50</sub> (Mouse): 350 mg/kg

Acute toxicity (other routes of administration) : LD<sub>50</sub> (Rat): 43 mg/kg  
Application Route: Intravenous

LD<sub>50</sub> (Mouse): 33 mg/kg  
Application Route: Intravenous

LD<sub>50</sub> (Dog): 33 mg/kg  
Application Route: Intravenous

### Piroxicam:

Acute oral toxicity : LD<sub>50</sub> (Rat): 216 mg/kg  
LD<sub>50</sub> (Dog): 108 mg/kg  
LD<sub>50</sub> (Hamster): 170 mg/kg  
LD<sub>50</sub> (Guinea pig): 388 mg/kg  
LD<sub>50</sub> (Monkey): 1,000 mg/kg

Acute dermal toxicity : LD<sub>50</sub> (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

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## Respiratory or skin sensitisation

### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

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

### Components:

#### Benzylpenicillin:

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

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

|         |                              |
|---------|------------------------------|
| Result  | : Strong sensitizer          |
| Remarks | : Based on human experience. |

#### Streptomycin sulphate:

|                 |  |
|-----------------|--|
| Test Type       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Dermal                                 |
| Species         | : Humans                                 |
| Result          | : Weak sensitizer                        |

#### Procaine hydrochloride:

|                 |  |
|-----------------|--|
| Exposure routes | : Dermal   |
| Result          | : Sensitiser   |
| Remarks         | : Based on human experience.<br>Based on data from similar materials |

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Benzylpenicillin:

|  |  |
|--|--|
| Germ cell mutagenicity -<br>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<br>Result: equivocal                                |
| Genotoxicity in vivo  | : | Test Type: Chromosomal aberration<br>Cell type: Human lymphocytes<br>Result: negative |

### Procaine hydrochloride:

|                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: equivocal |
|-----------------------|---|---|

### Piroxicam:

|                      |   |   |
|----------------------|---|---|
| Genotoxicity in vivo | : | Test Type: sister chromatid exchange assay<br>Species: Humans<br>Cell type: Human lymphocytes<br>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<br>Species: Mouse<br>Result: No effects on fertility |
|                      |   | Test Type: Fertility<br>Species: Rat<br>Result: No effects on fertility   |
|                      |   | Test Type: Fertility  |

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Effects on foetal development : Species: Rabbit  
Result: No effects on fertility

: 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

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

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

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.

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## Repeated dose toxicity

### Components:

#### **Streptomycin sulphate:**

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

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

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

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

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

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

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

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## 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: Diarrhoea, constipation, flatulence, Headache, Dizziness, tinnitus, skin rash, Ulceration, chest pain, Abdominal pain

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Benzylpenicillin:**



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|   |   |   |
|---|---|---|
| Toxicity to fish                                    | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 hrs<br>Method: OECD Test Guideline 203              |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 3.6 mg/l<br>Exposure time: 48 hrs<br>Method: OECD Test Guideline 202                         |
| Toxicity to algae/aquatic plants                    | : | EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201 |
|   |   | NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201    |
|   |   | EC50 (blue-green algae): 0.74 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201                                  |
|   |   | NOEC (blue-green algae): 0.14 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201                                  |
| M-Factor (Acute aquatic toxicity)                   | : | 1   |
| Toxicity to microorganisms                          | : | EC50: > 500 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                  |
|   |   | NOEC: 5 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                      |

### Streptomycin sulphate:

|   |   |   |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 487 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202   |
| Toxicity to algae/aquatic plants                    | : | EC50 (Microcystis aeruginosa (blue-green algae)): 0.007 mg/l<br>Exposure time: 72 h<br>Method: ISO 8692 |
|   |   | EC50 (Selenastrum capricornutum (green algae)): 0.133 mg/l<br>Exposure time: 72 h                       |

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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

### Bioaccumulative potential

#### Components:

##### 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

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**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

|                        |   |   |
|------------------------|---|---|
| Waste from residues    | : | Dispose of in accordance with local regulations.<br>Do not dispose of waste into sewer.   |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

|                           |   |  |
|---------------------------|---|--|
| UN number                 | : | UN 3082  |
| Proper shipping name      | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Benzylpenicillin, Streptomycin sulphate) |
| Class                     | : | 9  |
| Packing group             | : | III  |
| Labels                    | : | 9  |
| Environmentally hazardous | : | yes  |

**IATA-DGR**

|  |   |  |
|--|---|--|
| UN/ID No.                                | : | UN 3082  |
| Proper shipping name                     | : | Environmentally hazardous substance, liquid, n.o.s.<br>(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.<br>(Benzylpenicillin, Streptomycin sulphate) |
| Class                | : | 9  |
| Packing group        | : | III  |
| Labels               | : | 9  |

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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.

### National Regulations

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Not applicable

#### Substances Subject to be Indicated Names

Not applicable

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**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

|| Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

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## Waste Disposal and Public Cleansing Law

Industrial waste

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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## 16. OTHER INFORMATION

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

### Full text of other abbreviations

AIIIC - 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 - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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

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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; TECL - 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.

JP / EN