SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

Version 2.0  Revision Date: 2021/04/09  SDS Number: 7213849-00002  Date of last issue: 2020/10/30
Date of first issue: 2020/10/30

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: suspension
Colour: white to off-white
Odour: No data available

May be fatal if swallowed and enters airways. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life. May cause long lasting harmful effects to aquatic life.

GHS Classification
Respiratory sensitisation: Category 1
Skin sensitisation: Category 1
Specific target organ toxicity - repeated exposure: Category 2
Aspiration hazard: Category 1
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 4

GHS label elements
Hazard pictograms

Signal word: Danger

Hazard statements:
- H304 May be fatal if swallowed and enters airways.
- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H401 Toxic to aquatic life.
- H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements:

Prevention:
- P260 Do not breathe mist or vapours.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves.
- P284 Wear respiratory protection.

Response:
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P331 Do NOT induce vomiting.
- P333 + P313 If skin irritation or rash occurs: 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.

Storage:
- P405 Store locked up.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure. May be fatal if swallowed and enters airways.
Environmental hazards
Toxic to aquatic life. May cause long lasting harmful effects to aquatic life.

Other hazards which do not result in classification
None known.

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>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Sodium [2S-(2a,5a,6β)]-6-[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>985-16-0</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

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

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : May be fatal if swallowed and enters airways. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs through prolonged or repeated exposure. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

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

**Unsuitable extinguishing media**
- None known.

**Specific hazards during firefighting**
- Exposure to combustion products may be a hazard to health.

**Hazardous combustion products**
- Carbon oxides
- Metal oxides

**Specific extinguishing methods**
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

### 6. ACCIDENTAL RELEASE MEASURES

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

**Environmental precautions**
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for 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: Use only with adequate ventilation.
Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitizers. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

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

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<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>Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-one</td>
<td>985-16-0</td>
<td>TWA</td>
<td>0.7 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN, DSEN | Wipe limit | 100 µg/100 cm² | Internal |
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<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Wipe limit</th>
<th>Not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEL 2)</td>
<td></td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**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**

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

**Filter type**

Combined particulates and organic vapour type

**Eye/face 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.

**Hand protection**

Chemical-resistant gloves

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**

suspension

**Colour**

white to off-white
Odour : No data available
Odour 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
Vapour pressure : No data available
Relative vapour 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
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : 300 - 16,000 mPa.s
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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Molecular weight: No data available
Particle size: Not applicable

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Exposure routes:
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Paraffin oil:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Sodium [2S-(2α,5α,6β)-6-[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Acute oral toxicity: LDLo (Rat): > 5,000 mg/kg
Acute toxicity (other routes of administration):
LD50 (Dog): 633 mg/kg
Application Route: Intravenous
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>2021/04/09</td>
<td>7213849-00002</td>
<td>2020/10/30</td>
<td>2020/10/30</td>
</tr>
</tbody>
</table>

**LD50**
- (Mouse): 1,000 mg/kg  
  Application Route: Intravenous
- (Rat): 1,100 mg/kg  
  Application Route: Intravenous
- (Rat): 2,800 mg/kg  
  Application Route: Intramuscular
- (Rat): 1,200 mg/kg  
  Application Route: Intraperitoneal

**Dihydrostreptomycin sulphate**

**Acute oral toxicity**  
LD50 (Rat): 9,000 - 25,000 mg/kg
LD50 Oral (Mouse): 30,000 mg/kg

**Fatty acids, C14-26, aluminum salts**

**Acute oral toxicity**  
LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

**Acute inhalation toxicity**  
LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Not classified based on available information.

**Components**

**Paraffin oil**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Fatty acids, C14-26, aluminum salts**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OECD Test Guideline 431</td>
<td>Based on data from similar materials</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OECD Test Guideline 439</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No skin irritation</td>
</tr>
</tbody>
</table>
Serious eye damage/eye irritation
Not classified based on available information.

Components:

Paraffin oil:
- Species: Rabbit
  - Result: No eye irritation

Fatty acids, C14-26, aluminum salts:
- Species: Rabbit
  - Result: No eye irritation
  - Method: OECD Test Guideline 405
  - Remarks: Based on data from similar materials

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
  - Maximisation Test:
    - Species: Guinea pig
      - Method: OECD Test Guideline 429
      - Result: negative
      - Remarks: Based on human experience
  - Remarks: Based on data from similar materials

Fatty acids, C14-26, aluminum salts:
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative
- Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.
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Components:

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

Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:
- Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Dihydrostreptomycin sulphate:
- Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
  Test system: Human lymphocytes
  Result: negative

Fatty acids, C14-26, aluminum salts:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials
  Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:
- Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Dihydrostreptomycin sulphate:
- Species: Rat
- Application Route: Oral
- Exposure time: 2 Years
- NOAEL: 5 mg/kg body weight
- Result: negative

Reproductive toxicity
Not classified based on available information.
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Components:

Benzylpenicillin:

Effects on fertility:
- Test Type: Fertility
  Species: Mouse
  Result: No effects on fertility
- Test Type: Fertility
  Species: Rat
  Result: No effects on fertility
- Test Type: Fertility
  Species: Rabbit
  Result: No effects on fertility

Effects on foetal development:
- Test Type: Development
  Species: Mouse
  Result: No effects on foetal development
- Test Type: Development
  Species: Rat
  Result: No effects on foetal development
- Test Type: Development
  Species: Rabbit
  Result: No effects on foetal development

Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Effects on foetal development:
- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Oral
  General Toxicity Maternal: NOAEL: 4,000 mg/kg body weight
  Developmental Toxicity: NOAEL: 4,000 mg/kg body weight
  Symptoms: No foetal abnormalities, No maternal effects

Dihydrostreptomycin sulphate:

Effects on foetal development:
- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: NOAEL: 5 mg/kg body weight
- Test Type: Embryo-foetal development
  Species: Guinea pig
  Application Route: Intramuscular
  General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight
  Developmental Toxicity: NOAEL: 10 mg/kg body weight
  Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.
Fatty acids, C14-26, aluminum salts:

Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative
- Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Reproduction/Developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 414
- Result: negative
- Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Dihydrostreptomycin sulphate:

- Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Paraffin oil:

- Species: Rat, female
- LOAEL: 161 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

Dihydrostreptomycin sulphate:

- Species: Guinea pig
- LOAEL: 40 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: ear
- Symptoms: hearing loss

- Species: Cat
- LOAEL: 100 mg/kg
- Application Route: Oral
- Exposure time: 60 d
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Target Organs: ear
Symptoms: ataxia, hearing loss, Reduced body weight

Species: Cat
LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 21 d
Target Organs: ear
Symptoms: ataxia, hearing loss, Reduced body weight

Species: Rat
Application Route: Ingestion
Exposure time: 42 Days
Remarks: Based on data from similar materials

Fatty acids, C14-26, aluminum salts:
Species: Rat
Application Route: Ingestion
Exposure time: 42 Days
Remarks: Based on data from similar materials

Aspiration toxicity
May be fatal if swallowed and enters airways.

Components:
Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

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

Sodium [2S-(2α,5α,6β)-6-[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Skin contact:
Target Organs: Skin
Symptoms: Dermatitis
Target Organs: Respiratory system
Symptoms: Sensitisation

Ingestion:
Target Organs: Gastrointestinal tract
Symptoms: Diarrhoea
Target Organs: Respiratory system
Symptoms: anaphylaxis
Target Organs: Kidney
Symptoms: nephritis
Target Organs: Liver
Symptoms: Damage

Dihydrostreptomycin sulphate:
General Information:
Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension
### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

<table>
<thead>
<tr>
<th>Paraffin oil:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to daphnia and other aquatic invertebrates</th>
<th>EL50 (Acartia tonsa): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Skeletonema costatum (marine diatom)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>NOELR (Skeletonema costatum (marine diatom)): &gt; 1 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Test substance: Water Accommodated Fraction</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Benzylpenicillin:**

<table>
<thead>
<tr>
<th><strong>Toxicity to fish</strong></th>
<th>LC50 (Onchorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 hrs</td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>---------------------------------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 3.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 hrs</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>-------------------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Raphidocelis subcapitata (freshwater green alga)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 hrs</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l</td>
<td>Exposure time: 72 hrs</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| EC50 (blue-green algae): 0.74 mg/l                   |                                                                 |
Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (blue-green algae): 0.14 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 1
Toxicity to microorganisms: EC50: > 500 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

NOEC: 5 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

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

Fatty acids, C14-26, aluminum salts:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 81.2 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Paraffin oil:

Partition coefficient: n-octanol/water: log Pow: > 4
Remarks: Calculation

Benzylpenicillin:

Partition coefficient: n-octanol/water: log Pow: 1.83
11. octanol/water

  Fatty acids, C14-26, aluminum salts:

  Partition coefficient: n-octanol/water: log Pow: > 7

  Remarks: Calculation

  Mobility in soil
  No data available

  Other adverse effects
  No data available

13. DISPOSAL CONSIDERATIONS

  Disposal methods
  Waste from residues: Dispose of in accordance with local regulations.
  Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

  International Regulations

  UNRTDG
  Not regulated as a dangerous good

  IATA-DGR
  Not regulated as a dangerous good

  IMDG-Code
  Not regulated as a dangerous good

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

  National Regulations

  GB 6944/12268
  Not regulated as a dangerous good

  Special precautions for user
  Not applicable

15. REGULATORY INFORMATION

  National regulatory information

  Law on the Prevention and Control of Occupational Diseases

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

  DSL: not determined
### SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

**Version**: 2.0  
**Revision Date**: 2021/04/09  
**SDS Number**: 7213849-00002  
**Date of last issue**: 2020/10/30  
**Date of first issue**: 2020/10/30

<table>
<thead>
<tr>
<th>AICS</th>
<th>: not determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>IECSC</td>
<td>: not determined</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**
- 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**
  - ACGIH: USA. ACGIH Threshold Limit Values (TLV)
  - ACGIH / TWA: 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - 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 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN