SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.0 Revision Date: 2021/04/09 SDS Number: 7213863-00002 Date of last issue: 2020/10/30

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin 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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Respiratory sensitisation: Category 1
Skin sensitisation: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (ear, Kidney, inner ear)
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.
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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.

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 80 - &lt; 90</td>
<td></td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Sodium [2S-{(2α,5α,6β)-(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>
<td></td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>
### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>In case of eye contact</td>
<td>Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</td>
</tr>
<tr>
<td>If swallowed</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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 if swallowed.
- 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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

**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.
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**

**Advice on safe handling**: Use only with adequate ventilation. 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 sensitisers. Do not eat, drink or smoke when using this product.
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Avoidance of contact

Hygiene measures

Take care to prevent spills, waste and minimize release to the environment.

: 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

<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>OEL-M (Mist)</td>
<td>3 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></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-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>985-16-0</td>
<td>TWA</td>
<td>0.7 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN, DSEN

Wipe limit 100 µg/100 cm² Internal

Further information: OTO

Wipe limit Not required
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version: 2.0
Revision Date: 2021/04/09
SDS Number: 7213863-00002
Date of last issue: 2020/10/30
Date of first issue: 2020/10/30

<table>
<thead>
<tr>
<th>Fatty acids, C14-26, aluminum salts</th>
<th>97404-28-9</th>
<th>TWA (Respirable particulate matter)</th>
<th>1 mg/m3 (Aluminium)</th>
<th>ACGIH</th>
</tr>
</thead>
</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

**Hand protection**
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state**
- Suspension

**Colour**
- White to off-white

**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
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure:
- 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
  LD50 (Mouse): 1,000 mg/kg
  Application Route: Intravenous
  LD50 (Rat): 1,100 mg/kg
  Application Route: Intravenous
  LD50 (Rat): 2,800 mg/kg
  Application Route: Intramuscular
  LD50 (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:
- Species: Rabbit
- Result: No skin irritation

Fatty acids, C14-26, aluminum salts:

- Species: reconstructed human epidermis (RhE)
- Method: OECD Test Guideline 431
- Remarks: Based on data from similar materials

- Species: reconstructed human epidermis (RhE)
- Method: OECD Test Guideline 439
- Remarks: Based on data from similar materials

- Result: No skin irritation

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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
<tr>
<td>Maximisation Test</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

Remarks: Strong sensitizer

Based on human experience.

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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.

**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.

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

| Effects on foetal development | 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 (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

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
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

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:

Paraffin oil:

Toxicity to fish:
LL50 (Scophthalmus maximus (turbot)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other:
EL50 (Acartia tonsa): > 100 mg/l
### Aquatic Invertebrates

- **Exposure time:** 48 h
- **Test substance:** Water Accommodated Fraction
- **Remarks:** Based on data from similar materials

### Toxicity to Algae/Aquatic Plants

- **EL50 (Skeletonema costatum (marine diatom)):** > 100 mg/l
- **Exposure time:** 72 h
- **Test substance:** Water Accommodated Fraction
- **Remarks:** Based on data from similar materials

### NOELR (Skeletonema costatum (marine diatom)):** > 1 mg/l
- **Exposure time:** 72 h
- **Test substance:** Water Accommodated Fraction
- **Remarks:** Based on data from similar materials

### Benzylpenicillin

#### Toxicity to Fish

- **LC50 (Oncorhynchus mykiss (rainbow trout)):** > 100 mg/l
- **Exposure time:** 96 hrs
- **Method:** OECD Test Guideline 203
- **Remarks:** Based on data from similar materials

#### Toxicity to Daphnia and Other Aquatic Invertebrates

- **EC50 (Daphnia magna (Water flea)):** 3.6 mg/l
- **Exposure time:** 48 hrs
- **Method:** OECD Test Guideline 202
- **Remarks:** Based on data from similar materials

#### Toxicity to Algae/Aquatic Plants

- **EC50 (Raphidocelis subcapitata (freshwater green alga)):** > 100 mg/l
- **Exposure time:** 72 hrs
- **Method:** OECD Test Guideline 201
- **Remarks:** Based on data from similar materials

- **NOEC (Raphidocelis subcapitata (freshwater green alga)):** 50 mg/l
- **Exposure time:** 72 hrs
- **Method:** OECD Test Guideline 201
- **Remarks:** Based on data from similar materials

- **EC50 (blue-green algae):** 0.74 mg/l
- **Exposure time:** 72 hrs
- **Method:** OECD Test Guideline 201
- **Remarks:** Based on data from similar materials

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

#### M-Factor (Acute Aquatic Toxicity)

- **M-Factor:** 1

#### Toxicity to Microorganisms

- **EC50:** > 500 mg/l
- **Exposure time:** 3 h
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 209
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.0  Revision Date: 2021/04/09  SDS Number: 7213863-00002  Date of last issue: 2020/10/30

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

Fatty acids, C14-26, aluminum salts:
Partition coefficient: n-octanol/water: log Pow: > 7
Remarks: Calculation

Mobility in soil
No data available

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.
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
Refer to section 15 for specific national regulation.

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
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=80 - &lt;90</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
</tbody>
</table>

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
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not 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

Waste Disposal and Public Cleansing Law
Industrial waste
The components of this product are reported in the following inventories:
DSL : not determined
AICS : not determined
IECSC : not determined

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
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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
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.