SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.0  Revision Date: 09.04.2021  SDS Number: 7213862-00002  Date of last issue: 30.10.2020

Date of first issue: 30.10.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
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: 

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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 (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.
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 + P342 + P316 IF SWALLOWED or if experiencing respiratory symptoms: Get emergency medical help immediately.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P319 Get medical help if you feel unwell.
P331 Do NOT induce vomiting.
P333 + P317 If skin irritation or rash occurs: Get medical help.
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>
</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; 5</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 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

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

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 method: Use extinguishing measures that are appropriate to local cir-
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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

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 sensitisers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the

ods 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.
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

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 (Mist)</td>
<td>5 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m3</td>
<td>IN OEL</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>Further information: RSEN, DSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</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>
<tr>
<td>Further information: OTO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Not required</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., 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: Combined particulates and organic vapour type
Hand protection
Material: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
Hygiene measures: Work uniform or laboratory coat. 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
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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.
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
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
**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
- **Method:** OECD Test Guideline 405
- **Result:** No eye irritation
- **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
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<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>09.04.2021</td>
<td>7213862-00002</td>
<td>30.10.2020</td>
</tr>
</tbody>
</table>

#### Species
- **Result**: Mouse
- **Result**: Weak sensitizer

#### Test Type
- **Test Type**: Maximisation Test
- **Exposure routes**: Dermal
- **Species**: Guinea pig
- **Result**: positive
- **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.

#### 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>5 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

Reproductive toxicity
Not classified based on available information.

Components:

Benzylpenicillin:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Result: No effects on foetal development</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Result: No effects on foetal development</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
</tbody>
</table>
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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 (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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>161 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

### Dihydrostreptomycin sulphate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>40 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>ear</td>
</tr>
<tr>
<td>Symptoms</td>
<td>hearing loss</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Cat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>60 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>ear</td>
</tr>
<tr>
<td>Symptoms</td>
<td>ataxia, hearing loss, Reduced body weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Cat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>ear</td>
</tr>
<tr>
<td>Symptoms</td>
<td>ataxia, hearing loss, Reduced body weight</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>42 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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 aquatic invertebrates:** EL50 (Acartia tonsa): > 100 mg/l
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

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

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
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.0  Revision Date: 09.04.2021  SDS Number: 7213862-00002  Date of last issue: 30.10.2020

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

Sources of key data used to compile the Safety Data Sheet:


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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA : 8-hour, time-weighted average
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

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
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.