SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone: 353-51-601000
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Respiratory sensitisation, Category 1: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
   Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.
   Aspiration hazard, Category 1: H304: May be fatal if swallowed and enters airways.
   Long-term (chronic) aquatic hazard, Category 4: H413: May cause long lasting harmful effects to aquatic life.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Danger
   Hazard statements: H304 May be fatal if swallowed and enters airways.
**Precautionary statements**:  
**Prevention:**  
P273  Avoid release to the environment.  
P280  Wear protective gloves.  

**Response:**  
P301 + P310  IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
P304 + P340  IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P331  Do NOT induce vomiting.  
P342 + P311  If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  

**Hazardous components which must be listed on the label:**  
Paraffin oil  
Benzylpenicillin  
Dihydrostreptomycin sulphate  

**2.3 Other hazards**  
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.  

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.  

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.  

**SECTION 3: Composition/information on ingredients**  

**3.2 Mixtures**  

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1 232-384-2</td>
<td>Asp. Tox. 1; H304 Aquatic Chronic 4; H413</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>Resp. Sens. 1A</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 09.04.2021</th>
<th>Date of first issue: 30.10.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>27.08.2021</td>
<td>7213898-00003</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Category</th>
<th>M-Factor (Acute aquatic toxicity)</th>
</tr>
</thead>
<tbody>
<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>985-16-0 213-574-4</td>
<td>H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 STOT RE 1; H372 (ear, Kidney, inner ear)</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7 226-823-7</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.
4.2 Most important symptoms and effects, both acute and delayed

Risks:
- 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).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products:
- Carbon oxides
- Metal oxides

5.3 Advice for firefighters

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

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
SAFETY DATA SHEET
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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 environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m3</td>
<td>IE OEL</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]amin o]-3,3-dimethyl-7-oxo-4-thia-1-oxo-4-thia-1-</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>Azabicyclo[3.2.0]heptane-2-carboxylate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>TWA</td>
</tr>
<tr>
<td>5490-27-7</td>
<td>0.4 mg/m³ (OEB 2)</td>
</tr>
</tbody>
</table>

Further information: RSEN

Further information: OTO

Wipe limit Not required

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
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.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
Initial boiling point and boiling range : 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
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
   Viscosity, dynamic : 300 - 16,000 mPa.s
   Viscosity, kinematic : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
   Particle size : Not applicable

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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): LD50 (Mouse): 3,500 mg/kg
**SAFETY DATA SHEET**

**according to Regulation (EC) No. 1907/2006**

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**Application Route:** Intraperitoneal  
LD50 (Mouse): 329 mg/kg  

**Application Route:** Intravenous  
LD50 (Mouse): 1,000 mg/kg  
LD50 (Dog): 633 mg/kg  
LD50 (Rat): 1,100 mg/kg  
LD50 (Rat): 2,800 mg/kg  
LD50 (Rat): 1,200 mg/kg  

---

**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

---

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Paraffin oil:**

Species: Rabbit  
Result: No skin irritation

---

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Paraffin oil:**

Species: Rabbit  
Result: No eye irritation
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>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
<tr>
<td>Test Type</td>
<td>Maximisation Test</td>
</tr>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Result</td>
<td>Strong sensitizer</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on human experience.</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

**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
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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.

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
**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

**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.

**11.2 Information on other hazards**

**Endocrine disrupting properties**

**Product**:
**Assessment**: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**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

SECTION 12: Ecological information

12.1 Toxicity

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

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): 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

12.2 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

12.3 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
12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
**Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable


Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

DSL : not determined

AICS : not determined

IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H304 : May be fatal if swallowed and enters airways.
H317 : May cause an allergic skin reaction.
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Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H412 : Harmful to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Asp. Tox. : Aspiration hazard
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
SAFETY DATA SHEET
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Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

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Classification of the mixture:
Resp. Sens. 1 H334 Classification procedure:
Skin Sens. 1 H317 Calculation method
STOT RE 2 H373 Calculation method
Asp. Tox. 1 H304 Calculation method
Aquatic Chronic 4 H413 Calculation method

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.

IE / EN