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.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
H413 May cause long lasting harmful effects to aquatic life.

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC-No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Index-No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Registration number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Asp. Tox. 1; H304</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td>232-384-2</td>
<td>Aquatic Chronic 4; H413</td>
<td></td>
</tr>
</tbody>
</table>
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<td>30.10.2020</td>
</tr>
</tbody>
</table>

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**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.

---

For explanation of abbreviations see section 16.
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 an 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.
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>TWA (Vapour)</td>
<td>50 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m3</td>
<td>FOR-2011-12-06-1358</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-naphtyl(carboxy][amin o]-3,3-dimethyl-7-</td>
<td>985-16-0</td>
<td>TWA</td>
<td>0.7 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
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oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate

Further information: RSEN

Dihydrostreptomycin sulphate 5490-27-7 TWA 0.4 mg/m³ (OEB 2)

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 NS 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
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</table>

- 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
- Decomposition temperature: No data available
- pH: No data available
- Viscosity: No data available
- 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.
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</tbody>
</table>

- Evaporation rate: No data available
- Molecular weight: 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
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<td>30.10.2020</td>
</tr>
</tbody>
</table>

**Acute toxicity (other routes of administration):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>LD50: 3.500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>LD50: 329 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>

**Dihydrostreptomycin sulphate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>LD50: 633 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Mouse</td>
<td>LD50: 1.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Mouse</td>
<td>LD50: 1.100 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Rat</td>
<td>LD50: 2.800 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td>Rat</td>
<td>LD50: 1.200 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
</tbody>
</table>

**Acute oral toxicity:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>LD50: 9.000 - 25.000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>LD50 Oral: 30.000 mg/kg</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation:**

Not classified based on available information.

**Components:**

**Paraffin oil:**

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

**Serious eye damage/eye irritation:**

Not classified based on available information.

**Components:**

**Paraffin oil:**

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

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

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.
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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:
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:
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
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Target Organs: ear
Symptoms: ataxia, hearing loss, Reduced body weight

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

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

Benzylic penicillin:

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

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
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
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according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

Version 2.0 Revision Date: 09.04.2021 SDS Number: 7213903-00002 Date of last issue: 30.10.2020
Date of first issue: 30.10.2020

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 Other adverse effects

Product:

Endocrine disrupting potential
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 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

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
REACH - List of substances subject to authorisation (Annex XIV): 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

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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.
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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

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 Civil Aviation Organization; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bio-accumulative

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
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according to Regulation (EC) No. 1907/2006

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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<th>SDS Number:</th>
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<td>H413, Calculation method</td>
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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.

NO / EN