SAFETY DATA SHEET
according to the Hazardous Products Regulations

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

SECTION 1. IDENTIFICATION

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Respiratory sensitization : Sub-category 1A
Skin sensitization : Sub-category 1B
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (ear, Kidney, inner ear)
Aspiration hazard : Category 1

GHS label elements
Hazard pictograms :

Signal Word : Danger

Hazard Statements : H304 May be fatal if swallowed and enters airways.
                    H317 May cause an allergic skin reaction.
                    H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
                    H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:
                          P260 Do not breathe mist or vapors.
                          P264 Wash skin thoroughly after handling.
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P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P331 Do NOT induce vomiting.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>No data available</td>
<td>8012-95-1</td>
<td>80.667</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>No data available</td>
<td>61-33-6</td>
<td>10</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>No data available</td>
<td>985-16-0</td>
<td>3.333</td>
</tr>
<tr>
<td>Dihydrostreptomycin</td>
<td>No data available</td>
<td>5490-27-7</td>
<td>3.333</td>
</tr>
</tbody>
</table>
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Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

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<table>
<thead>
<tr>
<th>sulphate</th>
<th>ble</th>
<th>97404-28-9</th>
<th>2.667</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>Aluminum Stearate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 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 center 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. Causes 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8</td>
<td>09/30/2023</td>
<td>7213847-00009</td>
<td>04/04/2023</td>
<td>10/30/2020</td>
</tr>
</tbody>
</table>

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

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

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 vapors.
- 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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.

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

Conditions for safe storage:
- Keep in properly labeled 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
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEEV (Mist - Inhalable dust)</td>
<td>5 mg/m³</td>
<td>CA QC 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>600 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: RSEN, DSEN</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]carbonylamino]-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></td>
<td></td>
<td>Further information: OTO</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Not required</td>
<td></td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
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</tr>
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<td></td>
<td>Further information: OTO</td>
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<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</td>
<td>97404-28-9</td>
<td>TWA (Res-</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
</tbody>
</table>
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**Engineering measures**
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

**Personal protective equipment**

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type: Combined particulates and organic vapor type
- Hand protection: Chemical-resistant gloves

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

**Skin and body protection**
- Work uniform or laboratory coat.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**
- suspension

**Color**
- white to off-white

**Odor**
- No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
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</tr>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
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</tr>
<tr>
<td>Flammability (liquids)</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>300 - 16,000 mPa.s</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Particle size: Not applicable

SECTION 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.

SECTION 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: LD50 (Dog): 633 mg/kg
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administration) Application Route: Intravenous

LD50 (Mouse): 1,000 mg/kg
Application Route: Intravenous

LD50 (Rat): 1,100 mg/kg
Application Route: Intravenous

LD50 (Rat): 2,800 mg/kg
Application Route: Intramuscular

LD50 (Rat): 1,200 mg/kg
Application Route: Intraperitoneal

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

Fatty acids, C14-26, aluminum salts:
Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

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

Skin corrosion/irritation
Not classified based on available information.

Components:

Paraffin oil:
Species : Rabbit
Result : No skin irritation

Fatty acids, C14-26, aluminum salts:
Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Remarks : Based on data from similar materials

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

Result : No skin irritation
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Serious eye damage/eye irritation
Not classified based on available information.

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

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

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:
Benzylpenicillin:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Dermal
Species: Mouse
Result: Weak sensitizer

Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: positive
Remarks: Based on data from similar materials

Result: Strong sensitizer
Remarks: Based on human experience.

Fatty acids, C14-26, aluminum salts:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: 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:
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.

Effects on fetal development:
- Test Type: Fertility
  Species: Mouse
  Result: No effects on fertility.

Dihydrostreptomycin sulphate:
Effects on fetal development:
- Test Type: Fertility
  Species: Rat
  Result: No effects on fertility.

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:
Effects on fetal development:
- Test Type: Fertility
  Species: Rat
  Result: No effects on fetal development.

Dihydrostreptomycin sulphate:
Effects on fetal development:
- Test Type: Fertility
  Species: Rabbot
  Result: No effects on fetal development.

Effects on fetal development:
- Test Type: Development
  Species: Mouse
  Result: No effects on fetal development.

Effects on fetal development:
- Test Type: Development
  Species: Rat
  Result: No effects on fetal development.

Effects on fetal development:
- Test Type: Development
  Species: Rabbit
  Result: No effects on fetal development.

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:
Effects on fetal development:
- Test Type: Development
  Species: Rabbit
  Result: No effects on fetal development.

Dihydrostreptomycin sulphate:
Effects on fetal development:
- Test Type: Development
  Species: Guinea pig
  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 fetal 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
Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:
Dihydrostreptomycin sulphate:
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

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

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

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

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

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

Aspiration toxicity
May be fatal if swallowed and enters airways.

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

Experience with human exposure

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

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

Ingestion:
Target Organs: Gastrointestinal tract
Symptoms: Diarrhea
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,
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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SECTION 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 (Calanoid copepod)): > 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

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

Toxicity to algae/aquatic plants: EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.74 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201

Headache, hypotension
NOEC (blue-green algae): 0.14 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201

Toxicity to microorganisms:
EC50: > 500 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 5 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Benzylpenicillin:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 70.10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

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
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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not dispose of waste into sewer.
Disposal 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation
TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
DSL: not determined
AICS: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safe-
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ty, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

ACGIH / TWA: 8-hour, time-weighted average
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA AB OEL / STEL: 15-minute occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA QC OEL / TWA EV: Time-weighted average exposure value

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

Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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
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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.

CA / Z8