SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Manufacturer or supplier's details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Respiratory sensitization: Category 1
Skin sensitization: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (ear, Kidney, inner ear)
Aspiration hazard: Category 1
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 4

GHS label elements
Hazard pictograms: 
Signal Word: Danger
Hazard Statements: H304 May be fatal if swallowed and enters airways. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing
Precautionary Statements:

**Prevention:**
P260 Do not breathe mist or vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P284 Wear respiratory protection.

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

**Storage:**
P405 Store locked up.

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

Other hazards which do not result in classification:
None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture: Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 70 -&lt; 90</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>985-16-0</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>&gt;= 1 -&lt; 5</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.
May cause damage to organs through prolonged or repeated exposure if swallowed.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
Treat symptomatically and supportively.

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 products:
Carbon oxides
Metal oxides

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.
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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 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.
SAFETY DATA SHEET

Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

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
- 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>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></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)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>985-16-0</td>
<td>TWA</td>
<td>0.7 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></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>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures:

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or
exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type:
- Combined particulates and organic 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 face shield 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Color</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</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>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)
  Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity
  Viscosity, dynamic: 300 - 16,000 mPa.s

Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: Not applicable

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 administration)**: LD50 (Dog): 633 mg/kg
  Application Route: Intravenous
- LD50 (Mouse): 1.000 mg/kg
  Application Route: Intravenous
- LD50 (Rat): 1.100 mg/kg
  Application Route: Intravenous
- LD50 (Rat): 2.800 mg/kg
  Application Route: Intramuscular
- LD50 (Rat): 1.200 mg/kg
  Application Route: Intraperitoneal

**Dihydrostreptomycin sulphate:**
- **Acute oral toxicity**: LD50 (Rat): 9.000 - 25.000 mg/kg
- LD50 Oral (Mouse): 30.000 mg/kg

**Fatty acids, C14-26, aluminum salts:**
- **Acute oral toxicity**: LD50 (Rat, female): > 2.000 mg/kg
  Method: OECD Test Guideline 423
  Remarks: Based on data from similar materials
Acute inhalation toxicity: LC50 (Rat): > 5.15 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
Paraffin oil:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

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

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

| Result        | No skin irritation |

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Paraffin oil:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Fatty acids, C14-26, aluminum salts:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
<tr>
<td></td>
<td>Maximization Test</td>
</tr>
<tr>
<td></td>
<td>Dermal</td>
</tr>
<tr>
<td></td>
<td>Guinea pig</td>
</tr>
<tr>
<td></td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Remarks: Based on human experience.

Fatty acids, C14-26, aluminum salts:

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Benzylpenicillin:

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Dihydrostreptomycin sulphate:

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Fatty acids, C14-26, aluminum salts:

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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.

Species: Rat
Result: No effects on fertility.

Species: Rabbit
Result: No effects on fertility.

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

Species: Rat
Result: No effects on fetal development.

Species: Rabbit
Result: No effects on fetal 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 fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Oral
- General Toxicity Maternal: NOAEL: 4.000 mg/kg body weight
- Developmental Toxicity: NOAEL: 4.000 mg/kg body weight
- Symptoms: No fetal abnormalities., No maternal effects.

Dihydrostreptomycin sulphate:

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rabbit
- Application Route: Oral
- Developmental Toxicity: NOAEL: 5 mg/kg body weight
- Test Type: Embryo-fetal development
- Species: Guinea pig
- Application Route: Intramuscular
- General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight
- Developmental Toxicity: NOAEL: 10 mg/kg body weight
- Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.

Fatty acids, C14-26, aluminum salts:

Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative
- Remarks: Based on data from similar materials

Effects on 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
May cause damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:

Dihydrostreptomycin sulphate:
- Assessment: Causes damage to organs through prolonged or repeated exposure.
### Repeated dose toxicity

#### Components:

#### Paraffin oil:

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

#### Dihydrostreptomycin sulphate:

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

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>&gt;= 1000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>42 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Aspiration toxicity

May be fatal if swallowed and enters airways.

#### Components:

#### Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.
Experience with human exposure

Components:

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

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

**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): > 100 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

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

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

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

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

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

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

  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

- **Persistence and degradability**

**Components:**

- **Benzylpenicillin**: Biodegradability: Result: Readily biodegradable.
Biodegradability: 70.10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Fatty acids, C14-26, aluminum salts:

Biodegradability: Readily biodegradable.
Biodegradation: 81.2 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Paraffin oil:
Partition coefficient: n-octanol/water: log Pow: > 4
Remarks: Calculation

Benzylpenicillin:
Partition coefficient: n-octanol/water: log Pow: 1.83

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Not applicable

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

SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
AR OEL / CMP: TLV (Threshold Limit Value)
AR OEL / CMP - CPT: STEL (Short Term Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with...
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.