SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 1.8 Revision Date: 09/30/2023 SDS Number: 7213868-00009 Date of last issue: 04/04/2023
Date of first issue: 10/30/2020

SECTION 1. IDENTIFICATION

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization : Category 1
Skin sensitization : Category 1
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.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, 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.
P363 Wash contaminated clothing 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>80.667</td>
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<tr>
<td></td>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>10</td>
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<tr>
<td></td>
<td>Sodium [2S-{2a,5a,6β}-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>985-16-0</td>
<td>3.333</td>
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<tr>
<td></td>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>3.333</td>
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<tr>
<td></td>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>2.667</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 firefighting: 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 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.
**SAFETY DATA SHEET**  
according to the OSHA Hazard Communication Standard

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

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<td>10/30/2020</td>
</tr>
</tbody>
</table>

- **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 (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
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<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</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>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>Inside</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>
<tr>
<td>Further information: RSEN, DSEN</td>
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<td></td>
<td></td>
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<tr>
<td>Further information: OTO</td>
<td></td>
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</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:** General and local exhaust ventilation is recommended to
maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves

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

Skin and body protection: 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
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
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Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
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:
Species : Rabbit
Result : No skin irritation

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

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

Result : No skin irritation

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

Components:

Paraffin oil:
Species : Rabbit
Result : No eye irritation

Fatty acids, C14-26, aluminum salts:
Species : Rabbit
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-(2\alpha,5\alpha,6\beta)]-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

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

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

Test Type: 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
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
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- **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, 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 (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
   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

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
   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
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
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
49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization
Specific target organ toxicity (single or repeated exposure)
Aspiration hazard

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 1.8
Revision Date: 09/30/2023
SDS Number: 7213868-00009
Date of last issue: 04/04/2023
Date of first issue: 10/30/2020

US State Regulations

Pennsylvania Right To Know
Paraffin oil 8012-95-1
Benzylpenicillin 61-33-6
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 985-16-0
Dihydrostreptomycin sulphate 5490-27-7

California List of Hazardous Substances
Paraffin oil 8012-95-1

California Permissible Exposure Limits for Chemical Contaminants
Paraffin oil 8012-95-1

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

NFPA 704:
Flammability: 1
Health: 2
Instability: 0

HMIS® IV:

HEALTH: *
FLAMMABILITY: 1
PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-
Benzylpenicillin / Dihydrostreptomycin Sulfate / Nafcillin Formulation

SAFETY DATA SHEET  
according to the OSHA Hazard Communication Standard

Date of first issue: 10/30/2020
Date of last issue: 04/04/2023

ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA: 8-hour time weighted average

Safety Data Sheet; GLP; Good Laboratory Practice; ADG - American Dental Association; AIM - American Institute of Mineralogists; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; FLx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Korea Existing Chemicals 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 Bioaccumulative

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.

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