

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

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 in accordance with ABNT NBR 14725 Standard**

Hazard pictograms : 

Signal Word : Danger

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

**Hazard Statements** :

- H304 May be fatal if swallowed and enters airways.
- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H373 May cause damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.
- H401 Toxic to aquatic life.
- H413 May cause long lasting harmful effects to aquatic life.

**Precautionary Statements** :

**Prevention:**

- P273 Avoid release to the environment.
- P280 Wear protective gloves.

**Response:**

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

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1	Aspiration hazard, Category 1 Long-term (chronic) aquatic hazard, Category 4	>= 70 -< 90
Benzylpenicillin	61-33-6	Respiratory sensitization, Sub-category 1A Skin sensitization, Sub-category 1B Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 3	>= 10 -< 20
Sodium [2S-(2 $\alpha$ ,5 $\alpha$ ,6 $\beta$ )]-6-[[2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-	985-16-0		>= 1 -< 5

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

azabicyclo[3.2.0]heptane-2-carboxylate			
Dihydrostreptomycin sulphate	5490-27-7	Specific target organ toxicity - repeated exposure (Oral) (ear, Kidney, inner ear), Category 1	>= 1 -< 5
Fatty acids, C14-26, aluminum salts	97404-28-9		>= 1 -< 5

### 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 (CO<sub>2</sub>)

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

Unsuitable extinguishing media	:	Dry chemical 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 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.

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

- 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.
- 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.
- 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin oil	8012-95-1	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Benzylpenicillin	61-33-6	TWA	600 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN, DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Sodium [2S-(2α,5α,6β)]-6-[[2-ethoxy-1-	985-16-0	TWA	0.7 mg/m <sup>3</sup> (OEB 2)	Internal

# SAFETY DATA SHEET



## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate				
Dihydrostreptomycin sulphate	5490-27-7	TWA	0.4 mg/m <sup>3</sup> (OEB 2)	
Further information: OTO				
		Wipe limit	Not required	
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

### Personal protective equipment

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  
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.

## 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

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

---

Flash point	:	No data available
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

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**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.

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

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-(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:

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



**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

---

**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

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

---

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.
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##### **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:**

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

Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro
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**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

---

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

**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.

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

---

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

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

**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:**

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

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

---

### 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:

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  
 :  $\geq 1000$  mg/kg  
 Application Route : Ingestion  
 Exposure time : 42 Days  
 Remarks : Based on data from similar materials

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

### 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-(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:

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 : EL50 (*Skeletonema costatum* (marine diatom)): > 100 mg/l

## Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 2.7	Revision Date: 30.09.2023	SDS Number: 7213846-00009	Date of last issue: 04.04.2023 Date of first issue: 30.10.2020
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plants

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

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

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

### **Persistence and degradability**

#### **Components:**

#### **Benzylpenicillin:**

**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version 2.7      Revision Date: 30.09.2023      SDS Number: 7213846-00009      Date of last issue: 04.04.2023  
Date of first issue: 30.10.2020

---

**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.  
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.

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**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



**Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.7	30.09.2023	7213846-00009	Date of first issue: 30.10.2020

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**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**The ingredients of this product are reported in the following inventories:**

DSL : not determined

AICS : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION**Revision Date : 30.09.2023  
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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 x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-

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tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand 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; WHMIS - Workplace Hazardous Materials Information System

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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