

# Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 4.0      Revision Date: 2023/09/30      SDS Number: 7213863-00009      Date of last issue: 2023/04/04  
Date of first issue: 2020/10/30

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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## 2. HAZARDS IDENTIFICATION

### GHS classification of chemical product

Respiratory sensitisation : Category 1

Skin sensitisation : 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 :



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- Signal word : Danger
- Hazard statements : H304 May be fatal if swallowed and enters airways.  
 H317 May cause an allergic skin reaction.  
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 H373 May cause damage to organs (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:**  
 P260 Do not breathe mist or vapours.  
 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Paraffin oil	8012-95-1	>= 80 - < 90	

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Benzylpenicillin	61-33-6	>= 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-azabicyclo[3.2.0]heptane-2-carboxylate	985-16-0	>= 1 - < 10	
Dihydrostreptomycin sulphate	5490-27-7	>= 1 - < 10	
Fatty acids, C14-26, aluminum salts	97404-28-9	>= 1 - < 10	

### 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 centre 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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray

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	Alcohol-resistant foam
	Carbon dioxide (CO <sub>2</sub> )
	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 so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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### 7. HANDLING AND STORAGE

<b>Handling</b>	
Technical measures	: See Engineering measures under EXPOSURE

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- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
 Advice on safe handling : Use only with adequate ventilation.  
 : Do not get on skin or clothing.  
 : Do not breathe mist or vapours.  
 : Do not swallow.  
 : Avoid contact with eyes.  
 : Wash skin thoroughly after handling.  
 : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 : Keep container tightly closed.  
 : Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
 : Do not eat, drink or smoke when using this product.  
 : Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents  
 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.
- Storage**
- Conditions for safe storage : Keep in properly labelled 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
- Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible con-	Basis

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			centration	
Paraffin oil	8012-95-1	OEL-M (Mist)	3 mg/m <sup>3</sup>	JP OEL JSOH
	Further information: Group 1: carcinogenic to humans			
		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-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	985-16-0	TWA	0.7 mg/m <sup>3</sup> (OEB 2)	Internal
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> (Aluminium)	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 vapour 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	:	suspension
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	300 - 16,000 mPa.s
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available

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Density	:	No data available
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

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## 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.

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## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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### 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
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	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

### 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:**

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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 sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

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

**Components:****Benzylpenicillin:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Dermal  
Species : Mouse  
Result : Weak sensitizer

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : positive

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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)  
Exposure routes : 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-(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.

#### 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.

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### 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 foetal development : Test Type: Development  
Species: Mouse  
Result: No effects on foetal development

Test Type: Development  
Species: Rat  
Result: No effects on foetal development

Test Type: Development  
Species: Rabbit  
Result: No effects on foetal development

#### **Sodium [2S-(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 foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral

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General Toxicity Maternal: NOAEL: 4,000 mg/kg body weight  
 Developmental Toxicity: NOAEL: 4,000 mg/kg body weight  
 Symptoms: No foetal abnormalities, No maternal effects

### Dihydrostreptomycin sulphate:

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 5 mg/kg body weight

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

### 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 foetal 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.

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### 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  
LOAEL :  $\geq 1000$  mg/kg  
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.

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## 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: Sensitisation

Ingestion : Target Organs: Gastrointestinal tract  
Symptoms: Diarrhoea

Target Organs: Respiratory system  
Symptoms: anaphylaxis

Target Organs: Kidney  
Symptoms: nephritis

Target Organs: Liver  
Symptoms: Damage

#### **Dihydrostreptomycin sulphate:**

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension

## 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

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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

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



# Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 4.0      Revision Date: 2023/09/30      SDS Number: 7213863-00009      Date of last issue: 2023/04/04  
Date of first issue: 2020/10/30

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## 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

## Hazardous to the ozone layer

Not applicable

## Other adverse effects

No data available

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## 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.

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### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

##### IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

##### IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

#### National Regulations

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

#### Related Regulations

##### Fire Service Law

Not applicable to dangerous materials / designated flammables.

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### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Mineral oil	>=80 - <90	-

#### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Mineral oil	-

#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### Ordinance on Prevention of Lead Poisoning

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

#### Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

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**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof****||** Not applicable**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

DSL : not determined

AICS : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

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### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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 System; 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; TECl - 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.

JP / EN