

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard, Category 1	H304: May be fatal if swallowed and enters airways.
Long-term (chronic) aquatic hazard, Category 4	H413: May cause long lasting harmful effects to aquatic life.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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.
H373 May cause damage to organs through prolonged or repeated exposure.
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.

Hazardous components which must be listed on the label:

Paraffin oil
Benzylpenicillin
Dihydrostreptomycin sulphate

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 7213903-00014 Date of last issue: 11.02.2025
Date of first issue: 30.10.2020

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 70 - < 90
Benzylpenicillin	61-33-6 200-506-3	Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	>= 10 - < 20
Sodium [2S-(2 α ,5 α ,6 β)]-6-[[2-ethoxy-1-naphthyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	985-16-0 213-574-4		>= 1 - < 10
Dihydrostreptomycin sulphate	5490-27-7 226-823-7	STOT RE 1; H372 (ear, Kidney, inner ear)	>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- 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.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

ucts

Metal oxides

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| 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 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. |
| 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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 7213903-00014 Date of last issue: 11.02.2025
Date of first issue: 30.10.2020

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin oil	8012-95-1	TWA (Vapour)	50 mg/m ³	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m ³	FOR-2011-12-06-1358
Benzylpenicillin	61-33-6	TWA	600 µg/m ³ (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm ²	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 ³ (OEB 2)	Internal
		Wipe limit	100 µg/100 cm ²	Internal
	Further information: RSEN			
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m ³ (OEB 1)	
	Further information: OTO			

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m ³
	Workers	Inhalation	Short-term exposure	5 mg/m ³
	Workers	Inhalation	Long-term local effects	5 mg/m ³
	Workers	Inhalation	Acute local effects	5 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0,014 mg/l

8.2 Exposure controls

Engineering measures

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
Initial boiling point and boiling range	:	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
Flash point	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	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
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	Not applicable

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
---------------------	---	---

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 α ,5 α ,6 β)]-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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit
Result : No eye irritation

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Result	: positive
Remarks	: Based on data from similar materials

Result	: Strong sensitizer
Remarks	: Based on human experience.

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 α ,5 α ,6 β)]-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

Carcinogenicity

Not classified based on available information.

Components:

Sodium [2S-(2 α ,5 α ,6 β)]-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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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 α ,5 α ,6 β)]-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
		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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

II

STOT - single exposure

II Not classified based on available information.

STOT - repeated exposure

II May cause damage to organs through prolonged or repeated exposure.

Components:

Dihydrostreptomycin sulphate:

II Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Paraffin oil:

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

Dihydrostreptomycin sulphate:

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

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

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

Aspiration toxicity

II May be fatal if swallowed and enters airways.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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.

11.2 Information on other hazards

Endocrine disrupting properties

|| Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Benzylpenicillin:

|| Inhalation : Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

Sodium [2S-(2 α ,5 α ,6 β)]-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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

SECTION 12: Ecological information

12.1 Toxicity

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

		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

12.2 Persistence and degradability

Components:

Benzylpenicillin:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 70,10 % Exposure time: 28 d Method: OECD Test Guideline 301B
------------------	---	--

12.3 Bioaccumulative potential

Components:

Paraffin oil:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
------------	---	--

12.6 Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components consid-
------------	---	---

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

DSL : not determined

AICS : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-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 through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H412 : Harmful to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Asp. Tox. : Aspiration hazard
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Resp. Sens. 1	H334
Skin Sens. 1	H317
STOT RE 2	H373
Asp. Tox. 1	H304
Aquatic Chronic 4	H413

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	7213903-00014	Date of first issue: 30.10.2020

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.

NO / EN