

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

SECTION 1. IDENTIFICATION

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION


GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization : Category 1
Skin sensitization : Category 1
Specific target organ toxicity : Category 1 (ear, Kidney, inner ear)
- repeated exposure (Oral)
Aspiration hazard : Category 1

Other hazards

None known.

GHS label elements

Hazard pictograms	: 
Signal Word	: Danger
Hazard Statements	: H304 May be fatal if swallowed and enters airways. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.
Precautionary Statements	: Prevention:

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0 Revision Date: 06/17/2025 SDS Number: 7213868-00014 Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER.
P302 + P352 IF ON SKIN: Wash with plenty of 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 attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Paraffin oil	8012-95-1*	>= 65 - <= 85	TSC
Benzylpenicillin	61-33-6*	>= 7 - <= 13	TSC
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*	>= 1 - <= 5	TSC
Dihydrostreptomycin sulphate	5490-27-7*	>= 1 - <= 5	TSC
Fatty acids, C14-26, aluminum salts	97404-28-9*	>= 1 - <= 5	TSC

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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 | : 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.
Causes damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

- | | |
|---------------------------------------|---|
| Suitable extinguishing media | : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire fighting | : Exposure to combustion products may be a hazard to health. |

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

- | | | |
|--|---|---|
| Hazardous combustion products | : | Carbon oxides
Metal oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

SECTION 7. HANDLING AND STORAGE

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes. |

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0 Revision Date: 06/17/2025 SDS Number: 7213868-00014 Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
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 (Mist)	5 mg/m ³	OSHA Z-1
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
		TWA (Mist)	5 mg/m ³	NIOSH REL
		ST (Mist)	10 mg/m ³	NIOSH REL
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				
Fatty acids, C14-26, aluminum	97404-28-9	TWA (Res-	1 mg/m ³	ACGIH

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0 Revision Date: 06/17/2025 SDS Number: 7213868-00014 Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

salts		pirable particulate matter)	(Aluminum)	
-------	--	-----------------------------	------------	--

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material : Chemical-resistant gloves

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

Skin and body protection : Work uniform or laboratory coat.
Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0	Revision Date: 06/17/2025	SDS Number: 7213868-00014	Date of last issue: 04/14/2025 Date of first issue: 10/30/2020
----------------	------------------------------	------------------------------	---

Color	:	white to off-white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

Molecular weight : No data available

Particle characteristics
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Paraffin oil:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

Benzylpenicillin:

Acute oral toxicity	: LD50 (Rat): 8,000 mg/kg LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Mouse): 3,500 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 329 mg/kg Application Route: Intravenous

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

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 Application Route: Intravenous
	: LD50 (Rat): 1,100 mg/kg Application Route: Intravenous
	: LD50 (Rat): 2,800 mg/kg Application Route: Intramuscular
	: LD50 (Rat): 1,200 mg/kg Application Route: Intraperitoneal

Dihydrostreptomycin sulphate:

Acute oral toxicity	: LD50 (Rat): 9,000 - 25,000 mg/kg
	: LD50 Oral (Mouse): 30,000 mg/kg

Fatty acids, C14-26, aluminum salts:

Acute oral toxicity	: LD50 (Rat, female): > 2,000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials
Acute inhalation toxicity	: LC50 (Rat): > 5.15 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin oil:

Species	: Rabbit
Result	: No skin irritation

Fatty acids, C14-26, aluminum salts:

Species	: reconstructed human epidermis (RhE)
Method	: OECD Test Guideline 431
Remarks	: Based on data from similar materials

Species	: reconstructed human epidermis (RhE)
---------	---------------------------------------

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

Method	: OECD Test Guideline 439
Remarks	: Based on data from similar materials

Result	: No skin irritation
--------	----------------------

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Paraffin oil:

Species	: Rabbit
Result	: No eye irritation

Fatty acids, C14-26, aluminum salts:

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

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

Components:

Benzylpenicillin:

Test Type	: Local lymph node assay (LLNA)
Routes of exposure	: Dermal
Species	: Mouse
Result	: Weak sensitizer

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: positive
Remarks	: Based on data from similar materials

Result	: Strong sensitizer
Remarks	: Based on human experience.

Fatty acids, C14-26, aluminum salts:

Test Type	: Local lymph node assay (LLNA)
Routes of exposure	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

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 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

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 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0	Revision Date: 06/17/2025	SDS Number: 7213868-00014	Date of last issue: 04/14/2025 Date of first issue: 10/30/2020
----------------	------------------------------	------------------------------	---

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Benzylpenicillin:

Effects on fertility	:	Test Type: Fertility
		Species: Mouse
		Result: No effects on fertility.
		Test Type: Fertility
		Species: Rat
		Result: No effects on fertility.
		Test Type: Fertility
		Species: Rabbit
		Result: No effects on fertility.
Effects on fetal development	:	Test Type: Development
		Species: Mouse
		Result: No effects on fetal development.
		Test Type: Development
		Species: Rat
		Result: No effects on fetal development.
		Test Type: Development
		Species: Rabbit
		Result: No effects on fetal development.

Sodium [2S-(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 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0 Revision Date: 06/17/2025 SDS Number: 7213868-00014 Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight

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

Fatty acids, C14-26, aluminum salts:

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

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:

Dihydrostreptomycin sulphate:

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

Repeated dose toxicity

Components:

Paraffin oil:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

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
	: ≥ 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.

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
--------------	---

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0 Revision Date: 06/17/2025 SDS Number: 7213868-00014 Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

Ingestion : Target Organs: Respiratory system
Symptoms: Sensitization
Target Organs: Gastrointestinal tract
Symptoms: Diarrhea
Target Organs: Respiratory system
Symptoms: anaphylaxis
Target Organs: Kidney
Symptoms: nephritis
Target Organs: Liver
Symptoms: Damage

Dihydrostreptomycin sulphate:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin oil:

Toxicity to fish : LL50 (*Scophthalmus maximus* (turbot)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Acartia tonsa* (Calanoid copepod)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

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

Benzylpenicillin:

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 3.6 mg/l
Exposure time: 48 hrs
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (*Raphidocelis subcapitata* (freshwater green alga)): >

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

plants	100 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 EC50 (blue-green algae): 0.74 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 NOEC (blue-green algae): 0.14 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC50: > 500 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 5 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Benzylpenicillin:

Biodegradability	: Result: Readily biodegradable. Biodegradation: 70.10 % Exposure time: 28 d Method: OECD Test Guideline 301B
------------------	--

Fatty acids, C14-26, aluminum salts:

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

Bioaccumulative potential

Components:

Paraffin oil:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0	Revision Date: 06/17/2025	SDS Number: 7213868-00014	Date of last issue: 04/14/2025 Date of first issue: 10/30/2020
----------------	------------------------------	------------------------------	---

II

Fatty acids, C14-26, aluminum salts:

Partition coefficient: n-octanol/water	: log Pow: > 7 Remarks: Calculation
--	--

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

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

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Paraffin oil	8012-95-1
Benzylpenicillin	61-33-6
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
Dihydrostreptomycin sulphate	5490-27-7

California List of Hazardous Substances

Paraffin oil	8012-95-1
--------------	-----------

California Permissible Exposure Limits for Chemical Contaminants

Paraffin oil	8012-95-1
--------------	-----------

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

DSL	: not determined
AICS	: not determined
IECSC	: not determined

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

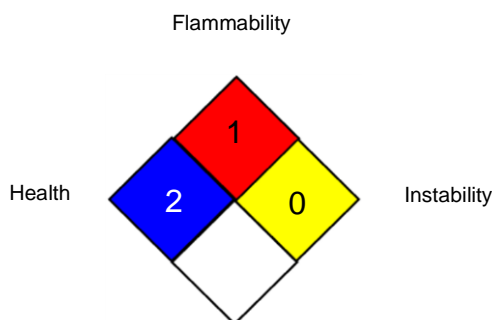
Version
3.0

Revision Date:
06/17/2025

SDS Number:
7213868-00014

Date of last issue: 04/14/2025
Date of first issue: 10/30/2020

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/17/2025	7213868-00014	Date of first issue: 10/30/2020

Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - 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

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/>

Revision Date : 06/17/2025

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 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.

US / Z8